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Healthcare Quarterly

SPECIAL ISSUE

Third in a Series

Papers

PATIENT SAFETY

3

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Editorial

Responses to the two previous issues of Patient Safety Papers suggest that there is a large audience for descriptions of effective patient safety practices. While few would argue that Canadian healthcare is measurably safer today than it was five years ago, there are important initiatives that have laid the groundwork for improvements. For example, the Safer Healthcare Now! (SHN) campaign has engaged teams across the country in six critical areas where current performance has lagged behind knowledge of what is needed for safer care. Yet, SHN nicely illustrates the continuing challenges to improve safety. Even with evidence-based bundles of changes, useful metrics to assess improvement and well-orchestrated supports for teams, overall progress in SHN is uneven: some teams have been very successful, but others struggle to make and sustain improvements in their performance.

Despite the slow pace of progress, there is a growing awareness of risks, which is the first step in augmenting safety defences. Still, most organizations have a limited understanding of the extent to which care is safe or unsafe. And strategies to share learning, for example, from root-cause analyses, are still in early stages across most of Canada.

Experience in Canada and elsewhere suggests that there are three critical elements for making and sustaining improvement. Measurement is vital for identifying current performance, assessing the impact of improvements and holding the gains. Knowledge of the improvement skills necessary to plan and test changes, learn from results and anchor improvements into ongoing systems of care is essential for reaching higher levels of reliability. And, finally, leadership at all levels – front-line, middle management and senior leadership – is needed to ensure a relentless focus on patient safety. Healthcare is complex, and there are many demands on leaders' time. Only a continued emphasis on the goals of safer care and a strategic investment in safety will ensure that we build on the momentum of effective practices and the experiences of implementing them in Canadian healthcare organizations.

This special issue of *Healthcare Quarterly* provides continuing evidence of work across the country to make healthcare safer. In "Improving Care at the Front Lines," several articles detail efforts to reduce falls, lessen the numbers of infections and institute safer practices to prevent harm. The articles included in "Medication Safety" outline strategies to develop better measures, assess current performance, identify risks and design safer medication practices. The tools used by these authors to assess and improve practice are likely to find uses in many other settings.

Although there are many unique risk factors that threaten patient safety, one common feature of many incidents is a failure in communication and teamwork. In several articles in "Teamwork and Communication," authors outline strategies for improving these practices. Safe practice requires the communication of patient and client needs and agreement across disciplines, shifts and organizations about what care is needed. Efforts to improve teamwork and communication build upon shared values and work habits that support safety.

In "Creating a Patient Safety Culture," authors discuss new tools to assess and shift the culture, helping to create an environment where patient safety practices will flourish. One core aspect of a safe culture is the recognition that safer care must involve patients and their families. Three articles address challenges of "Involving Patients and Families." The authors outline efforts to engage patients, improve communication and reduce the fears that such involvement may expose individual practitioners and organizations to unwanted publicity or legal actions. Much remains to be done in this area.

Finally, in "Broadening the Patient Safety Agenda," several articles describe the initiation of patient safety in long-term care and rehabilitation settings and the use of the balanced scorecard to integrate patient safety into strategy. Acute care remains the area with the greatest experience with patient safety practices. And while the underlying principles of safe practice are consistent across settings, their implementation in settings where clients are residents and have continuing relationships with staff raises new challenges.

The range of issues, settings and ideas provided in this issue reminds us of the complexity of patient safety and the need to keep the challenge of providing safer care at the forefront of the healthcare agenda. We welcome your feedback on the ideas and experiences shared by authors from across the country.

– G. Ross Baker

Professor, Department of Health Policy, Management and Evaluation, University of Toronto. Dr. Baker is the guest editor of the special issue series of *Healthcare Quarterly* focused on Patient Safety.

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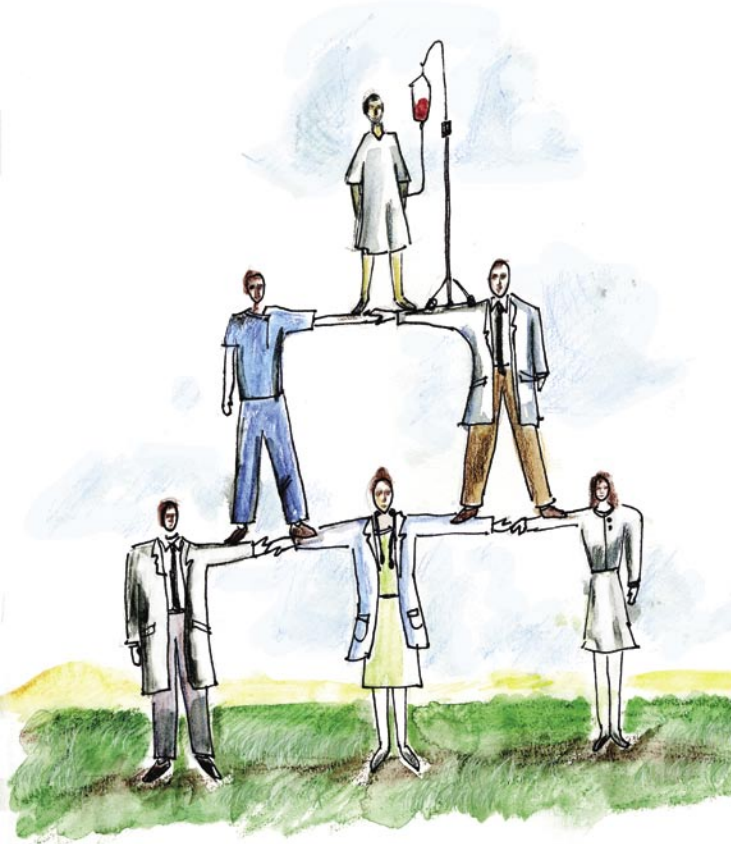

Teamwork and Communication

Involving Patients and Families

Improving Care at the Front Lines

PATIENT SAFETY *Papers*

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Canadian Patient Safety Institute

On behalf of the Canadian Patient Safety Institute (CPSI), I would like to briefly reflect on the year that has passed since the last issue of Patient Safety Papers. The progress you have achieved is beyond my vision of where I thought we would be. I am profoundly impressed with the unbridled enthusiasm and high levels of participation I am witnessing for advancing the patient safety agenda across Canada.

Over the past year, CPSI has worked in partnership with professionals, healthcare organizations and others to make many advances on several fronts in patient safety. Here are a few highlights from a long list of accomplishments:

- Safer Healthcare Now! has continued to grow. By the end of 2007, 800 teams from across the country were signed up, compared with about 550 at the beginning of the year.
- Canadian Disclosure Guidelines were agreed upon after almost two years of intensive efforts by a working group of key stakeholders who gave everything to the process and end results. The guidelines, essentially as recommended by the working group, were approved by the CPSI Board in early December and will be finalized and published early this year.
- CPSI began providing secretariat support for Patients for Patient Safety. This national advocacy group, which represents patients and the families of patients who have been subjected to harm while in care, wants to be involved in making positive changes and is leading the world in its efforts.
- The inaugural Patient Safety Officer Course was held in Toronto in September, providing knowledge and training to healthcare professionals on how to develop and implement patient safety programs and strategies within their organizations.
- Delivering Patient Safety, a DVD educational/learning series, was launched at the Halifax 7 Conference in early October and is now available to healthcare providers and the public as a tool for learning and teaching.
- In late October, CPSI joined with the Community and Hospital Infection Control Association, the Canadian Council on Health Services Accreditation and the Public Health Agency of Canada in announcing the Getting Ready phase of Canada's Hand Hygiene Campaign. The aim is to prepare healthcare organizations to adopt and measure hand hygiene practices and compliance. Train-the-trainer sessions for this initiative are starting early in 2008.

In the coming year, we are expanding on these and other initiatives and beginning work in new areas. These include the following, to mention just a few:

- We are expanding Safer Healthcare Now! interventions in four new areas: methicillin-resistant Staphylococcus aureus (antibiotic-resistant organisms), venous thromboembolism, medication reconciliation in long-term care and falls in long-term care. We are also working on two pilot projects – one with the Canadian Association of Pediatric Health Centres on the use of high-risk medications in pediatrics, and the second with the Victoria Order of Nurses, in collaboration with the Institute for Safe Medication Practices Canada and others, on medication reconciliation in home care.
- We are completing a consultation paper for the Canadian Adverse Event Learning and Reporting System. The paper will be used to inform partners, the provinces and territories – all of whom will be invited to attend consultation meetings planned to take place across Canada in 2008.
- With modest funding from Health Canada, we are beginning work on the development of a National Simulation Strategy for healthcare. The objective of this initiative is to create a national vehicle for the promotion and endorsement of simulation, including an infrastructure for pan-Canadian collaboration.
- We are moving beyond the acute care setting to develop new national patient safety initiatives that focus on community healthcare settings, including long-term, home, mental health, pre-hospital and primary care.

Much has been done, and we all know that this is just the beginning of our transformational journey for patients and caregivers. I urge everyone in healthcare to join with us as we strive to make patient safety the foremost priority.

I personally want to extend heartfelt thanks to all people and organizations involved for their dedication; my congratulations to each and every one of you for your commitment to your patients and professions. You are the real leaders in making these important changes happen. HQ

– **Philip Hassen**, Chief Executive Officer, Canadian Patient Safety Institute

Health Council of Canada

Once again, the Health Council of Canada is proud to co-sponsor an edition of *Healthcare Quarterly* dedicated to issues of patient safety. Over 85% of the population accesses the healthcare system annually in some capacity, whether through visits to family doctors or emergency rooms or admission to hospital; all these people share an expectation of safe, effective and patient-centred care.

One high priority area for the Health Council surrounds the safe prescribing of medications. In June 2007, the Health Council hosted a symposium titled Safe and Sound: Optimizing Prescribing Behaviour. The symposium brought together a wide range of stakeholders to explore what helps and hinders optimal prescribing in Canada. Participants at the symposium made the following recommendations:

- Continue to develop processes that support evidence-based decision-making about prescribing and drug coverage, and educate Canadians about drug cost, safety and effectiveness. This could help Canadians understand that not all funding decisions are based strictly on cost. To manage costs, it is more equitable and supportive of population health to base prescribing and coverage decisions on science rather than to arbitrarily restrict access to public funding for prescription drugs.
- Accelerate efforts to improve access to prescription drugs for Canadians with no or inadequate insurance coverage.
- Strengthen legislation to ban all forms of direct-to-consumer advertising of prescription drugs. Legislation should clearly prohibit help-seeking and reminder ads.
- Encourage medical training programs to devote an appropriate amount of curriculum time to covering quality use of medicines.
- Create a systematic pan-Canadian surveillance strategy (i.e., post-marketing surveillance) to monitor and respond to unanticipated and unintended health effects of medication use after drugs are on the market. For example, a system of regional surveillance centres could monitor drug use and clinical outcomes throughout Canada, helping to inform policy and initiate quality improvement projects on a large scale.
- Assess the merits of adding a graduated-licencing provision to all new drugs released in Canada to build on the knowledge gained through the surveillance strategy.
- Accelerate the development of population-based drug information systems linked to other patient health information. Electronic health records are the only way to fully integrate patient information and to assess the impact of prescription medications on patient outcomes and the cost to the healthcare system.

For those wishing for more details of the symposium proceedings, they are available at www.healthcouncilcanada.ca.

The Health Council of Canada remains committed to supporting efforts and initiatives that pursue a sustainable high-performing healthcare system that, by its very definition, provides care that is safe, equitable, patient-centred, efficient, integrated, appropriately resourced, focused on population health, effective and accessible for all Canadians. HQ

– Donald Juzwishin, Chief Executive Officer, Health Council of Canada

Canadian Council on Health Services Accreditation

Over the past three years, the Canadian Council on Health Services Accreditation (CCHSA) has been working with partners and key stakeholders on the development and pilot testing of enhanced accreditation processes. These developments have resulted in the 2008 launch of CCHSA's new accreditation program Qmentum, Taking Quality to New Heights. Among the key attributes of the new program is a strengthened focus on safety and measurement.

Thanks to the input of many experts and extensive national consultation, in the area of standards, the Qmentum program includes new quality- and safety-related standards in areas such as managing medications, infection prevention and control, operating room and surgical care services and sterilization. Given the significant healthcare challenges across Canada, a strengthened focus in these areas is essential. All other standards areas have a heightened emphasis on key sector-specific safety issues. In 2008, CCHSA requires compliance with 25 specific required organizational practices (ROPs). As a key component of the accreditation program, these 25 ROPs have been integrated into the Qmentum standards.

Since 2001, CCHSA has included a focus on the importance of performance measures and indicators within the accreditation program. Over time, we have received feedback from healthcare stakeholders that a core set of performance measures would be an important addition to the accreditation program, increasing the rigour and relevance of accreditation. In response, we have worked with safety and measurement experts to develop and pilot test a core set of patient safety performance measures.

The following four performance measures are now a mandatory component of CCHSA's Qmentum program: Patient Safety Culture Survey; Medication Reconciliation Admission; Healthcare Associated Infection – infection rate of methicillin-resistant Staphylococcus aureus or Clostridium difficile; and Surgical Site Infection. The purpose of these performance measures is to assist organizations and CCHSA to evaluate the achievement of standards.

In 2007, the CCHSA Board of Directors approved CCHSA's phase 2 patient safety strategy, titled Strengthening Capacity and Connecting the Dots, 2007–2010. The framework centres on heightening the accreditation program's focus on patient safety through strategic activities. These include enhancing organization and surveyor capacity through the development of targeted education and training (e.g., medication safety and infection prevention and control); determining the role of adverse and sentinel events in the accreditation process; and identifying in an ongoing manner patient safety performance measures and ROPs.

Under the guidance of the strategy, CCHSA began the process of identifying new ROPs for inclusion in the 2009 accreditation program. In this development process, consideration is being given to the identification of sector-specific ROPs, which are applicable beyond the acute care environment. Sector-specific safety requirements relevant to home care, mental health and long-term care are being investigated. These new ROPs will be released in mid-2008 and be applicable to organizations surveyed in 2009 and beyond.

Partnerships with key national and provincial organizations are fundamental. Working together in a coordinated manner is key to making a difference in the patient safety agenda. There are insufficient resources, both human and fiscal, for any of us to walk this journey independently. CCHSA is committed to working with our partners, including the Canadian Patient Safety Institute, the Canadian Institute for Health Information, the health quality councils, provincial patient safety organizations and others, to ensure that there is no duplication of effort and to capitalize on initiatives currently under way. Through partnerships and collaboration, patient care in Canada is becoming safer – the quality of care is improving. HQ

– **Wendy Nicklin**, President and Chief Executive Officer, Canadian Council on Health Services Accreditation

Patient Safety Events

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April 1–2, 2008
Washington, DC
More information – http://www.ama-assn.org/ama/pub/category/14350.html

OHA Region 1 North East/ North Central Sub-Regions Conference Advancing Safety and Quality of Care: Critical Health Issues and Strategies
April 2–4, 2008
Sudbury, ON
More information – http://www.oha.com/conferences

OHA Region 1 North West Sub-Region Conference Advancing Safety and Quality of Care: Critical Health Issues and Strategies
April 16–18, 2008
Thunder Bay, ON
More information – http://www.oha.com/conferences

The International Forum on Quality and Safety in Health Care
April 22–25, 2008
Paris, France
More information – http://internationalforum.bmj.com/

Patient Safety Congress 2008
May 22–23, 2008
London, UK
More information – http://www.patientsafetycongress.co.uk

Diagnostic Error in Medicine
May 31–June 1, 2008
Phoenix, AZ
More information – http://www.amia.org

Healthcare Systems Ergonomics and Patient Safety 2008
June 25–28, 2008
Strasbourg, France
More information – http://www.heps2008.org

Improving Patient Safety 2008: From Safe Design to Safe Practice
July 16–18, 2008
Cambridge, UK
More information – http://www.ergonomics.org.uk

The 26th International System Safety Conference: The Next Generation of Safety Professionals
August 25–29, 2008
Vancouver, BC
More information – http://www.system-safety.org/~issc2008/

Adverse Events and Patient Safety in Long-Term Care Settings: Connecting Research and Clinical Care
October 17, 2008
Toronto, ON
More information – http://www.klaru-baycrest.on.ca

Halifax 8 – The Canadian Healthcare Safety Symposium
October 23–25, 2008
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Patient Safety Culture Improvement Tool: Development and Guidelines for Use

Mark Fleming and Natasha Wentzell

Abstract

The Patient Safety Culture Improvement Tool (PSCIT) was developed to assist healthcare organizations in identifying practical actions to improve their culture. This article describes the development process of the PSCIT and provides a guide to using the PSCIT. The tool is based on a safety culture maturity model, which describes five stages of cultural evolution, from pathological to generative. The PSCIT consists of nine elements that cover five patient safety culture dimensions, namely, leadership, risk analysis, workload management, sharing and learning and resource management. Each element describes the systems in place at each level of maturity, enabling organizations to identify their current level of maturity and actions to move to the next level. The PSCIT should be used with caution as there is currently a lack of reliability and validity data.

The importance of considering safety culture in patient safety improvement is widely accepted within the healthcare industry. The Institute of Medicine report *To Err Is Human* highlighted the importance of safety culture by stating that "health care organizations must develop a culture of safety such that an organization's care processes and workforce are focused on improving the reliability and safety of care for patients" (2000: 14). Pronovost and Sexton (2005) suggest that having a culture that promotes safety within your organization is an important and necessary precursor to improving the insufficiencies in patient safety. In January 2005, the Canadian Council on Health Services Accreditation (CCHSA) formally recognized the importance of culture in healthcare standards by including a culture of safety as one of their patient safety goals and also specifying five required organizational practices to promote a positive culture. The emphasis on creating the *right* culture to support patient safety is recognition that a poor culture is a significant risk factor that can threaten patient safety (Nieva and Sorra 2003) and that until the culture within healthcare changes, nothing else will (Vincent 2005). There are two fundamental assumptions underlying much of the safety culture research: (1) a positive safety culture is associated with improved safety performance (Clarke 1999) and (2) it is possible to improve the culture of an organization (Guldenmund 2000). Yet, there is a lack of empirical data on what a good culture looks like (Cox and Cox 1996) and how to develop a good safety culture (Parker et al. 2006).

Currently, patient safety culture is commonly assessed via self-completion questionnaires. This process typically involves mailing questionnaires to all staff and collating and calculating mean responses to items or factors (see Fleming and Hartnell 2007). Safety culture surveys provide much information about employee attitudes, but it is difficult to use the results to identify practical actions to improve the culture. In fact, safety culture

surveys have been likened to "describing the water to a drowning man; they tell you how bad things are but do little to help in solving the problem" (Fleming 2003). Therefore, there is a need to provide healthcare organizations with more solution-focused safety culture instruments. This can be achieved by identifying the organizational practices required to promote a positive patient safety culture since an effective way to improve a culture is by changing the organization's systems and processes.

Safety culture surveys have been likened to "describing the water to a drowning man; they tell you how bad things are but do little to help in solving the problem."

Schein (1990) argues that organizational culture is shaped through leadership action and systems that promote desired behaviours, including the following:

- Areas that leaders pay attention to, measure and control
- Deliberate role-modelling and coaching by leaders
- Operational criteria for the allocation of rewards and status
- Operational criteria for recruitment, selection and promotion
- The organization's design and structure
- Organizational systems and procedures

Schein's (1990) view of culture suggests that the patient safety culture is a reflection of the extent to which the above mechanisms support patient safety. For example, if managers are rewarded for reducing cost or cutting budgets with no consideration for quality or patient safety, this is likely to limit the priority they place on safety, which is a key component of safety culture (Flin et al. 2000; Zohar 2000).

Similarly, Parker et al. (2006) argue that safety culture is affected by organizational changes, such as a change in leadership or the introduction of new systems and processes. This suggests that safety culture is influenced by the systems, processes and practices of the organization. For example, an organization with a poor safety culture will have limited safety systems, while an organization with a positive culture will have many systems in place to promote patient safety. This argument suggests that it should be possible to assess the extent to which systems and processes promote a positive safety culture by evaluating organizational practices that influence the culture. This approach is supported by Zohar (2000) and Parker et al. (2006), who have demonstrated that safety culture consists of both concrete and abstract aspects. The concrete aspects of safety culture are tangible and observable and can therefore be used to develop a list of organizational practices that support a positive safety culture. More recently, Flin (2007) has argued that organizational indicators of a positive safety culture allow management to both monitor patient safety culture and influence patient safety outcomes. This argument is further supported by the recent development and initial validation of a safety culture improvement tool for the petrochemical industry by the current authors. This tool uses concrete organizational indicators to assess the maturity of the safety culture (Fleming et al. 2007). Based on the success of the petrochemical industry tool, we decided to develop a similar tool for healthcare. The Patient Safety Culture Improvement Tool (PSCIT) was developed to assess a number of important organizational practices that influence patient safety culture.

Developing the Tool

The development of patient safety culture indicators requires the specification of the cultural attributes that distinguish between "poor" and "good" safety cultures. Safety culture maturity models describe the stages of safety culture development (Fleming 2000). They are useful to organizations as they enable them to assess their current level of maturity (Paulk et al. 1993) and to identify areas of particular strength and weakness (National Patient Safety Agency and School of Psychological Sciences, University of Manchester 2006) and actions that need to be taken to reach the next level of maturity (Paulk et al. 1993). The safety culture maturity model of Ashcroft et al. (2005) describes the stages of safety culture development; thus, it is a useful framework to use for the basis of the patient safety culture indicators.

The safety culture maturity model used by Ashcroft et al. (2005) to develop the Manchester Patient Safety Framework was based on the work of Westrum (2004) and Reason (1998). Ashcroft et al. (2005) described five levels of culture: pathological, reactive, calculative, proactive and generative. At the pathological level of maturity, organizations see safety as a problem; they suppress information and focus on blaming individuals to support the personal needs, power and glory of those in charge. Organizations at the reactive level view safety as important but respond only after significant harm has occurred. Calculative organizations tend to be fixated on rules, positions and departmental territory. After a safety incident has occurred, information may be ignored by this type of organization and failures explained away or resolved, with no deeper inquiry into them. Organizations at the proactive level focus their efforts on anticipating safety issues before they occur by involving a wide range of stakeholders in safety. Generative organizations actively seek out information to understand why they are safe and unsafe. Inquiries into safety-related events serve as a means to attack the underlying conditions, not just the immediate causes of the failures. The characteristics of a high-reliability organization can be likened to the characteristics of an organization that has

reached the generative level of cultural maturity. This model can be used to describe how organizations at different levels of maturity approach safety culture improvement (Table 1).

Table 1. Patient safety culture maturity levels

Maturity Levels	Approach to Improving Patient Safety Culture
Pathological	No systems in place to promote a positive safety culture
Reactive	Systems are piecemeal, developed only in response to occurrences and/or regulatory or accreditation requirements
Calculative	Systematic approach to patient safety exists, but implementation is patchy and inquiry into events is limited to circumstances surrounding specific event
Proactive	Comprehensive approach to promoting a positive safety culture exists; evidence-based intervention implemented across the organization
Generative	Creation and maintenance of a positive safety culture are central to mission of the organization; organization evaluates the effectiveness of interventions and drains every last drop of learning from failures and successes and takes meaningful action to improve

Although this model provides a useful framework for safety culture improvement and general guidance on the nature of a positive culture, it does not specify the systems and processes associated with a positive patient safety culture. Therefore, patient safety culture indicators were developed by reviewing the literature on patient safety culture perception surveys and current guidelines on safety culture improvement (e.g., CCHSA Required Organizational Practices).

Patient safety culture is commonly assessed via a self-report perception survey (Fleming and Hartnell 2007). Reviews of patient safety culture instruments (e.g., Colla et al. 2005; Flin et al. 2006; Singla et al. 2006) have identified common cultural dimensions. Given that these instruments were developed independently using different populations, the common elements identified could be considered the fundamental building blocks of patient safety culture. Table 2 identifies the common dimensions from these patient safety survey reviews. From the literature review on patient safety culture surveys, five main patient safety indicators were identified and included in the PSCIT. To fully assess the systems and processes influencing patient safety, these five patient safety indicators were further broken down into more detailed elements of patient safety (see Table 2).

Consultation with Patient Safety Experts

The content and face validity of the original version of the PSCIT was tested by interviewing patient safety experts across

Table 2. PSCIT elements and common healthcare safety elements

Common Healthcare Safety Climate Elements	CCHSA Required Organizational Practices to Create Culture of Safety	PSCIT
Leadership (Colla et al. 2005; Flin et al. 2006; Singla et al. 2006)	Client/patient safety as a written strategic priority or goal Quarterly reports to board on client/patient safety	Patient safety leadership • Patient safety education and training • Patient safety performance evaluation
Safety systems (Flin et al. 2006; Singla et al. 2006) Risk perception (Flin et al. 2006; Singla et al. 2006)	One prospective analysis per year	Risk analysis: safety analysis systems
Job demands (workload issues) (Colla et al. 2005; Flin et al. 2006; Singla et al. 2006)		Workload management • Workload • Fatigue management
Organizational learning and occurrence reporting (Colla et al. 2005; Flin et al. 2006; Singla et al. 2006)	Reporting system for actual and potential adverse events Policy and process of disclosures of adverse events	Sharing and learning • Organizational learning • Incident reporting • Disclosure
Teamwork (Flin et al. 2006; Singla et al. 2006) Communication/feedback (Colla et al. 2005; Flin et al. 2006; Singla et al. 2006) Personal resources (e.g., stress management) and safety attitudes (Flin et al. 2006; Singla et al. 2006)		Resource management: teamwork training (interpersonal skills, teamwork and self-awareness)

CCHSA = Canadian Council of Health Services Accreditation; PSCIT = Patient Safety Culture Improvement Tool.

Canada. Experts were sent the PSCIT in advance of the interview and asked to evaluate the tool for clarity, the extent to which the indicators were objective and the completeness of the tool. They were also asked to consider the extent to which the indicators would differentiate between organizations at different levels of cultural maturity.

Five interviews with patient safety experts were completed. Interviews were conducted over the telephone or face to face and were tape-recorded with the participant's permission. During the interviews, participants commented on their ability to assess their own organization's maturity and benefits of using the PSCIT. The participants identified a number of potential improvements to the PSCIT, such as the need to clarify some of the terms used as they differ across organizations. All the participants indicated that the PSCIT covered the important aspects of patient safety culture and that it was easy to assess the maturity of their systems using the instrument. Participants also indicated that reviewing the PSCIT was a useful exercise. In the words of one participant, "This was excellent. I have identified a list of improvement actions." The PSCIT was revised as a result of the feedback provided during these interviews.

Using the PSCIT

The PSCIT was developed to enable healthcare organizations to assess the maturity of the systems currently in place to promote a positive patient safety culture. (See Appendix 1 at http://www.longwoods.com/product.php?productid=19604 for the revised PSCIT.) The PSCIT outlines increasing levels of cultural maturity and describes the systems associated with each level. The PSCIT provides organizations with a straightforward and structured process for reviewing the extent to which current systems promote a positive safety culture. Improvement actions are identified by comparing current systems with the practices associated with the next level of maturity.

For the best results, the PSCIT should be completed by a multidisciplinary team, consisting of those with expertise in the operation of current patient safety systems, those with budgetary authority and healthcare providers. The PSCIT can be used at the organizational or departmental level. The appropriate level of analysis depends on the organizational structure; the important issues are budgetary authority and the ability to implement new systems. For example, a surgical department could use the tool to identify opportunities for improvement as long as it has the autonomy to implement new systems such as leadership training. If departments or units do not have control over all the elements (e.g., leader performance evaluation), they should skip those elements that they cannot change and focus on evaluating the elements that they can improve.

Initially, team members should individually complete the tool, after which they should meet as a group to discuss their results and reach a consensus. For each element, the team should assess the level of maturity of each indicator (e.g., incident reporting) by reviewing each level of maturity (from 0 to 4) and choosing the maturity level that best describes the systems and

Figure 1. Example of a completed patient safety indicator from the PSCIT

Resource Management				
		Select Level		
Maturity Level	**Training**	**Clinical**	**Non-clinical**	**Managers**
0	No resource management training (interpersonal skills, communication, team working, personal awareness or decision-making) is provided.			
1	Information about resource management is provided to promote working effectively within a team environment.		M	
2	Knowledge-based interdisciplinary resource management training is provided.	L		M
3	Skill-based (includes practice, role play and feedback) resource management training is provided. The training program is developed/adapted to address the specific needs of the interdisciplinary team and is based on analysis of team working challenges.			
4	Resource management training includes practice in a simulated environment and is followed by behavioural observation of performance using validated indicators. Feedback is provided to all individuals after training, and a formal evaluation of the training's effectiveness is conducted.			

processes within their organization. Once the level of maturity has been chosen, the team should assess the degree of implementation within their organization. Thus, for every indicator, the team assesses the degree to which the systems described have been implemented across the organization or department by classifying it as low (i.e., implemented in less than a third of the organization/target group), medium (i.e., implemented in less than two thirds of the organization/target group) or high (i.e., implemented in over two thirds of the organization/target group) and inserting L, M or H in the box that corresponds to this level. Figure 1 provides an example of what one indicator from the PSCIT looks like upon completion. The next step in the process is to discuss the current systems and processes in more detail (e.g., why it was developed, how effective it is) and to consider barriers to moving to the next level of maturity. The team should only use the practices associated with the next level of maturity as a starting point for discussion and should not automatically adapt these practices as an action plan. The focus of the discussion should be the development of a strategic plan for improving the culture, including specific action plans that describe the steps the organization is going to take to reach the next level of maturity.

Conclusions

Creating a positive culture that promotes patient safety is one of the key challenges facing healthcare organizations. Recently, many healthcare organizations have conducted safety culture surveys to assess their current culture and identify areas for improvement. It is likely that these organizations have experienced similar difficulties as those encountered by other industries when they try to use their survey results to identify concrete actions to improve their culture (Fleming and Hartnell 2007). The PSCIT was developed to assist organizations in their efforts to improve their culture. It assesses the organizational practices, systems and processes related to nine patient safety culture elements. The results of the PSCIT provide a description of the current state of an organization's patient safety culture and can be used to develop strategic plans to improve its level of patient safety culture maturity.

The PSCIT has only recently been developed; thus, the psychometric properties (i.e., the reliability and validity) have not been determined. Therefore, this tool should be used with caution to facilitate discussion and support the identification of actions for cultural improvement. Given the early developmental stage, the PSCIT may not be a comprehensive assessment of patient safety culture and should be considered a guide; therefore, improvement teams should not limit the coverage of patient safety culture aspects they may wish to improve to those covered by this tool. The maturity model approach to safety culture improvement is only one way to improve patient safety culture and is offered as a tool that healthcare organizations can use on their journey to creating a positive safety culture. Additional research is currently being developed and conducted to address the lack of reliability and validity data. HQ

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References

Ashcroft, D.M., C. Morecroft, D. Parker and P.R. Noyce. 2005. "Safety Culture Assessment in Community Pharmacy: Development, Face Validity, and Feasibility of the Manchester Patient Safety Assessment Framework." *Quality and Safety in Healthcare* 14(6): 417–21.

Bellamy, G.T., L. Crawford, L.H. Marshall and G.A. Coulter. 2005. "The Fail-Safe Schools Challenge: Leadership Possibilities from High Reliability Organizations." *Educational Administration Quarterly* 41(3): 383–412.

Canadian Council on Health Services Accreditation. 2007. *CCHSA Patient/Client Safety Goals and Required Organizational Practices: Evaluation of Implementation and Evidence of Compliance.* Ottawa: Author. Retrieved January 16, 2008. <http://www.cchsa.ca/upload/files/pdf/Patient%20Safety/PS%20ROP%20version%202%201%20for%202007%20E.pdf>.

Clarke, S. 1999. "Perceptions of Organizational Safety: Implications for the Development of Safety Culture." *Journal of Organizational Behavior* 20(2): 185–98.

Colla, J.B., A.C. Bracken, L.M. Kinney and W.B. Weeks. 2005. "Measuring Patient Safety Climate: A Review of Surveys." *Quality Safety in Health Care* 14: 364–6.

Cox, S. and T. Cox. 1996. *Safety, Systems and People.* Oxford: Butterworth-Heinemann.

Fleming, M. 2000. *Developing a Draft Safety Culture Maturity Model.* Suffolk: HSE Books.

Fleming, M. 2003. "A Solution Focused Approach to Safety Culture Measurement." *HR Professional* August/September.

Fleming, M. and N. Hartnell. 2007. "Safety Culture and Climate in Healthcare." In N. MacKinnon, ed., *Safe and Effective.* Canadian Pharmacists Association.

Fleming, M., N. Wentzell, B. Gatien, S.M. Smith and V. Stinson. 2007. *Understanding Your Dark Matter to Prevent a Big Bang: Safety Culture Audit.* Paper presented at the Petroleum Research Atlantic Canada Research and Development Forum, St. John's, NL.

Flin, R. 2007. "Measuring Safety Culture in Healthcare: A Case for Accurate Diagnosis." Safety Science 45: 653–67.

Flin, R., C. Burns, K. Mearns, S. Yule and E.M. Robertson. 2006. "Measuring Safety Climate in Health Care." *Quality and Safety in Health Care* 15: 109–15.

Flin, R., K. Mearns, P. O'Connor and R. Bryden. 2000. "Measuring Safety Climate: Identifying the Common Features." *Safety Science* 34: 177–92.

Guldenmund, F.W. 2000. "The Nature of Safety Culture: A Review of Theory and Research." *Safety Science* 34: 215–57.

Institute of Medicine. 2000. *To Err Is Human: Building a Safer Health System.* Washington, DC: National Academy Press.

National Patient Safety Agency and School of Psychological Sciences, University of Manchester. 2006. *Manchester Patient Safety Framework.* Retrieved August 10, 2006. <http://www.saferhealthcare.org/IHI/Products/OtherProducts/MaPSaF.htm>.

Nieva, V.F. and J. Sorra. 2003. "Safety Culture Assessment: A Tool for Improving Patient Safety in Healthcare Organizations." *Quality and Safety in Health Care* 12: 7–23.

Parker, D., M. Lawrie and P. Hudson. 2006. "A Framework for Understanding the Development of Organizational Safety Culture." *Safety Science* 44(6): 551–62.

Paulk, M.C., B. Curtis, M.C. Chrissis and C.V. Weber. 1993. *Capability Maturity Model for Software*, Version 1.1. Software Engineering Institute.

Pronovost, P. and B. Sexton. 2005. "Assessing Safety Culture: Guidelines and Recommendations." *Quality and Safety in Health Care* 14: 231–3.

Reason, J. 1998. *Managing the Risks of Organizational Accidents.* Aldershot, United Kingdom: Ashgate.

Schein, E.H. 1990. "Organizational Culture." *American Psychologist* 45(2): 109–19.

Singla, A.K., B.T. Kitch, J.S. Weissman and E.G. Campbell. 2006. "Assessing Patient Safety Culture: A Review and Synthesis of the Measurement Tools." *Journal of Patient Safety* 2(3): 105–15.

Vincent, C. 2005. *Patient Safety.* Edinburgh: Churchill Livingstone.

Waller, M.J. and K.H. Roberts. 2003. "High Reliability and Organizational Behavior: Finally the Twain Must Meet." *Journal of Organizational Behavior* 24(7): 813–4.

Weick, K.E. and K.M. Sutcliffe. 2001. *Managing the Unexpected: Assuring High Performance in an Age of Complexity.* San Francisco, CA: Jossey-Bass.

Westrum, R. 2004. "A Typology of Organizational Cultures." *Quality and Safety in Health Care* 13(2): ii22–7.

Zohar, D. 2000. "A Group-Level Model of Safety Climate: Testing the Effect of Group Climate on Microaccidents in Manufacturing Jobs." *Journal of Applied Psychology* 85(4): 587–96.

Patient Safety Culture Improvement Tool: Development and Guidelines for Use

Mark Fleming and Natasha Wentzell

Appendix 1. Patient Safety Culture Improvement: Self Assessment Tool

Completed by: _____
Date: _____
Level of Assessment (Organization/Department): _____

Safety culture consists of shared perceptions and beliefs about safety. These perceptions are formed in part by leadership priorities and systems that promote the relative importance of safety. Improving the culture involves organizational change by implementing new systems and processes. The first step in developing an action plan is reviewing the current systems in place to promote a positive patient safety culture. Once this has been established, then the organization must identify opportunities for improving current systems. This tool is designed to support improvement teams to develop a strategic plan for improving the culture. Initially, team members should individually complete the assessment and then meet as a group to discuss their results and reach consensus. Then, for each element, the team should consider ways of improving their current systems. It is often useful to use the description of the next highest level as a starting point for discussions, although teams should not simply use the descriptor of the next level as their action item.

Assess your current systems by selecting the maturity level corresponding to the most accurate description of the systems that exist within your organization. Indicate the degree to which it has been implemented across the organization/department by classifying it as low (L – implemented in less than a third of the organization/department), medium (M – implemented in less than two thirds of the organization/department) and high (H – implemented in over two thirds of the organization/department). For example, if you judged the "Patient Safety Leader Education and Training" for senior managers in your organization to be at level 1 and more than two thirds of senior managers had been provided with the information, you would insert an "H" in the box that corresponds to level 1 under the senior managers column. If you have no knowledge of a particular system, then leave that section blank.

Patient Safety Leadership

		Select Level			
Maturity Level	**Patient Safety Leader Education and Training**	**Senior Managers**	**Physician Leaders**	**Middle Managers**	**Front-Line Managers**
0	No patient safety education/training is provided to leaders.				
1	General information on patient safety, including how it is measured, policies and procedures, is provided to leaders.				
2	Leaders receive information about their role in improving patient safety. They receive nonrecurring knowledge-based training about leadership behaviours that promote patient safety.				
3	Leaders are taught interpersonal competencies (through skill-based training) to motivate colleagues and subordinates to improve patient safety. Training is recurrent (at least annual) and includes target setting to improve interpersonal skills.				
4	Leaders receive mandatory individualized patient safety leadership development based on upward appraisal and evaluation. There is a formal ongoing evaluation of leaders' behavioural change.				

Patient Safety Leadership cont'd

		Select Level			
Maturity Level	**Patient Safety Leader Performance Evaluation**	**Senior Managers**	**Physicians Leaders**	**Middle Managers**	**Front-Line Managers**
0	Leaders are not evaluated on patient safety.				
1	Promoting and assessing patient safety is included in the leaders' job description. Leader performance is evaluated following a significant patient safety event (e.g., unexpected death) within their area of responsibility.				
2	There is a formal system in place to monitor performance and performance reviews are conducted for leaders. Leaders' performance is monitored through regular discussions of cases and outcomes.				
3	Performance is routinely monitored using a variety of techniques (e.g., performance reviews, retrospective chart reviews). Input from colleagues is sought. Results from monitoring are discussed with individual being reviewed.				
4	Performance is monitored with leading indicators of patient safety. Ongoing and systematic observations of practice are conducted. The results from performance monitoring are used to develop individual learning plans. Peers routinely monitor each other's performance and provide constructive feedback for improvement.				

Workload Management

		Select Level			
Maturity Level	**Workload**	**Physicians**	**Nurses**	**Residents**	**Allied Health Professionals**
0	No consideration of the impact of workload on patient safety.				
1	Guidelines for the ratio of healthcare workers to patients are used to manage workload levels.				
2	Minimum healthcare worker–to–patient ratios are set based on available evidence and best practice. These levels are monitored closely and actions taken when minimum standards are not met.				
3	In addition to evidence-based minimum staffing levels, staffing decisions take into consideration client group's needs and the experience and skill mix of the healthcare team.				
4	There is a holistic approach to workload management that considers all the demands placed on healthcare workers, such as the intensity of the work environment (i.e., the tasks to be performed, number of client interactions), client acuity and the skill mix of the healthcare team. This approach involves providing additional resources for high-intensity situations, where treatment must be provided immediately and when members of the healthcare team are less experienced.				

Workload Management cont'd

		Select Level			
Maturity Level	**Fatigue Management**	**Physicians**	**Nurses**	**Residents**	**Allied Health Professionals**
0	No consideration of the impact of fatigue on patient safety.				
1	Fatigue is acknowledged as a patient safety risk factor. Fatigue-management efforts focus on limiting the number of hours worked per shift and per week.				
2	Strategic plan developed to redesign shift rotations (length and timing) that are increasing fatigue or are contrary to evidence and best practice.				
3	Fatigue-management plan (ensures shift rotation does not contribute to increasing healthcare worker fatigue) is implemented and monitored. This plan includes leading practices in fatigue management such as sleep contracts (formal agreements about the amount of sleep between shifts that encourage healthcare workers to rest while they are off shift).				
4	Fatigue is identified as a form of impairment influencing cognitive performance (e.g., decision-making, digit span). Performance is routinely monitored using validated instruments to provide information on the level of impairment and enables healthcare workers to self-assess their performance and take remedial action (e.g., request support from colleagues).				

Resource Management

		Select Level		
Maturity Level	**Training**	**Clinical**	**Non-clinical**	**Managers**
0	No resource management training (interpersonal skills, communication, team working, personal awareness or decision-making) is provided.			
1	Information about resource management is provided to promote working effectively within a team environment.			
2	Knowledge-based interdisciplinary resource management training is provided.			
3	Skill-based (includes practice and feedback) resource management training is provided. The training program is developed/adapted to address the specific needs of the interdisciplinary team and is based on analysis of team working challenges.			
4	Resource management training includes practice in a simulated environment and is followed by behavioural observation of performance using validated indicators. Feedback is provided to all individuals after training, and a formal evaluation of the training's effectiveness is conducted.			

Sharing and Learning

Maturity Level	Organizational Learning	Select Level
0	There are no systems in place to support organizational learning.	
1	Events that result in significant harm (e.g., wrong-site surgery) are investigated, and actions are specified to prevent the reoccurrence of this specific event.	
2	All event reports are investigated using validated tools and processes (e.g., root-cause analysis). Patient safety improvement actions are identified from the investigation and implementation tracked.	
3	An integrated investigation system is implemented (e.g., incident reporting system, retrospective chart reviews and clinical audit process). Detailed results of investigations for each department are discussed with staff on a regular basis, and summary results are shared across the organization.	
4	A comprehensive organizational learning system is in place that includes incident reporting, retrospective chart review and audits. The organization learns from both negative and positive outcomes by identifying the practices that protect patients as well as those that increase risk.	

Maturity Level	Incident Reporting	Select Level
0	There are no reporting systems in place.	
1	Incident report forms or electronic reporting system is available to enable staff to report patient safety events and concerns.	
2	Incident reporting system (either paper or electronic) is in place. Training on how to use the system is provided to all staff. Learning from reported incidents is used in patient safety training. Reports have the option for individuals to identify themselves so that additional information about the incident can be obtained.	
3	Independent incident reporting system is used to facilitate confidential (not anonymous) reporting. Managers identify common themes from the reports and discuss them at department meetings. There are mechanisms in place to provide information to all staff (e.g., monthly summaries are provided to all staff).	
4	Incident reporting system includes detailed description of the event. Events are coded by a human factors expert and follow-up discussions (e.g., by telephone) are conducted with the person who reported the incident. There is a formal process in place to track every incident and the outcomes associated with it. Incidents are used as learning tools; each incident is described to all staff members and the actions resulting from the report are explained.	

Maturity Level	Disclosure*	Select level
0	No disclosure policy in place.	
1	Disclosure policy in place as per the Canadian Council on Health Services Accreditation (CCHSA) guidelines.†	
2	Disclosure training offered to all staff (including physicians) including requirements under the policy.	
3	Disclosure training is given to all staff (including physicians). Patients and families of those involved in an adverse event provide input into the training and are consulted on an ongoing basis to seek feedback on how disclosure is managed.	
4	Use of retrospective chart audit to assess quality (and extent) of disclosure when harm has occurred.	

*The core elements of disclosure as identified by CCHSA are discussing the adverse event itself, acknowledging/apologizing for the adverse event, reviewing the actions taken to mitigate the circumstances, discussing the corrective action to prevent further adverse events and answering the questions of the patient/client and/or family.

†CCHSA (2007) guidelines state that a "formal (transparent) policy and process of disclosure of adverse events to patients/families, including support mechanisms for patients, family and care/service providers" must be implemented.

Risk Analysis

Maturity Level	Safety Analysis Systems	Select Level
0	No systematic use of safety analysis systems to promote patient safety.	
1	Safety analysis tools are used for major events. For example, retrospective analysis tools (e.g., root-cause analysis) are used to investigate the causes of events that resulted in significant harm (e.g., wrong-site surgery), and prospective analysis tools are used when planning major organizational changes such as a new building.	
2	Safety analysis tools are used frequently. The analysis is led by patient safety specialists with involvement of healthcare workers.	
3	A wide range of healthcare workers are competent in using safety analysis tools. Healthcare workers regularly use these tools to learn from incidents and identify ways of improving patient care.	
4	Safety analysis systems are integrated into the routine activities of healthcare workers; the effectiveness of the system is monitored. For example, actions identified during a prospective analysis are tracked to ensure they were implemented and worked as intended.	

An Evaluation of Patient Safety Leadership Walkarounds

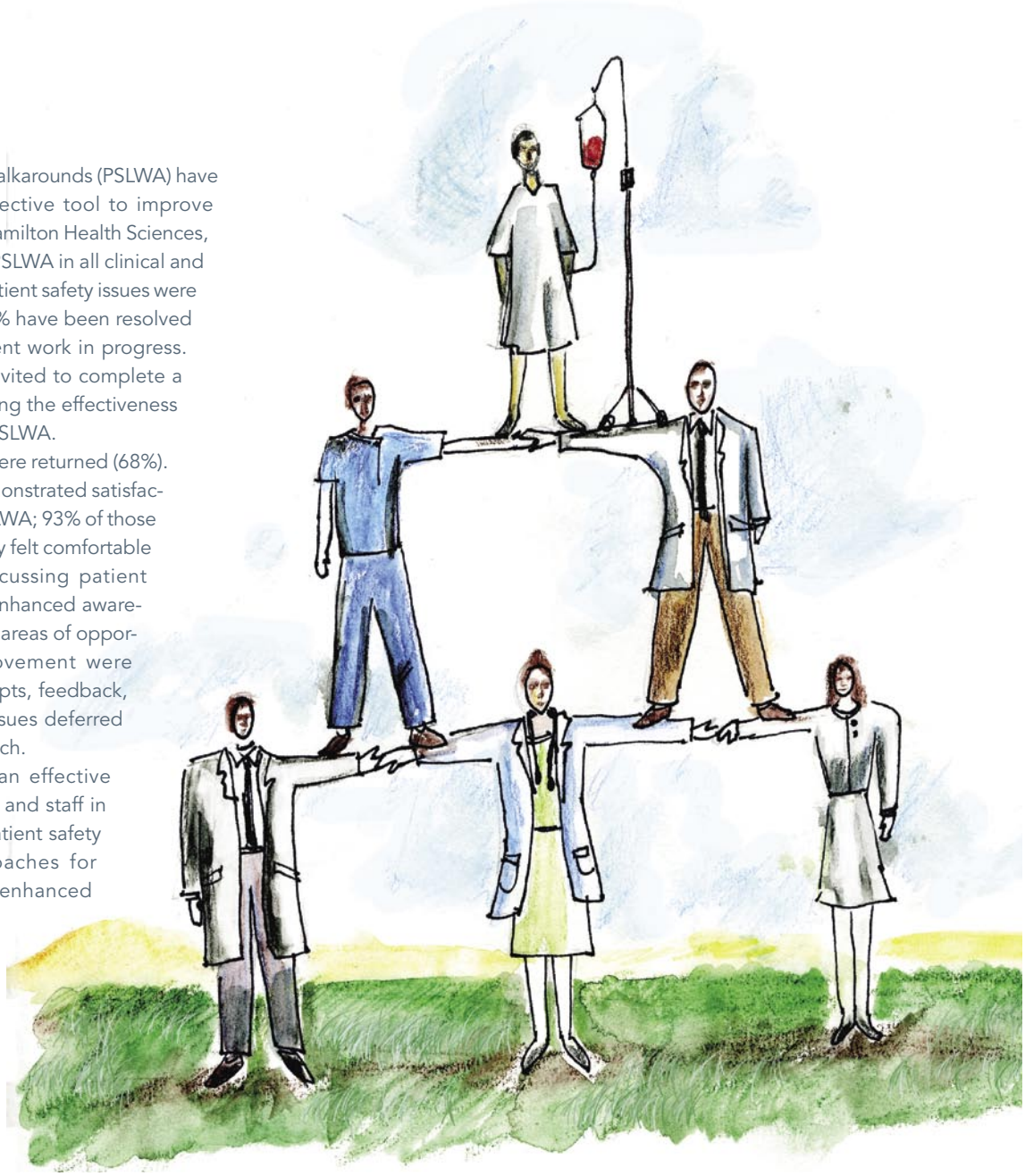
Rosanne Zimmerman, Ivan Ip, Charlotte Daniels, Teresa Smith and Jill Shaver

Abstract

Patient safety leadership walkarounds (PSLWA) have been identified as an effective tool to improve patient safety culture. At Hamilton Health Sciences, after one year of monthly PSLWA in all clinical and service programs, 1,351 patient safety issues were identified, of which 64–80% have been resolved or have active improvement work in progress. Five hundred staff were invited to complete a process evaluation regarding the effectiveness of the current process of PSLWA.

A total of 341 surveys were returned (68%). The overall evaluation demonstrated satisfaction with the process of PSLWA; 93% of those surveyed reported that they felt comfortable openly and honestly discussing patient safety issues and had an enhanced awareness of patient safety. Five areas of opportunity for process improvement were identified: scheduling, scripts, feedback, reporting and resolving issues deferred for an organization approach.

PSLWA have offered an effective way to engage leadership and staff in open discussions about patient safety and collaborative approaches for solutions suggesting an enhanced patient safety culture.



"The patient safety movement is striving to develop a culture of safety whereby each individual, whether on the receiving or delivery end of care, is preoccupied with safety, is armed with the skills to evaluate his or her environment for potential harm, and is supported and rewarded for making appropriate choices" (Frankel et al. 2003: 16). Patient safety leadership walkarounds (PSLWA) have been identified in the literature as a powerful tool to develop patient safety culture by connecting senior leaders and front-line staff in open dialogues about patient safety (Leonard et al. 2004). Additionally, this strategy promotes teamwork, opens communication channels and offers an opportunity for teams to engage in working together to improve patient safety.

At Hamilton Health Sciences (HHS), PSLWA were initiated in March of 2006, in conjunction with other initiatives to address patient safety culture. HHS is a four-site, 1,000-bed regional tertiary care facility that is composed of five hospitals and a cancer centre. PSLWA offered a unique way to address the challenges of developing patient safety culture in a large organization of 10,000 staff spread over four sites. In the first year of implementation, 984 walkarounds were scheduled. During these PSLWA, 1,351 patient safety issues were identified (Table 1), of which 64–80% were resolved or have active improvement work in progress (Figure 1). The identified patient safety issues were categorized using Vincent's (2006) themes (Figure 2). Following the first year of implementation of this strategy, a process evaluation was completed regarding the current process of PSLWA at HHS.

PSLWA at HHS

There are different processes described in the literature for conducting PSLWA. HHS has adapted the original WalkRounds framework created by Dr. Alan Frankel (Frankel et al. 2003) at Brigham and Women's Hospital in Boston. Although the majority of literature related to PSLWA suggests the application to clinical or clinical support areas, at HHS, PSLWA are conducted in all clinical and service areas in alignment with our philosophy that patient safety is the responsibility of everyone at HHS. PSLWA occur each month in every clinical unit or service area and are led by the manager in the absence of the director or senior team. The director attends PSLWA in all areas of accountability once per quarter, and senior team members attend walkarounds monthly in rotating areas. A central shared access scheduling drive is provided to allow for ease of scheduling multiple leaders. Scripted themed questions are provided to the leaders each quarter to facilitate leading the PSLWA and are to be posted prior to the walkaround for staff. Accountability for resolution of patient safety issues occurs at the unit or area leadership level for most issues and is delegated up for program- or organizational-level issues. Quarterly reports of patient safety issues and the corresponding action plans are summarized by the managers in a computer database. As well, these unit- or area-level reports are then summarized into program reports, which are submitted by the directors to the Patient Safety Team for collation into an organizational report. This report is presented quarterly to the Patient Safety Steering Team.

Recognizing that communication of response to issue identification is a critical success factor for the sustainability of this initiative, all levels of the organization are responsible to provide feedback to staff of action taken on the issues for their relevant level. Formal training for all of the leadership team was provided initially and is ongoing.

In the first year of implementation … 1,351 patient safety issues were identified, of which 64–80% were resolved or have active improvement work in progress.

Evaluation Method and Demographics of Respondents

In March of 2007, 500 staff (including the leadership team and five front-line members from each unit or area) were asked to complete a survey to evaluate the PSLWA process. Each area was asked to include one staff member who had not yet taken part in PSLWA, if possible. The survey tool consisted of demographic questions, 15 four-point scale questions and four open-ended questions related to the process. In addition, leaders were asked to complete an additional 10 questions related to their role in PSLWA. All surveys were submitted to the Patient Safety Team for analysis. Of a possible 500 responses, 341 were received from 26 programs, which represented a return rate of 68%. Front-line staff comprised 57% of the respondents, and the remaining 43% were formal and informal leaders. Clinical areas represented 71% of the responses, and service areas 28%. A total of 11% of respondents had never attended a walkaround, 56% had attended between one and five PSLWA and the remaining 33% had attended more than five PSLWA.

Results and Next Steps

Strengths

The overall evaluation demonstrated satisfaction with the process of PSLWA and identified some minor improvement opportunities. Some of the strengths identified in the process included the following: 93% of respondents agreed that the PSLWA had enhanced awareness of patient safety issues and that they felt comfortable openly and honestly discussing patient safety issues; 70% of respondents felt they were always heard at PSLWA; and 91% of leaders felt comfortable leading PSLWA (96% clinical,

86% service). Five areas of the process were identified as opportunities for improvement. These areas for improvement were brought to a stakeholder team for discussion and to provide input into resolutions.

Opportunity 1: Scheduling

Consistent with known and ongoing workload issues, 48% of respondents indicated that attendance at PSLWA was difficult or somewhat difficult. Front-line staff reported this more frequently (49%) than leaders (46%), and clinical staff more frequently (54%) than service staff (34%). The stakeholder group further elaborated that general workloads, competing priorities and time of day were contributors to this difficulty. To improve this part of the process, leaders have been encouraged to schedule PSLWA up to a year in advance in the shared schedule and to consider workload patterns for front-line staff in choosing the time of day to conduct PSLWA.

Opportunity 2: Scripting

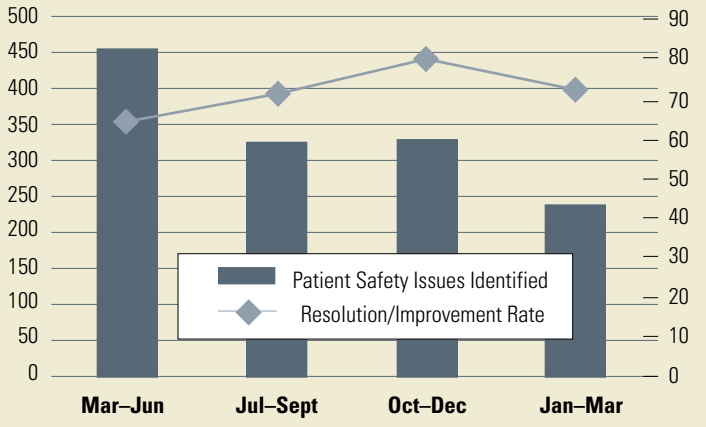
The scripted questions were reported to be easy to answer (93%) and most of the time led to discussions about patient safety (91%). As well, 66% of PSLWA were reported to take 45 minutes or less. Some of the narrative comments in the survey suggested that there was room to improve transferability and relevance of questions to all areas and to shorten the number of questions to ensure more timely completion of PSLWA.

To address this concern, the scripts were decreased to a standardized format of four questions. The first question is an organizationally generated question to prompt dialogue about a current initiative, work or safety concern that has contextual and temporal relevance at a corporate level. The second question is an open-ended question asking what patient safety issues staff have observed in the past week. The third question allows the unit to choose a question that was specifically relevant to their area or unit in the time frame when it was being asked. To facilitate the selection of a third question, a dictionary of over 100 themed questions was developed from the patient safety literature and from a stakeholder group. This dictionary allows each area the flexibility to customize a relevant discussion to their current issues. The final question asks each participant how they will contribute to resolving the issues discussed at the PSLWA. This is meant to continue to engage all participants to work as a team to solve patient safety issues.

Table 1. Examples of patient safety issues and solutions

Patient Safety Issue Identified	Patient Safety Solution Implemented
Shortcuts can and do result in a risk to patients	Implementation of a quality assurance education and auditing plan to ensure that standard operating proceducres were met in clinical support services
Insufficient transfer of information when patients arrive to ambulance and patient care area at cancer clinic	Transfer of accountability process implemented for patients arriving in ambulance care
Need for a forum to openly discuss errors and learn from them	Adoption of regular occurrence reporting rounds – presentations of case studies by staff involved in errors
Turnaround time for equipment repair too long	Monthly engineering shop meetings at every site to identify barriers to repair and to generate solutions
Need to improve reporting of adverse events and near misses	Implementation of the Eagle Eye project to reward and recognize reporting by staff
Pharmacist shortage and medication errors	Fourth medication check by pharmacy technician

Figure 1. Identified Patient Safety Issues and Rate (%) of Resolution



A second issue identified related to scripting was that 40% of respondents indicated that pre-posting of the scripted questions to allow front-line staff time to consider and prepare for the walkaround did not occur. Upon further investigation of this with the stakeholder group, it was found that managers were unaware of the need to post questions or had competing priorities. This requirement of the process has been re-communicated at multiple forums as well as the suggestion to delegate this role.

Figure 2. Mean Distribution of Vincent Themes for Identified Patient Safety Issues

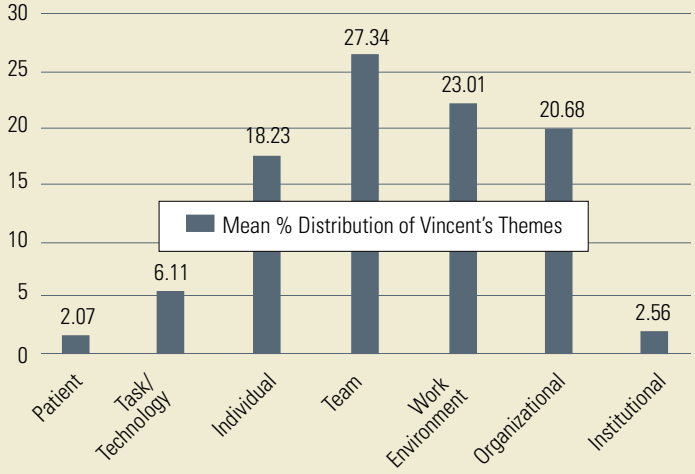


Table 2. Report database fields

Date of PSLWA
Identified Issue
Number of Units Reporting Identified Issue
Theme
Subtheme
Severity of Impact on Patient Safety
Likelihood of Occurrence
Assessed Impact/Risk
Impact on Resources
Corrective Action/MRP
Date Status Reported
Status of Issue Resolution
Estimated Timeline for Improvement Work
Barriers to Issue Resolution

MRP = most responsible person; PSLWA = patient safety leadership walkarounds.

Opportunity 3: Feedback

Despite the expectation that all levels of the organization would provide feedback of their relevant improvement work related to identified issues, 32% of respondents felt that feedback was below or somewhat below expectations. Clinical areas (30%) reported this less frequently than service areas (39%). To facilitate this feedback, the script introduction now includes a section in which the manager will communicate the ongoing resolution or work in progress related to the identified issues of the previous walkaround at the beginning of the current one. As well, all program directors and the Patient Safety Team are responsible quarterly to report program and organizational level work being done related to patient safety. Respondents also suggested that feedback should be given in multiple forms of media, such as newsletters, bulletin board postings, staff meetings, e-mails and program meetings.

Opportunity 4: Reporting

Currently, quarterly reports are in an Excel-based database format with multiple fields of drop-down boxes (Table 2). The time required to complete the quarterly report was noted by the majority of respondents to be less than one hour (82%); however, a large number of respondents (45%) indicated the need for an easier reporting template to use. Several revisions and changes have already been made to the reporting template including a self-generating risk matrix of severity and likelihood that assigns patient safety risk and standardized sub-themes. A stakeholder group has provided some recommendations to be considered for further revisions, and work is in progress to improve the ease of use of the current report.

Respondents clearly reported an increased awareness of patient safety issues, and there was an expression of a level of comfort in openly and honestly discussing them.

Opportunity 5: Accountability for Issues Requiring an Organizational Approach

The final area identified for improvement was the need for a clear process and accountability for the resolution of issues that have been deferred from programs because they require an organizational approach. Patient safety issues referred to the organization for resolution are now presented to the director group, which will determine an action plan for resolution and provide a report of progress to the Patient Safety Steering Team.

Conclusion

The purpose of PSLWA is to encourage open dialogue about patient safety issues and to enhance patient safety culture. The initial process evaluation of PSLWA has proven this to be a beneficial strategy that may suggest an enhanced patient safety culture. Respondents clearly reported an increased awareness of patient safety issues, and there was an expression of a level of comfort in openly and honestly discussing them. The overwhelmingly positive feedback to the process is reflected in the many narrative comments in the survey (Table 3).

Table 3. Survey comments related to the PSLWA process

"Staff identify that the PSLWA are useful and important."

"I think that PSLWA are brilliant."

"Staff are now looking forward to LWA; more and more staff want to attend. We are getting more physician attendance as well."

"A very positive initiative … extremely pleased with the process and staff feedback."

"Pleasantly surprised by how the staff have embraced the initiative."

"This is a fantastic avenue for the minds to meet to attain our common goal of patient safety. The forum is open and one feels that together, we can make anything happen."

"They make me feel that we are a team,… meaning all of us can make a difference regarding how we work together to improve all aspects of care … When you feel you are making a difference daily … workload no longer feels like workload but a service done, and I feel good about how the day goes."

LWA = leadership walkarounds; PSLWA = patient safety leadership walkarounds.

After the first year of PSLWA, we continue to refine and improve the process to ensure a sustainable and valued process. We continue to address the challenges related to the creation of a robust reporting and feedback system. As well, changes related to the script, scheduling and accountability for issues related to organizational processes are ongoing. Senior leadership support has been key in the success and sustainability of this initiative.

Our next step includes assessing the impact to patient safety culture through a patient safety culture survey. As the Health and Safety Commission stated, "Organizations with a positive patient safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventative measures" (Vincent 2006). PSLWA have offered an effective way to engage leadership and staff in open discussions about patient safety and collaborative approaches for solutions. HQ

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References

Frankel, A., E. Graydon-Baker, C. Neppi, T. Simmonds, M. Gustafson and T. Gandhi. 2003. "Patient Safety Leadership WalkRounds™." *Joint Commission Journal of Quality and Safety* 29(1): 16–26.

Leonard, M., A. Frankel and T. Simmonds. 2004. *Achieving Safe and Reliable Healthcare: Strategies and Solutions.* Boston: Institute for Healthcare Improvement and the American Organization of Nurse Executives.

Vincent, C. 2006. *Patient Safety*. UK Health and Safety Commission. Toronto: Elsevier.

Implementation of a Safety Framework in a Rehabilitation Hospital

Gaétan Tardif, Elaine Aimone, Carol Boettcher, Carol Fancott, Angie Andreoli and Karima Velji

Abstract

This patient safety initiative was implemented at the Toronto Rehabilitation Institute, a fully affiliated hospital of the University of Toronto that operates in-patient and outpatient facilities on five sites. A working group was created to engage the leaders and employees in defining and implementing our "ideal" safety culture.

A subset of this group became the Research Team, mandated to do the "discovery work" with external groups and internal stakeholders to provide valuable input for designing the safety culture model. This involved identifying the key components required to support a safety culture, testing this model with findings from the academic literature and best in class organizations and identifying the who, what, when, where and how of each key component.

Future activities will focus on the integration of safety into existing programs, initiatives and policies, seeking feedback from staff, patients and families, and evaluating the effectiveness of our intervention and the extent of the culture change.

Safety literature specific to rehabilitation is extremely sparse. Most of the attention to date has been on developing standards for acute care hospitals, an environment of short stays, acute illnesses, invasive interventions and frequent changes in applied therapeutic modalities. At the other end of the spectrum, long-term care standards are also being developed, primarily focusing on input measures (e.g., number of medications, use of restraints). We do not know if these standards can be appropriately applied whole or in a modified manner to a medium-sized rehabilitation hospital that falls between these two sectors in terms of acuity and intensity of intervention. The purpose of this article is to describe an organizational patient safety change management plan within a large academic rehabilitation institution, how this plan was developed and implemented and key learnings from this initiative as we continue to move forward.

This safety initiative was undertaken at the Toronto Rehabilitation Institute, an institution born in 1998 from a four-hospital merger. The hospital, a fully affiliated hospital of the University of Toronto, operates in-patient and outpatient facilities on five sites and employs approximately 1,800 people.

The academic role is a relatively new phenomenon for much of the staff. Our exponential growth in research and education demonstrates an extremely rapid organizational change superimposed on a mosaic of merging cultures.

As the clinical and academic programs rapidly evolved, senior leaders agreed to place an emphasis on patient safety, particularly in relation to organizational culture. Our main objective was to ensure that Toronto Rehabilitation Institute had in place the right organizational structure and processes to minimize risks to patients and staff. Such a framework would have the ability to accomplish the following:

- Identify key goals for patient and staff safety on an ongoing basis
- Bring together key stakeholders to address identified safety issues
- Support optimal reporting of incidents, near misses and unsafe situations in a "just culture" environment
- Identify key metrics, collect data and share findings in a timely and efficient manner
- Empower staff to resolve safety issues at the point of service
- Ensure sustainability of achieved improvements through appropriate outcome measures monitoring, benchmarking and reporting to senior management and the board of directors
- Implement a safety-conscious continuous quality improvement approach to the delivery of services

Evidence Review

As forecasted, rehabilitation-specific patient safety literature was extremely limited. To augment the literature, we conducted semi-structured interviews with Canadian and US hospitals deemed to be leaders in the field of patient safety. An aviation safety expert was also consulted to draw parallels between high-reliability industries and hospitals. Key questions were kept in mind during the knowledge-seeking process:

- What are the major contributors to the delivery of quality patient care and minimization of risk at the front lines?
- Are there risk issues specific to rehabilitation?
- Which administrative structures best facilitate knowledge sharing, discussion, evaluation and integration of safety-related activities?
- How can hospital leadership best support the implementation of a safety framework?
- What are key considerations in implementing an accountability model based on a paradigm of just culture?

A literature review of management did yield several good references on safety culture, incident management and accountability models but relied heavily on case reports. Few had a true qualitative research design, and even fewer had quantitative outcome measures. Many overarching principles were extracted that had excellent face validity in the context of sound management principles:

- That a just culture approach is effective in optimizing safety in a healthcare organization (Note: Just culture is defined by James Reason 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" [Reason 1997])
- The importance of executive sponsors in creating the vision and advocating for safety practices using explicit methods

Table 1. Results of a culture survey

Safety Culture Dimension	Percentage in 2006	Percentage in 2007	US Hospital (382 participants) Average (%)
Overall perceptions of safety	55	56	63
Frequency of events reported	52	51	59
Manager expectations	68	71	74
Organizational learning/continuous improvement	66	70	69
Teamwork within units	74	76	78
Communication openness	52	53	61
Feedback about error	52	52	62
Non-punitive response to error	40	43	43
Staffing	49	52	55
Management support of safety	65	71	69
Teamwork across units	55	57	57
Handoffs and transitions	43	43	45

Source: Culture survey from Agency for Healthcare Research and Quality 2007

such as executive walkabouts focused on safety
- The need for clear governance of accountability and reporting structures for adverse events including a rigorous review and follow-up process
- A long-term view on change in attitude toward safety – "changing culture is by definition a slow process" (Reason, cited by Leape 2006)

As part of a research project, a validated culture survey (Agency for Healthcare Research and Quality [AHRQ] 2007) was sent to all hospital staff in the spring of 2006 (Velji et al. 2008). The survey gave us a baseline measure that can be followed over time as well as compared with data from other institutions. Our results were very much "average," with four of the 12 dimensions receiving slightly lower scores than the US composite average (Table 1). We repeated the survey in the spring of 2007, with similar results, pointing to a stable baseline.

"Changing culture is by definition a slow process."

Change Management Plan

The initial step was to identify executive sponsors and ensure that they were in agreement with a multi-stage approach that would draw heavily from the hospital's leadership community in defining the needs as well as creating and implementing solutions. This initial step proved vital to fully engage the executive sponsors who, naturally, came with their own priorities and also had to deal with day-to-day issues related to safety within their portfolios, many of which arose from ongoing external pressures such as Ontario's Quality of Care Protection Act, surveys on safety (e.g., that of the Ontario Hospital Association) and the inclusion of new safety standards by the Canadian Council on Health Services Accreditation.

The three identified executive sponsors were the vice-president of patient care and chief nursing executive, the vice-president of patient care and chief medical officer and the vice-president of human resources and organizational effectiveness. Our joint role was to provide the overall leadership and define the scope, focus and expected outcomes, approve the project plan and resources, approve the recommendations for action, align the change initiative with the hospital strategic direction and priorities, coordinate major activities with other change initiatives and liaise with the senior management team to keep members fully informed and supportive. We also led a Safety Working Group whose role was to engage the leaders and employees of Toronto Rehabilitation Institute in a process to define and implement our "ideal" safety culture. Members of this team were carefully selected to represent the views, interests and expertise necessary to bring a whole systems view to this challenge. Specific duties were assigned to the working group:

- Defining the change process or road map for the change
- Conducting a stakeholder analysis and readiness for change assessment
- Defining an accountability model for how to enable a safety culture
- Communicating the case for change, the vision, first steps and next steps
- Tracking progress, capturing learnings, enabling progress and removing barriers
- Embedding the new culture into "the way we do things around here"

The Safety Working Group facilitated a group session with all stakeholders identified as leaders and influencers of the safety process. The group of over 80 people was composed of leaders at all levels, from senior managers to front-line managers, formal and informal leaders such as educators and advanced practice leaders, medical directors of all clinical programs and leaders in support services, human resources, occupational health and safety and finance. The 10-hour session held over two days engaged leaders in critical conversations on the why, what and how of safety culture and sought input on Toronto Rehabilitation Institute's safety blueprint and its implementation. Through a series of facilitated small-group discussions followed by plenary sessions, participants examined their own assumptions, shared their experiences, refined the blueprint and started charting a course of action for patient safety at the institute.

Table 2. Top 10 safety-related "irritants"

1. Inconsistent top up of supplies on in-patient units
2. Unreliable preventative maintenance program
3. Insufficient availability and refilling of hand sanitizers in clinical areas
4. Long turnaround time for radiology reporting
5. Complicated incident reporting system
6. Urgent training needs in non-violent crisis intervention
7. Outdated safety-related policies
8. Lack of a safe home-like environment for rehabilitation training
9. Lack of administrative tools impacting nursing direct patient care hours
10. Poor housekeeping response time to safety and infection-control issues

In terms of making "first steps," the consensus was that early accomplishments – "removing long-standing irritants" – would be of utmost importance in initiating a culture change. At the end of the leadership engagement session, the senior team committed to develop a list of the top 10 safety-related irritants that needed to be resolved and set an example of responsiveness and commitment to resolving safety issues. The top 10 list was developed by polling staff through their managers and supervisors who attended the meeting (Table 2). The executive sponsors assigned project leads, who were given responsibility for each of the 10 items on the list. Rapid progress was expected and reviewed regularly by the Senior Operations Committee.

The consensus was that early accomplishments – "removing long-standing irritants" – would be of utmost importance in initiating a culture change.

Implementation of Change

The key action items identified by the executive sponsors as a result of the group sessions can be summarized as follows:

- Create a working definition of safety culture that resonates with our leaders, staff, patients and families
- Develop the safety infrastructure, including incident reporting, analysis, follow-up and escalation process
- Integrate safety into existing programs, initiatives and policies
- Obtain input from patients and family members
- Plan a follow-up leadership retreat
- Plan the communication and launch with all staff
- Initiate and evaluate leadership safety walkabouts
- Develop a safety scorecard of outcome measures and benchmarks
- Embed the change and dismantle the working group
- Ensure an ongoing evaluation of culture change

We decided to create a new position of patient safety officer for the organization, maintain the existing position of risk manager and refocus the position of director of organizational effectiveness and risk management to take a greater role in patient safety – to become the de facto "chief patient safety officer" (not a job title) reporting directly to the president and chief executive officer (CEO) rather than to a vice-president. We saw this approach as providing the organization with a higher profile for patient safety through direct reporting to the CEO and a dedicated front-line resource in the new patient safety officer; these changes would enable the risk manager to better focus on analyses of incidents and near misses.

In reassigning responsibilities, we looked for synergies and created a new position of director of clinical services to oversee all corporate services cutting across program areas. This new director's areas of responsibility include pharmacy, laboratories and diagnostics and infection control – all areas of high risk with respect to safety.

We initially proposed that a regular review of incidents, near misses and proposed actions should occur through a newly formed patient safety committee; but, upon further consultations, we assigned this responsibility to the Senior Operations Committee. The committee's core membership includes the vice-presidents responsible for patient care, finance and support services, and human resources and organizational effectiveness as well as four executive directors who report to them. Other members of the senior management team, including the CEO, participate as needed based on the agenda for any particular meeting. Since the committee meets every second week, it can be much more responsive to issues than a specially constituted committee that would only meet a few times a year. We believe this will contribute to a more effective integration and sustainability of the project objectives into day-to-day operations of the institution.

To enhance the profile of safety as a key priority within our institution, safety issues need to be communicated regularly and effectively across the organization. Throughout the project, communication on safety took several forms: e-mails to all staff from the CEO reiterating the organizational commitment to safety; the inclusion of a "Focus on Safety" section in LINK, the staff biweekly newsletter; the development of a safety column on the hospital intranet; continued education on incident and near-miss reporting; and a standing agenda item at Management Forum, a meeting of all management staff taking place the day following the hospital board meetings. As agreed, we reconvened the large group of institutional leaders to reorient them to the safety framework, obtain input on how well we reflected their feedback and obtain their commitment for the safety activities planned.

The official kickoff took place in March 2007, with further communications to managers and staff and the initiation of leadership walkarounds. The launch reached every member of our staff directly – an exponential jump from 80 managers and leaders to 1,800 staff. In preparation for the launch, two "warm-up" events took place. Firstly, results from the AHRQ patient safety culture survey were presented to staff through video-conference rounds. This was communicated in the context of the research project through which the survey took place and emphasized the need to change current perceptions and practices regarding safety issues and concerns. Secondly, an update showing the resolution to the top 10 list was posted on our intranet to demonstrate strong management support for safety initiatives. Our managers were also provided with

training, including a short guide on the purpose and logistical aspects of the leadership walkabouts.

Life after the Project

Prior to the inception of the intervention project, and indeed throughout its life, hospital initiatives in support of patient safety continued to take place. Some established initiatives benefited from the project, such as our electronic incident reporting system, which was changed to have a much easier interface and a stronger data analysis capability. Feedback received through our managers-and-leaders meetings was invaluable in improving its interface and usage. A telephone hotline to report incidents and near misses was also implemented. The implementation of a picture archiving and communications system for radiology was accelerated as a result of the top 10 list.

Some other initiatives were implemented as planned: a new pharmacy computer system, unit-dose distribution and an improved night-cupboard integrating state-of-the-art hardware and software. A real-time dashboard-type interface for key outcomes also became available to all managers within the organization, allowing them to access key information in a timely manner.

Other initiatives, such as the full implementation of an electronic health record, are still in plans for the future due to the scope of the project. Appropriate resources have been assigned in support of implementation.

In our spring 2007 walkabouts, 154 issues were raised by the staff, half of which were deemed medium- or high-priority items. Risks of falls and infection-control issues were cited most often. Within three months, over 100 of these issues were satisfactorily resolved. We are continuing to address these issues as we embark on our next series of walkabouts, and anticipate continued dialogue with staff regarding their safety concerns.

We have no doubt that continued emphasis on safety will be important to sustain the journey toward culture change. In particular, we will need to address how to accomplish the following:

- Truly integrate safety into existing programs, initiatives and policies – how will we know that we have created empowerment at the point of service?
- Obtain input from patients and families; this will be done initially as part of a formal externally funded research project
- Evaluate the effectiveness of our leadership safety walkabouts
- Determine and apply outcome measures and benchmarks in respect to safety
- Evaluate culture change; we plan on repeating the AHRQ survey on a regular basis to assess our continuing progress.

We also have established a new research program that has demonstrated success in obtaining external grants to develop new knowledge on patient safety in rehabilitation and complex continuing care. This type of development activity using our institution as a living laboratory is core to our institutional vision and mission. Supports are being put in place to further the training of promising young researchers in this domain.

We identified up front the challenge we faced in defining patient safety in a rehabilitation and complex continuing care environment. Our research will no doubt bring us closer to the answer. As we share our experience with our colleagues in healthcare, we will also gain useful insight from their reactions. Will they be surprised by the items in our top 10 list? Will the issues raised in the leadership walks in other institutions be similar or different to those raised in our institution? Our prediction is that there will be significant overlap between sectors, with different areas of primary focus required to ensure the safety of staff and patients. HQ

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References

Agency for Healthcare Research and Quality. 2007. *Culture Surveys*. <http://www.ahrq.gov/qual/hospculture/>.

Leape, L. 2006. "Safety Is about Systems, but Safety Is Really about Relationships." Paper presented in a seminar held at the University of Toronto, Toronto, ON.

Reason, J. 1997. *Managing the Risks of Organizational Accidents.* Hants, England: Ashgate.

Velji, K., G.R. Baker, C. Fancott, A. Andreoli, N. Boaro, G. Tardif, E. Aimone and L. Sinclair. 2008. "Effectiveness of an Adapted SBAR Communication Tool for a Rehabilitation Setting." *Healthcare Quarterly* 11 (Special issue): 72–9.

Developing a Patient Safety Plan

Rosanne Zimmerman, Ivan Ip, Emily Christoffersen and Jill Shaver

Abstract

Many healthcare organizations are focused on the development of a strategic plan to enhance patient safety. The challenge is creating a plan that focuses on patient safety outcomes, integrating the multitude of internal and external drivers of patient safety, aligning improvement initiatives to create synergy and providing a framework for meaningful measurement of intermediate and long-term results while remaining consistent with an organizational mission, vision and strategic goals. This strategy-focused approach recognizes that patient safety initiatives completed in isolation will not provide consistent progress toward a goal, and that a balanced approach is required that includes the development and systematic execution of bundles of related initiatives.

This article outlines the process used by Hamilton Health Sciences in adopting Kaplan and Norton's strategy map methodology underpinned by their balanced scorecard framework to create a comprehensive multi-year plan for patient safety that integrates best practice literature from patient safety, quality and organizational development.

Background

Since the releases of the Institute of Medicine's report *To Err Is Human* (Kohn et al. 1999) and the Canadian Adverse Events Study (Baker et al. 2004), there has been a growing emphasis on patient safety with a resulting deluge of literature related to patient safety processes, standards, goals and practices. As well, organizations, such as the Canadian Council on Health Services Accreditation (CCHSA), the Canadian Patient Safety Institute, Safer Healthcare Now!, the Institute for Healthcare Improvement, the Institutes for Safe Medication Practices, the National Patient Safety Foundation and the Joint Commission on Accreditation of Healthcare Organizations, have suggested embracing specific practices to successfully enhance patient safety. While healthcare organizations are undoubtedly focused on the need to develop a strategic plan to address patient safety, the challenge becomes creating a plan that focuses on patient safety outcomes, integrating the multitude of internal and external drivers of patient safety, aligning improvement initiatives to create synergy and providing a framework for meaningful measurement of intermediate and long term results while remaining consistent with an organizational mission, vision and strategic goals.

"An organization's strategy describes how it intends to create value for its shareholders, customers and citizens" (Kaplan and Norton 2004: 4). Kaplan and Norton recommend using a strategy map to create focus and alignment, enabling staff to clearly see the linkages of the strategy to the goal and vision. "A strategy map provides a visual representation of the cause and effect relationships among the components of an organization's strategy" and makes the links between performance drivers and outcomes explicit (Kaplan and Norton 2004: 9). While there are many credible tools that use performance measurement to drive organizational improvement, Hamilton Health Sciences (HHS) chose the Kaplan and Norton balanced scorecard and strategy map framework to develop the patient safety plan. The application of these management tools effectively aligns processes, people and technology to the outcomes to be achieved and results in a balance between outcome measures (financial and customer perspectives) and performance drivers (internal processes and learning and growth perspectives). These tools help translate strategy into action by identifying key processes and establishing a balance of key measures within the four quadrants of outcome and performance drivers previously noted. This strategy-focused approach recognizes that patient safety initiatives completed in isolation do not provide consistent progress to the goal; instead, a balanced approach is required.

The patient safety plan was intended to help achieve the HHS patient safety goal of "zero preventable deaths in four years (2010)"; it was aligned with the organization's mission, vision and values.

Objective of the Development of a Patient Safety Plan

The patient safety plan was intended to help achieve the HHS patient safety goal of "zero preventable deaths in four years (2010)"; it was aligned with the organization's mission, vision and values. The plan incorporated recommended strategies, practices and processes focused on achieving safer care for patients, and it addressed organization development and learning needs necessary to achieve and sustain results.

Setting

HHS is a four-site tertiary care facility with five distinct hospitals and a cancer centre. The patient safety plan was developed by the Organizational Effectiveness team, which was composed of patient safety, quality and organizational development specialists.

Process

The Organizational Effectiveness team began with an extensive review of the current best practice literature related to patient safety, quality and organizational development and a scan of internal and external standards and expectations for patient safety in hospitals. The purpose of the review was to determine the current reality of patient safety at HHS, assessing work in progress, current structures and frameworks, human resources to support the work and the results of patient safety culture assessments. Prior to the development of the patient safety plan, HHS had established patient safety as a priority, articulated the goal of zero preventable deaths, developed a patient safety model and initiated over a dozen organization-wide and hundreds of unit-level improvement initiatives. Systems that strongly supported the patient safety work were also well established, including a Senior Leadership team committed to the patient safety goal, a Patient Safety Steering team, more than 300 patient safety champions at the unit and area levels and dedicated patient safety, quality and patient relations/risk management specialists.

Once consensus was reached on the current reality, the group brainstormed how the organization would be once the goal of zero preventable deaths had been reached. The shared attributes that described the organization in the future were identified as a "high reliability learning organization" and provided the content for moving forward in the development of the patient safety plan.

The shared attributes that described the organization in the future were identified as a "high reliability learning organization."

Organization leaders believed that to support and enable successful patient safety initiatives (internal processes), there needed to be a significant foundation of patient safety culture and quality improvement knowledge and application (learning and growth). To achieve the patient safety plan, HHS needed to shape the workforce and build capacity to meet the current and future needs; this would require significant sustainable change at many levels. By applying the balanced scorecard, the organization could develop a plan that would enable the achievement of the desired patient care outcomes, ensure financial stewardship and achieve a balance between outcome measures and performance drivers.

The Balanced Scorecard and Strategy Map

The first step was to create the focus for the strategy map by defining the overall goal as *zero preventable deaths in four years.* Once the focus was determined, the Organizational Effectiveness team created the strategy map for achieving the patient safety goal using the four perspectives of the balanced scorecard. The

following outlines the four perspectives of the balanced scorecard as applied to the achievement of the patient safety goal at HHS (Figure 1).

Outcome Measures

The Customer

The key organizational question related to the customer perspective using Kaplan and Norton's (1996) balanced scorecard was, "What would patients and families see or perceive in an organization that had zero preventable deaths?" The outcomes for patient safety from the patient's perspective included no harm or adverse events, patient- and family-centred care and a perception of a safe and clean environment. The primary mission at HHS is to provide high-quality service and safe care to the patients, families and communities we serve. Meeting this obligation requires a focus on the outcomes within this perspective that are monitored and measured.

Finances

The key question related to financial outcomes was, "How would HHS be viewed by funders when zero preventable deaths had been achieved?" There was a shared belief that the internal process improvements in clinical and service operations, supported by the necessary learning and development within the organization, would have a direct relationship to the financial performance of HHS and have an impact on the funds raised by the foundation. The key to measuring these outcomes was to "connect the dots" among components of the strategy with financial measures.

Performance Drivers

Internal Processes

The first performance driver of the balanced scorecard is internal processes, that is, the processes at which HHS must excel to meet "customer expectations" of patient safety. These include the critical processes that contribute to the articulated outcomes of the customer perspective and the hospital accountability agreements, performance management expectations and the external requirements of agencies such as CCHSA. An extensive number of processes were identified from the literature and external agencies using an affinity diagram; six categories or bundles of internal processes were identified including infection control practices (e.g., preventing surgical site infections), medication practices (e.g., pharmacy automation), proven best practices (e.g., rapid response teams), patient safety communication practices (e.g., transfer of accountability), team process and model (e.g., simulation) and patient involvement (e.g., partnering with patients).

To ensure sustainability of these internal processes, changes need to be embedded into the organization's design; that is, its strategy, technology, structure (role accountabilities and department design), measurement systems and human resource systems (competencies and behaviours) (Cummings and Worley 2001).

Learning and Growth

The final perspective of the balanced scorecard – learning and growth – addresses how the organization will sustain its ability to change and improve (Kaplan and Norton 1996). In other words, it includes the key processes required for learning and development of the organization to achieve improvements in patient safety and quality. In alignment with the HHS values, this part of the strategy map was renamed "learning and innovation." Two critical aspects underpinned the learning and innovation of the organization required to achieve the patient safety goal: the HHS Patient Safety Model and the vision of a high reliability learning organization.

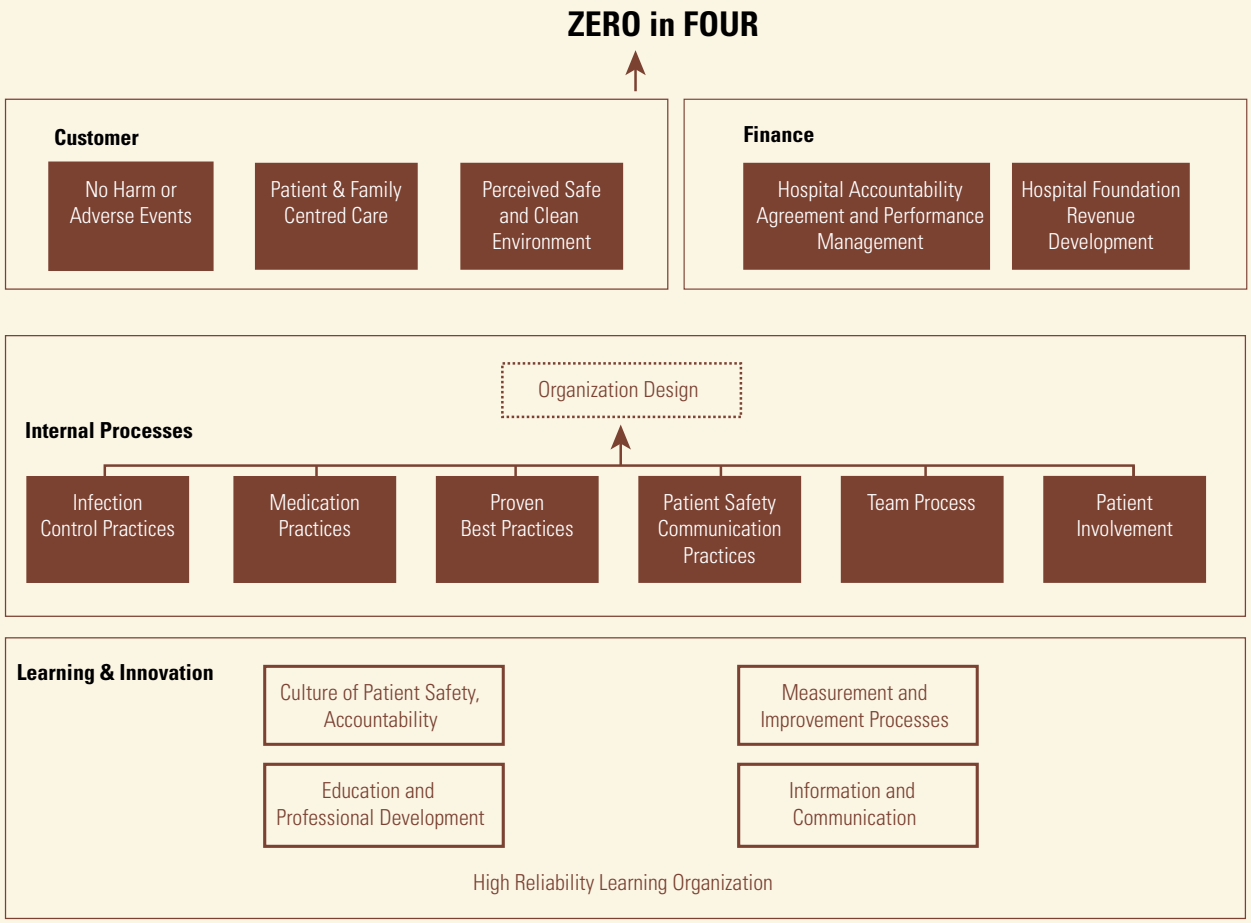
A learning organization "tries to make a working reality of such desirable attributes as flexibility, teamwork, continuous learning, employee participation and development" (Mabey and Salaman 1995, cited in Garavan 1997: 18). This is similar to high reliability organizations "where individuals can communicate openly about concerns, and design systems that make it difficult for failures to occur. Effective communication, teamwork and shared learning are inherent properties of these organizations" (Leonard et al. 2004: 16). The initiatives and categories of this perspective were categorized within the four cornerstones of the HHS Patient Safety Model. The components of this part of the plan included quality improvement processes and tools, education and training related to patient safety, integration and management of data and information and organizational culture.

Indicators to Monitor Progress toward the Goal

The patient safety strategy map provides a foundation to select a core set of quality and patient safety performance indicators for the scorecard. Examples of core indicators include process and outcome indicators from specific initiatives as well as the Hospital Standardized Mortality Ratio or infection control measures, such as rates for *Clostridium difficile*. Indicators such as these identify the need for and drive continuous improvement toward the achievement of the quality and patient safety goals. Measurement of key indicators is required to set goals and measure achievement; these measurements also provide a visible scorecard to monitor performance levels and assist with prioritization of quality initiatives. Dashboards (succinct visual displays of data to monitor quality improvement) are being developed that will make data measures accessible, visible and meaningful to users and provide a mechanism as performance tools.

Once the balanced scorecard of concrete performance indicators and measures has been derived from the strategy map and performance has been monitored, the cause-and-effect relation-

Figure 1. Hamilton Health Sciences patient safety strategy map



ships of the strategy map can be analyzed to inform chosen strategies. The strategy map framework and the balanced scorecard performance measurement methodology offer an effective means to manage human resources and information-capital development and deployment.

The Patient Safety Plan

The four-year patient safety plan includes the strategy map and details of the specific initiatives included within the six bundles of internal processes. The plan also includes the sequencing of all the initiatives within the four balanced scorecard perspectives over a four-year period. The actual selection of initiatives to be undertaken each year is based on organizational priorities, current initiatives and the need to adhere with CCHSA required organizational practices for our accreditation in May 2008. The initiatives within the learning and innovation perspective were sequenced in the four-year plan to ensure that they would be addressed prior to, or in conjunction with, the organization embarking on specific internal process improvement initiatives. The completed patient safety plan identified 59 initiatives categorized into bundles of strategies within the balanced scorecard perspectives. Each initiative had clearly defined metrics, which would be reported on a regular basis to the Patient Safety Steering team. The 59 initiatives were presented in a graphic format that allowed for a visual perspective of how the initiatives align and overlap as well as the timing of the initiatives over four years.

The development of a strategy map and a comprehensive patient safety plan requires a significant initial commitment of time and expert resources.

Lessons Learned

Four key lessons were learned in the development of the patient safety plan. Firstly, the development of a strategy map and a comprehensive patient safety plan requires a significant initial commitment of time and expert resources. However, its hope is that the future benefits will provide exceptional value. Secondly, flexibility and adaptability are essential. The plan must allow for revisions to meet internal and external constraints and drivers as they become apparent. There needs to be commitment to evaluate and update the plan yearly based on these new internal and external drivers and with consideration of the organizational capacity.

The third lesson includes assessing the demands of other organizational initiatives (unrelated to patient safety) for resources such as education, information technology and decision support.

Finally, it is important that the plan accounts for the impact and finite capacity for change at a unit level and includes reserve capacity to support and sustain ongoing issues of patient safety that are raised through occurrence reporting, patient safety leadership walkarounds and root-cause analysis of sentinel events.

Conclusion

The Kaplan and Norton balanced scorecard and strategy map framework offer an effective method to plan strategically for patient safety and allow for an easy-to-understand visually formatted presentation of the plan that depicts the cause-and-effect relationships of patient safety strategies. It provides alignment with the organizational mission, vision and values with a clearly articulated goal, and provides a balanced approach in terms of the perspectives of the balanced scorecard and the components of the HHS Patient Safety Model. HQ

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References

Baker, G.R., P. Norton, V. Flintoft, R. Blais, A. Brown, J. Cox, E. Etchells, W. Ghali, P. Hebert, S. Majumdar, M. O'Beirne, L. Palacois-Derflingher, R. Reid, S. Sheps and R. Tamblyn. 2004. "The Canadian Adverse Events Study: The Incidence of Adverse Events among Hospital Patients in Canada." *Canadian Medical Association Journal* 170(11): 1678–86.

Cummings, T.G. and C.G. Worley. 2001. *Organizational Development and Change* (7th ed.). Cincinnati, OH: South-Western College Publishing.

Garavan, T. 1997. "The Learning Organization: A Review and Evaluation." *The Learning Organization* 4(1): 18–29.

Kaplan, R. and D. Norton. 1996. *Translating Strategy into Action: The Balanced Scorecard.* Boston, MA: Harvard Business Press.

Kaplan, R. and D. Norton. 2004. *Strategy Maps: Converting Intangible Assets into Tangible Outcomes.* Boston, MA: Harvard Business Press.

Kohn, L., J. Corrigan and M. Donaldson. 1999. *To Err Is Human: Building a Safer Health System.* Washington: National Academy Press.

Leonard, M. 2004. *Achieving Safe and Reliable Healthcare.* Chicago: Health Administrative Press.

Broadening the Patient Safety Agenda to Include Safety in Long-Term Care

Tiana B. Rust, Laura M. Wagner, Carolyn Hoffman, Marguerite Rowe and Iris Neumann

Abstract

The recent patient safety literature has included less of an emphasis on long-term settings than on research in the acute care sector. Recognizing this knowledge gap in our understanding of safety in the long-term care sector, the Canadian Patient Safety Institute, Capital Health (Edmonton) and CapitalCare (Edmonton) have collaborated to create a research and action agenda for improving resident safety in Canadian long-term care settings. This collaboration resulted in the development of a background paper highlighting the current state of the science and 14 key-informant interviews with stakeholders across Canada. The background paper subsequently informed an invitational round-table discussion. Key findings from the key-informant interviews as well as implications for research are described in this article.

The Canadian Patient Safety Institute, Capital Health (Edmonton) and CapitalCare (Edmonton) have jointly identified a gap in our current understanding of safety in Canadian healthcare settings: unlike the acute care setting, there has been little written about improving safety and adverse event prevention in Canadian long-term care (LTC) settings. More recently, Canadian researchers have increased the research capacity regarding common safety issues in the areas of improving medication safety (Rochon et al. 2005, 2006), falls (Gallagher et al. 2005; Krueger et al. 2001), pressure ulcers (Woodbury and Houghton 2004) and nosocomial infections (Loeb et al. 1999, 2001, 2003). However, these adverse events continue to be a daily challenge for LTC providers, and the research is still lacking in how to best minimize their occurrence.

To explore and address the need for new knowledge in this field, 14 key informants were interviewed and a background paper (Wagner and Rust 2007) was produced that informed an invitational round-table meeting held in Edmonton, Alberta, on May 31, 2007. This coordinated and collaborative effort is a critical step toward identifying the key issues and research priorities for resident safety in Canadian LTC settings. The highlights of the key-informant interviews follow.

Key-Informant Interviews

Key informants were selected so that the views of people in diverse groups (e.g., family members, front-line staff, researchers, policy makers and managers) from LTC settings across Canada would be captured. Fourteen key informants, identified by an advisory committee, participated in audiotaped, semi-structured telephone interviews. The purpose of the interviews was to identify safety issues in LTC. These interviews were transcribed verbatim, and a thematic analysis of the transcripts

was conducted. Data were independently reviewed and coded, and 12 themes were developed. Factors, priorities and gaps in resident safety in LTC identified by key informants, as well as representative quotations, are provided in Figure 1.

Barriers to adequate training include availability of adequate training programs for best practices and the ability to cover staff when they are off the floor.

Balance between Safety and Quality of Life

LTC requires a balance between protecting the rights of the resident and ensuring public safety. Similarly, a balance is needed between ensuring that residents are safe and that their quality of life (QOL) is not being adversely affected by the safety measures being put into place. It is important to examine both the effects of safety interventions on the incidence of adverse events and the impact of those interventions on residents' QOL.

Staff Knowledge, Skills and Training

The majority of direct care staff in LTC have had little training, and that training may not be sufficient to consistently ensure a safe care environment. Priority areas for education include techniques around redirecting and re-focusing frustrated and aggressive residents, dementia care, identifying and recognizing risks, use of equipment and infection control. Barriers to adequate training include availability of adequate training programs for best practices and the ability to cover staff when they are off the floor.

Increasing Clinical Complexity of Residents

The care needs of residents in LTC have been increasing steadily over the years. Residents are older, are frailer, have more behavioural issues and are on more medication. Staffing levels and staff knowledge and abilities have not increased to meet the rise in need. Recruiting and retaining staff to work with the increasingly complex LTC client has become more difficult.

Figure 1. Factors, priorities and gaps in resident safety in long-term care as identified by key informants

LTC = long-term care.

Equipment and Technology

Advances have been made in technology and equipment. Many choices for equipment exist, which makes the process of selection difficult. Due to resource limitations, it is not always possible to purchase appropriate equipment. Risk is increased if staff members are not trained in the proper use of the equipment, proper protocols are not in place regarding the use of the equipment, equipment is not in good working order and the equipment is not appropriate for the resident.

Physical Environment

Many elements of the design of LTC facilities impact safety. Respondents discussed challenges with older buildings resulting from

small or shared bathrooms, insufficient storage space, too much clutter, poor lighting and insufficient access to sinks. Respondents also indicated that renovations and upgrades to older buildings can have a positive impact on safety when the changes are made with safety in mind.

Working short staffed is common and results in staff rushing to provide care.

Communication between Management, Staff, Residents and Families

When residents are unable to communicate with staff because of an inability to speak, cognitive impairment or language barriers, risk is increased. Accurate and complete documentation is essential to prevent errors and ensure consistent and adequate care. Additionally, communication with family about the progression of residents' diseases is important so that family members do not put residents in unsafe situations.

Medication Management

Medication management is multi-faceted. There is a need to ensure that the drugs prescribed are appropriate for the residents, medication reviews are effective, instructions regarding medications are communicated accurately and the right drugs are administrated to the right people, in the right dose, at the right time.

Aggressive Resident Behaviours

Physically, verbally and sexually aggressive resident behaviour is an emerging issue that can affect the safety of other residents, staff, visitors and the aggressive residents themselves. Managing the behavioural challenges posed by residents with dementia, brain injury and mental health issues can be difficult, especially when one is attempting to minimize the use of restraints.

Falls

Falls are a key safety issue in LTC because of the frailty of the population. Medications, physical environment, social environment, equipment and facility policies can impact residents' risk of falling.

Infection Control

Because the LTC population is frail, infection can have devastating consequences. The risk of transmission of infection is heightened in LTC because of aggregate living. Hand-washing, glove use and influenza vaccinations reduce risks. Ensuring buy-in on infection-control procedures from staff on the front lines is essential.

Restraints

Restraints are not being used as frequently now as they once were. However, there is still some resistance to the policy of least-restraint from family and staff. Funding for alternatives to restraint is sometimes an issue.

Staffing

The type of staff, staff-to-patient ratios and the ability to recruit and retain qualified staff all affect resident safety in LTC. There is insufficient funding to ensure adequate staff-to-patient ratios and adequate numbers of support people such as educators and infection-control practitioners. It has become more difficult to recruit and retain staff; this has sometimes led to a less competent workforce. Working short staffed is common and results in staff rushing to provide care.

Implications for Research

The interviews suggest that research needs to be encouraged and supported to answer a number of questions: How does one manage risk so that a proper balance can be struck between safety and quality of life? What knowledge and skills are important, and how can they best be acquired? What should be done to reduce the risks that have accompanied the increase in the complexity of care required? Which existing technologies and equipment are appropriate, and how can they be improved? How does one ensure that equipment is used appropriately? What design features of LTC facilities reduce risks, and what can be done to improve older facilities? How can effective communication be facilitated? What policies, procedures and training are required to avoid adverse drug events? How can aggressive behaviours be prevented, reduced and managed? How can the risk of falls be reduced? What role do nurse managers play in preventing adverse events? What infection-control processes are required in LTC, and how does one encourage compliance?

Several priority safety issues were identified in the key-informant interviews that are not well addressed in the literature. For example, issues requiring further inquiry include the following: aggressive resident behaviour and related adverse events; innovative methods to nurture the balance between safety and quality of life among LTC residents; and how best to maintain safe environments with the increasing clinical complexity of residents in LTC, especially among those transferring from the acute care setting.

Research has been conducted on adverse events in LTC such as falls, pressure ulcers, medication errors and infections and their relationship to key patient safety concepts. Despite this research, these adverse events are ubiquitous and continue to pose serious challenges for quality improvement. Research on barriers to uptake in the LTC sector is required to ensure that the occurrence of these events is fully minimized.

Conclusion

Despite the emerging research conducted on patient safety in the past decade, little research has focused on LTC and other areas outside of the acute care setting. Progress in resident safety in Canadian LTC settings is imperative to improve the safety of frail elders in this setting. Research on safety in LTC is necessary to guide policy and to improve the quality of care. Such research will provide stakeholders with the tools necessary to address the issues that continue to persist. HQ

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References

Gallagher, E.M., V.J. Scott, M. Brussoni, J. Kozak and S. Johnson. 2005. *Stepping In: Long-Term Care Collaborative Falls Prevention Project*. Vancouver: British Columbia Injury Research and Prevention Unit at the Centre for Community Health & Health Evaluation Research at the Children's and Women's Health Centre of B.C. Retrieved August 27, 2007. <http://www.coag.uvic.ca/resources/publications/reports/Stepping_In-_Falls_Long_Term_Care.pdf>.

Krueger, P.D., K. Brazil and L.H. Lohfeld. 2001. "Risk Factors for Falls and Injuries in a Long-Term Care Facility in Ontario." *Canadian Journal of Public Health* 92(2): 117–20.

Loeb, M., B.S. Craven, A.J. McGeer, A.E. Simor, S.F. Bradley, D.E. Low, M. Armstrong-Evans, L.A. Moss and S.D. Walter. 2003. "Risk Factors for Resistance to Antimicrobial Agents among Nursing Home Residents." *American Journal of Epidemiology* 157(1): 40–7.

Loeb, M., A.E. Simor, L. Landry and A. McGeer. 2001. "Adherence to Antibiotic Guidelines for Pneumonia in Chronic-Care Facilities in Ontario." *Clinical and Investigative Medicine – Medecine Clinique et Experimentale* 24(6): 304–10.

Loeb, M., A.E. Simor, L. Mandell, P. Krueger, M. McArthur, M. James, S. Walter, E. Richardson, M. Lingley, J. Stout, D. Stronach and A. McGeer. 1999. "Two Nursing Home Outbreaks of Respiratory Infection with Legionella sainthelensi." *Journal of the American Geriatrics Society* 47(5): 547–52.

Rochon, P.A., T.S. Field, D.W. Bates, M. Lee, L. Gavendo, J. Erramuspe-Mainard, J. Judge and J.H. Gurwitz. 2005. "Computerized Physician Order Entry with Clinical Decision Support in the Long-Term Care Setting: Insights from the Baycrest Centre for Geriatric Care." *Journal of the American Geriatrics Society* 53(10): 1780–9.

Rochon, P.A., T.S. Field, D.W. Bates, M. Lee, L. Gavendo, J. Erramuspe-Mainard, J. Judge and J.H. Gurwitz. 2006. "Clinical Application of a Computerized System for Physician Order Entry with Clinical Decision Support to Prevent Adverse Drug Events in Long-Term Care." *Canadian Medical Association Journal* 174(1): 52–4.

Wagner, L.M. and T.B. Rust. 2007. *Safety in Long-Term Care Settings: Broadening the Patient Safety Agenda to Include Long-Term Care Service.* Edmonton: Canadian Patient Safety Institute. http://www.patientsafetyinstitute.ca/uploadedFiles/LTC_paper.pdf

Woodbury, M.G and P.E. Houghton. 2004. "Prevalence of Pressure Ulcers in Canadian Healthcare Settings." *Ostomy Wound Management* 50(10): 22–38.

Nursing Education: A Catalyst for the Patient Safety Movement

Kim Neudorf, Netha Dyck, Darlene Scott and Diana Davidson Dick

Abstract

Creating a culture of safety in healthcare systems is a goal of leaders in the patient safety movement. Commitment of leadership to safety in the Saskatchewan Institute of Applied Science and Technology (SIAST) Nursing Division has resulted in the development of the Patient Safety Project Team (PSPT) and a steady shift in the culture of the organization toward a systems approach to patient safety. Graduates prepared with the competencies necessary to be diligent about their practice and skilled in determining the root causes of system error in healthcare will become leaders in shifting the healthcare culture to strengthen patient safety. The PSPT believes this cultural shift begins with the education system. It involves modifications to curricula content, facilitation of multidisciplinary processes, and inclusion of theory and practice that reflect critical inquiry into healthcare and nursing education systems to ensure patient safety.

In this paper the practical approaches and initiatives of the PSPT are reviewed. The integration of Patient Safety Core Curriculum modules for competency development is described. The policy for reporting adverse events and near misses is outlined. In addition, the student-focused reporting tool, the results and the implications for teaching in the clinical setting are discussed. Processes used to engage faculty are also addressed.

A call for "a healthcare education and professional development program at the under-graduate, graduate and post graduate levels" of healthcare provider education was set forth in the landmark document *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Healthcare* (National Steering Committee on Patient Safety 2002: 20). This call served as the catalyst to begin the process of education and integration of the systems approach to patient safety at the Nursing Division of the Saskatchewan Institute of Applied Science and Technology (SIAST).

Nursing students can be involved in events that contribute to the harm of a patient. Adverse events involving medications are common during students' clinical learning experiences (Affonso et al. 2003), as in the other areas of practice (Anderson and Webster 2001; Baker et al. 2004). Students may experience a "failure to rescue" event (Silber et al. 1992: 67, cited in Clarke 2004) where the student, faculty and other healthcare providers fail to recognize the downward spiral of a patient as he or she succumbs to complications of surgery or disease. Beginning students are surprised to learn that the healthcare system is experiencing a "vulnerable system syndrome" (Reason et al. 2001) – students expect that illness and injury will be alleviated, not introduced, in healthcare settings.

The nursing education system has a responsibility to alert nursing students to the realities of healthcare systems and to prepare them to practise with the competencies necessary to make surveillance, reporting and analyzing common practice.

The patient safety literature focuses predominantly on healthcare systems where patients receive care from healthcare providers. This report identifies processes adopted by a nursing education system to prepare students and faculty with the requisite competencies for patient safety.

The nursing education system has a responsibility to alert nursing students to the realities of healthcare systems and to prepare them to practise with the competencies necessary.

Patient Safety Project

The SIAST Nursing Division delivers 14 different nursing and other health-related programs across Saskatchewan. The Patient Safety Project was launched in 2004 with a plan for the incremental development of a culture of safety within the Nursing Division through curriculum revision, faculty education and data analysis.

Curriculum Enhancements

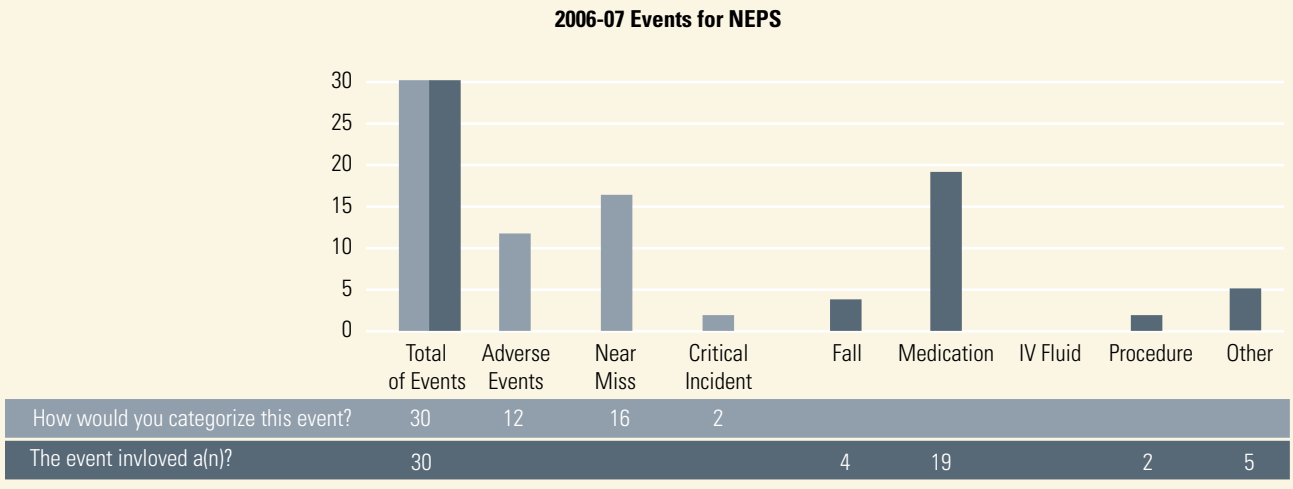
First-year students of a four-year baccalaureate nursing program are introduced to the topic of safety in their first clinical course. They are exposed to the language, key patient safety research, authentic cases and poignant multimedia presentations. Examination questions relevant to patient safety are included, recognizing that the curriculum does not change until the tests are changed.

With funding from SIAST, SIAST Nursing Division Core Curriculum in Patient Safety (SIAST 2006b) was developed, which includes seven modules that can be incorporated into any program in the nursing division. The competencies developed by the Canadian Association of Schools of Nursing Patient Safety Task Force (2006) served as a benchmark for curriculum validation. The modules include the following learning outcomes relevant to patient safety:

1. Examine key elements from a contemporary perspective
2. Explore current trends from local, provincial, national and global perspectives
3. Analyze contemporary models used to improve safety and reduce harm
4. Explore the concept of a systems approach
5. Analyze theories of change, transformation theory and transformation learning
6. Examine the relationship between culture and patient outcomes
7. Analyze medication administration practices, standards and policies that contribute to harm

Each module incorporates a variety of teaching and learning strategies such as reading assignments, media clip reviews, case discussions, web searches, compare-and-contrast activities, collaborative learning activities and activities suitable for healthcare settings. The modules and the learning steps can be applied sequentially, but the instructional design strategy enables any module or learning step within the module to stand alone. For example, from SIAST's 2006 module Analyze Contemporary Models Used to Improve Patient Safety and Reduce Harm, a faculty member may involve first-year students in the learning step that illustrates the Swiss Cheese model (Reason 2000), while another may choose to post an online case study and ask nurse practitioner students to consider the situation of an

Figure 1. 2006–2007 events for the Nursing Education Program of Saskatchewan



elderly client with three prescriptions for a beta-blocker, each with a different method of delivery. The modules serve as a suite of resources to assist faculty in integrating the concepts of systems and safety throughout curricula.

To our knowledge, no other nursing program in Canada has developed their patient safety curriculum to this degree. In the United States, the Faculty Leadership in Interprofessional Education to Promote Patient Safety developed the 2004 Best Practices in Patient Safety Education module handbook, which was designed as a train-the-trainer approach to developing leaders who can influence education change. The Canadian Patient Safety Institute (CPSI 2007b) is currently developing a competency framework that will become a useful standard to evaluate the core curriculum in patient safety.

The modules and the learning steps can be applied sequentially, but the instructional design strategy enables any module or learning step within the module to stand alone.

Reporting Tool and Database

Previous reporting policies within the Nursing Division were outdated and in contravention with reporting guidelines established by the provincial regional health authorities. The division could no longer rely on incident reports retrieved from healthcare facilities to provide the information necessary to understand factors that contribute to an adverse event and to subsequently determine where change is needed. Furthermore, the Nursing Division did not have a consistent means of collecting, aggregating and analyzing the data, rendering data uninformative and not useful for guiding change.

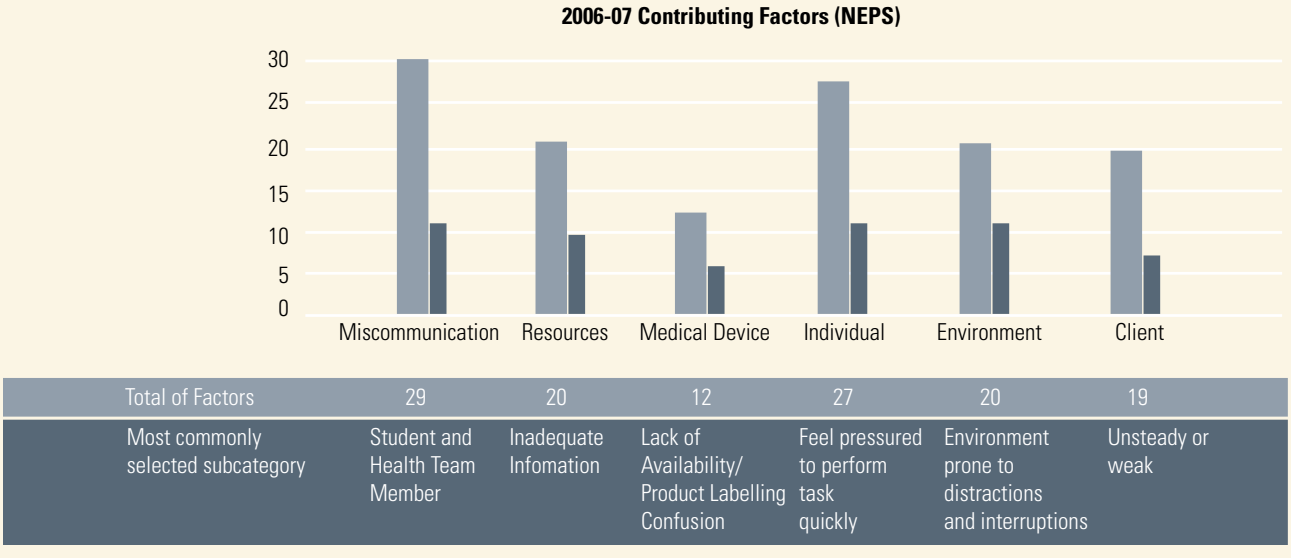
To this end, a student-focused, anonymous reporting form was developed. The Adverse Event, Near Miss and Critical Incident Report Form (SIAST 2006a) is currently paper based and uses a simple check-box approach. Designed to be blame free, it serves as a learning tool that assists students to consider factors that contributed to a near miss, adverse event or critical incident. The data are entered into a customized Microsoft Access database for report generation and data analysis.

Results for first and second year students in the Nursing Education Program of Saskatchewan (NEPS) for the 2006–2007 academic year indicated that most of the reported events were near misses (53%) and most involved medications (63%) (Figure 1). Students were not directly involved in the two critical incidents that resulted in harm not death; however, reporting did result in action taken by the SIAST Nursing Division. Although students practise in acute medicine, surgery and mental health settings, most events occurred in long-term care facilities (70%).

Miscommunication was significantly the most frequently reported contributing factor, influencing most events reported (Figure 2). Miscommunication has been reported previously in the literature as a leading contributing factor (Sanford-Ring 2006; Woolf et al. 2004). Contributing factors are chosen from six primary categories and subcategorized to capture more specific information. Respondents may choose multiple factors including "other"; this option allows for the provision of data that might otherwise be missed.

Several interesting questions arose from the analysis of data. For example, should the learning environment be modified

Figure 2. 2006–2007 contributing factors to events for the Nursing Education Program of Saskatchewan



Total of Factors	29	20	12	27	20	19
Most commonly selected subcategory	Student and Health Team Member	Inadequate Infomation	Lack of Availability/ Product Labelling Confusion	Feel pressured to perform task quickly	Environment prone to distractions and interruptions	Unsteady or weak

to improve learning and reduce harm, or should strategies be deployed to prepare students for the dynamic environments they will practise in? For example, should a "zone of silence" (Agenda for Health Research Quality 2007) be created near medication carts in acute care settings to reduce distractions that contribute to error? Further analysis and dissemination of this data to faculty and students will help improve the understanding of the learning environment and foster improvements to structures and processes within education and practice settings.

An encouraging number of reports were received in the first year of data collection, but some programs and clinical sites report more frequently than do others. Despite the inconsistencies, a reporting system is effective when processes are improved and harm is prevented.

Designed to be blame free, the reporting form serves as a learning tool that assists students to consider factors that contributed to a near miss, adverse event or critical incident.

Shifting the Culture

Leadership is crucial in establishing a culture that leads to quality programming. Our existing policy was revised to incorporate contemporary language and processes to reflect the responsibility of the individual, the system and shared practice when a near miss, adverse event or critical incident occurs (Benner et al. 2002). In formalizing processes, faculty members' attention was drawn to the changes in philosophy and mandatory reporting. This resulted in significant data collection and improved program quality and risk management.

Curricular enhancements are ongoing. Patient safety education has been provided to four key groups: administration, faculty, students and the curriculum development committee. A team is reviewing the use of the modules in course delivery to ensure key concepts are embedded in curricula and that duplication of content is avoided.

Other important leadership strategies include placing patient safety on the leadership team's monthly agenda, providing annual presentations to faculty on results from the reporting system, circulating an annual newsletter authored by the Patient Safety Project team and disseminating key readings. A state-of-the-art inter-professional learning centre using low-, intermediate- and high-fidelity simulations has recently been launched to assist students with communication, critical thinking and skill acquisition. There is an enhanced recognition of information competence as fundamental to safe nursing practice; this has resulted in the purchase of personal digital assistants for clinical faculty. The latest project involves a multi-media presentation for new faculty to introduce key concepts, resources and respective policy. Cultural shifts occur in increments, and these approaches provide the impetus needed to keep patient safety robust within the division.

Conclusion

Nursing education can act as a catalyst by providing leadership to improve health education systems and patient safety. Graduates who have the foundational competencies relevant to the systems approach to patient safety will make a difference to the quality of patient care. The SIAST Nursing Division has made changes to several of its structures and processes and looks forward to the realization of "patient safety curricula for all disciplines involved in patient care, healthcare administration and health policy development" (CPSI 2007a). HQ

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References

Affonso, D., L. Jeffs, D. Doran and M. Ferguson-Pare. 2003. "Patient Safety to Frame and Reconcile Nursing Issues." *Nursing Leadership* 16(4): 69–81.

Agenda for Health Research Quality. 2007. *Ten Patient Safety Tips for Hospitals* (AHRQ Publication No. 0-7-P004). Rockville, MD: Author. Retrieved May 8, 2007. <http://www.ahrq.gov/qual/10tips.htm>.

Anderson, D. and C. Webster. 2001. "A Systems Approach to the Reduction of Medication Error on the Hospital Ward." *Journal of Advanced Nursing* 35(1): 34–41.

Baker, G.R., P.G. Norton, V. Flintoft, R. Blais, A. Brown, J. Cox, E. Etchells, W.A. Ghali, P. Hébert, S.R. Majumdar, M. O'Beirne, L. Palacios-Derflingher, R.J. Reid, S. Sheps and R. Tamblyn. 2004. "The Canadian Adverse Events Study: The Incidence of Adverse Events among Hospital Patients in Canada." *Canadian Medical Association Journal* 170(11): 1678–86.

Benner, P., V. Sheets, P. Oris, K. Malloch, K. Schwed and D. Jamison. 2002. "Individual Practice and System Causes of Errors in Nursing and Taxonomy." *Journal of Nursing Administration* 32(10): 509–23.

Canadian Association of Schools of Nursing. 2006. Position Statement: Patient Safety in Nursing Education, Appendix 2. Ottawa: Author.

Canadian Patient Safety Institute. 2007a. *Building the Foundation for a Safer Health System Strategic Business Plan 2004/2005–2007/2008.* Edmonton, AB: Author. Retrieved September 4, 2007. <http://www.patientsafetyinstitute.ca>.

Canadian Patient Safety Institute. 2007b. *The Safety Competencies: Enhancing Patient Safety Across the Health Professions.* Edmonton, AB: Author. Retrieved December 1, 2007. <http://www.patientsafetyinstitute.ca/education/safetycompetencies.html>.

Clarke, S.P. 2004. "Failure to Rescue: Lessons from Missed Opportunities in Care." *Nursing Inquiry* 11(2): 67–71.

Faculty Leadership in Interprofessional Education to Promote Patient Safety. 2004. *Best Practices in Patient Safety Education: Module Handbook.* University of Washington: Authors. Retrieved December 1, 2007. <http://interprofessional.washington.edu/ptsafety/files/Handbook_Jan_05.pdf>.

National Steering Committee on Patient Safety. 2002. *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Healthcare.* Retrieved September 4, 2007. <http://rcpsc.medical.org/publications/building_a_safer_system_e.pdf>.

Reason, J. 2000. "Human Error: Models and Management." *British Medical Journal* 320: 768–70.

Reason, J.T., J. Carthey and M.R. de Leval. 2001. "Diagnosing 'Vulnerable System Syndrome': An Essential Prerequisite to Effective Risk Management." *Quality in Health Care* 10(Suppl. 2): ii21–5.

Sanford-Ring, S. 2006. *Patient Safety.* Presented at the University of Wisconsin Hospital and Clinics, Coralville, IA. Retrieved Dec. 1, 2007. <http://www.uihealthcare.com/depts/cqspi/newsevents/training/sanfordring.ppt>.

Saskatchewan Institute of Applied Science and Technology. 2006a. *SIAST Nursing Division Adverse Event, Near Miss and Critical Incident Report Form*. Saskatoon, SK: Author.

Saskatchewan Institute of Applied Science and Technology. 2006b. *SIAST Nursing Division Core Curriculum in Patient Safety*. Saskatoon, SK: Author.

Woolf, S.H., A.J. Kuzel, S.M. Dovey and R.L Phillips. 2004. "A String of Mistakes: The Importance of Cascade Analysis in Describing, Counting and Preventing Medical Errors." *Annals of Family Medicine* 2: 317–26. Retrieved December 12, 2007. <http://annfammed.org/cgi/content/full/2/4/317>.

Using ISMP Canada's Framework for Failure Mode and Effects Analysis: A Tale of Two FMEAs

Tim Nickerson, Margie Jenkins and Julie Greenall

Abstract

Patient safety concerns in healthcare are not new or unexpected, and one goal of all healthcare organizations is to provide the safest possible care for patients and their families. With that goal in mind, Annapolis Valley Health, a rural district health authority in Nova Scotia, identified the need to develop expertise in the use of failure mode and effects analysis (FMEA) as a tool to promote quality processes within the organization. Staff members were aware of the value of this type of analysis but also recognized that real learning would best be achieved through completing an FMEA of an existing process or situation, rather than through a simulation or staff training. Annapolis Valley Health identified two high-risk situations requiring attention: transcription of medication orders for in-patients and overcrowding in the emergency department. The Institute for Safe Medication Practices Canada provided training and support to two staff teams and visited the organization eight months later for an update on progress. This article chronicles the journey of Annapolis Valley Health to improve patient safety through the application of FMEA to two high-risk processes for one of its hospital sites.

In fall 2006, Annapolis Valley Health, in conjunction with another rural district health authority in Nova Scotia, engaged the Institute for Safe Medication Practices Canada (ISMP Canada) to provide training and support for a facilitated failure mode and effects analysis (FMEA). Each organization identified two healthcare processes associated with significant risks for patient safety and assembled a team for each process. This article chronicles the Annapolis Valley Health experience with the application of the ISMP Canada framework for FMEA (Institute for Safe Medication Practices Canada 2006) to two high-risk processes for one of its hospital sites.

FMEA is a team-based systematic and proactive approach for identifying ways in which a process or design can fail, why it might fail and how it can be made safer. FMEA is not a new concept, and it has been used for many years in a variety of industries to determine the potential effects of system and equipment failures. The automotive, chemical, aviation, nuclear power and aerospace industries all rely on FMEA as an essential aspect of improving safety and quality (McDermott et al. 1996). Completion of one proactive risk assessment project annually, using FMEA or a similar process, is now a required organizational practice for accreditation by the Canadian Council on Health Services Accreditation (2007).

A typical FMEA includes eight steps (Table 1) and is conducted systematically (Joint Commission on Accreditation of Healthcare Organizations 2002).

Table 1. Steps in a failure mode and effects analysis

Step	Description
1	Select the process to be analyzed and assemble the team.
2	Diagram the process to be analyzed.
3	Brainstorm potential failure modes for the process and determine their effects.
4	Identify the causes of potential failure modes.
5	Prioritize the failure modes.
6	Redesign the process to address the potential failure modes.
7	Analyze and test the changes.
8	Implement and monitor the redesigned processes.

FMEA requires a multidisciplinary team, including process experts and those with decision-making authority. FMEA is resource intensive and, as such, is most suitable for high-risk processes, that is, those in which failure is likely to jeopardize the safety of those served by the organization.

Topic Selection and Team Development

Selected members of the Annapolis Valley Health Patient Safety Committee met to determine the topics for analysis and to identify team members. Some aspect of the medication-use system was a natural choice for analysis, given that ISMP Canada, the organization that would be providing training and facilitation, has strong expertise in this area. A review of medication incident reports for Annapolis Valley Health showed that the incident type most frequently reported was related to the transcription process; the management of in-patient medication orders was therefore the first process identified for analysis. The group decided to base the analysis on the current processes for the Medical Unit at Valley Regional Hospital (VRH), one of six sites within the District Health Authority. It was hoped that solutions developed within this unit could later be shared across the district.

In the search for a second topic for analysis, it was noted that problems with "at or near capacity" status (also called "Code Purple") in the emergency department (ED) at VRH had been an ongoing concern and, in the opinion of the Patient Safety Committee representatives, presented a significant risk to patient safety across the district. This is a well-recognized

Figure 1. In-patient medication process for the Medical Unit at Valley Regional Hospital

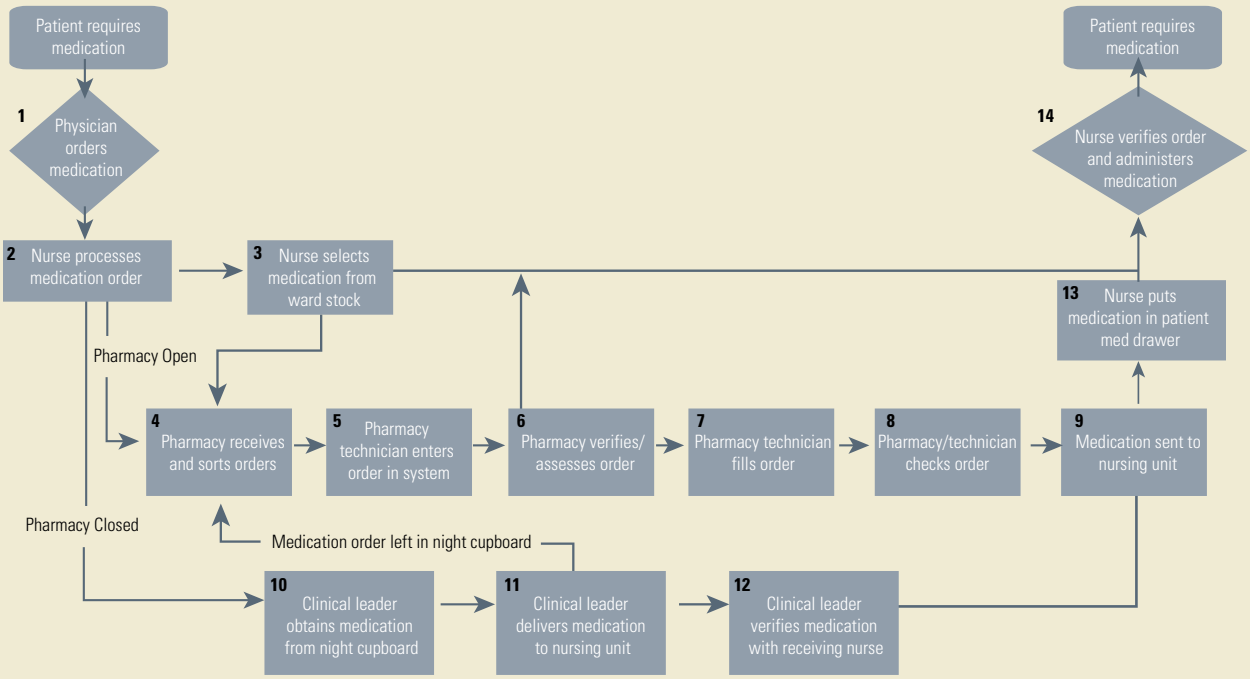


Figure 2. Sub-substeps and potential failures in substep 5 (transcription) of "Nurse processes medication order"

problem across Canada (Noseworthy 2004; Physician Hospital Care Committee 2006; Rowe et al. 2006).

Once the topics had been selected, identification of the members of the analysis teams proceeded quickly. Individuals were chosen on the basis of their involvement in front-line care and their demonstrated understanding of departmental processes. Most of those who were invited to participate were enthusiastic and readily agreed to become part of the project.

In-patient Medication Process: Team Medication

Team Medication included a physician (general practitioner), registered nurse, licensed practical nurse and ward clerk from the medical unit, as well as the director of pharmacy. The team was led by the interim director of risk management and patient safety. Before the off-site facilitated session (led by an ISMP Canada staff member), the team reviewed background material on FMEA and mapped out the steps of the in-patient medication process at VRH (Figure 1).

"Nurse processes medication order," step 2 in the 14-step high-level process, was selected as the starting point for analysis through FMEA as it was deemed to be a key point where failures tended to occur and where existing systems were weak because of difficult-to-control manual processes. Within this step, team members identified seven substeps and 31 sub-substeps. The sub-substeps in the transcription step, along with the identified potential failure modes, are shown in Figure 2. During the off-site facilitated session, the team analyzed the first two substeps in the transcription process, including identification of potential failure modes, the effects and causes of those failure modes, assessment of single-point weaknesses, calculation of criticality scores, development of potential solutions and re-scoring of criticality. The balance of the project was completed during more than 30 hours of meeting time over the subsequent seven months (for a total of 180 person-hours for the project).

"At or Near Capacity" Status in the Emergency Department: Team Code Purple

Team Code Purple included a physician (the VRH chief of staff), the ED nurse manager and an ED staff nurse, a clinical leader for the site and the director of quality and system performance. The team was led by the incoming director of risk management and patient safety. The team decided to first consider the issue of capacity assessment in the ED and how the organization responds to this form of crisis, which was step 1 of a nine-step process (Figure 3).

During the off-site facilitated session, the team completed the FMEA for all of the substeps related to capacity assessment in the ED, including the calculation of criticality scores and development of solutions. On return to the home institution, Team Code Purple found that there was some duplication and overlap among the nine steps; the team was therefore able to collapse the process into six substeps (Figure 4). The team completed the FMEA over the following seven months using approximately 150 person-hours.

Figure 3. Process for managing capacity crisis in the emergency department (ED) at Valley Regional Hospital

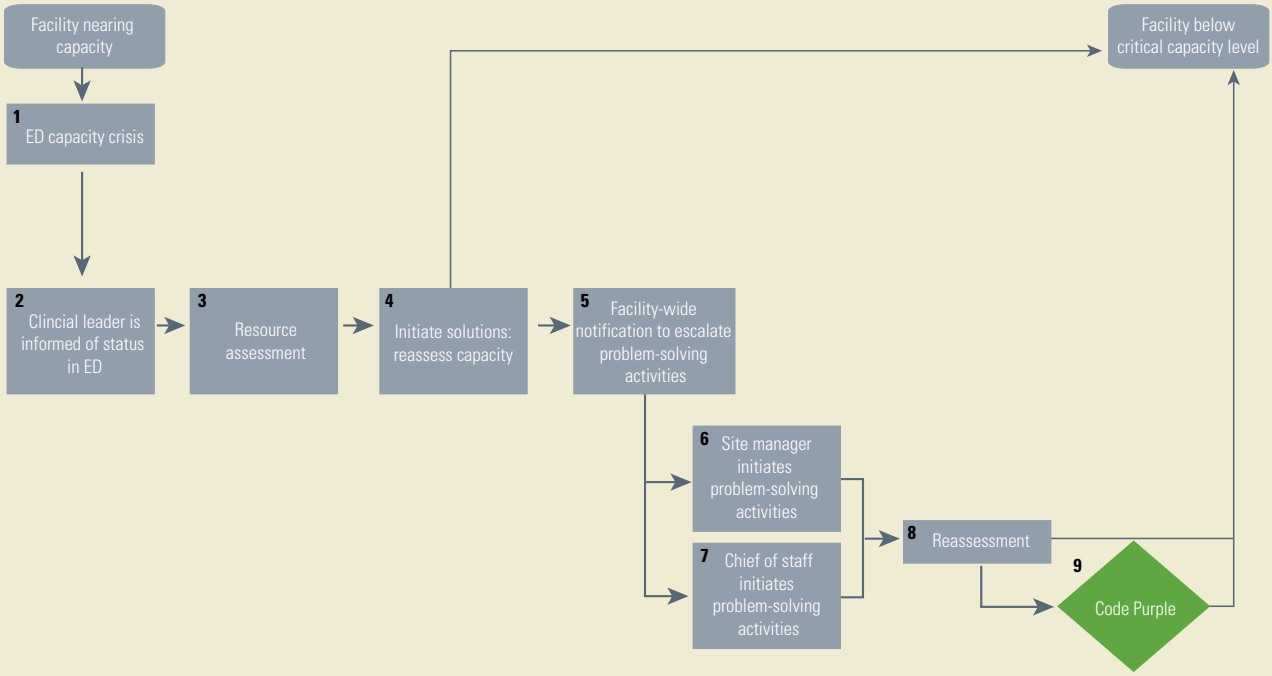
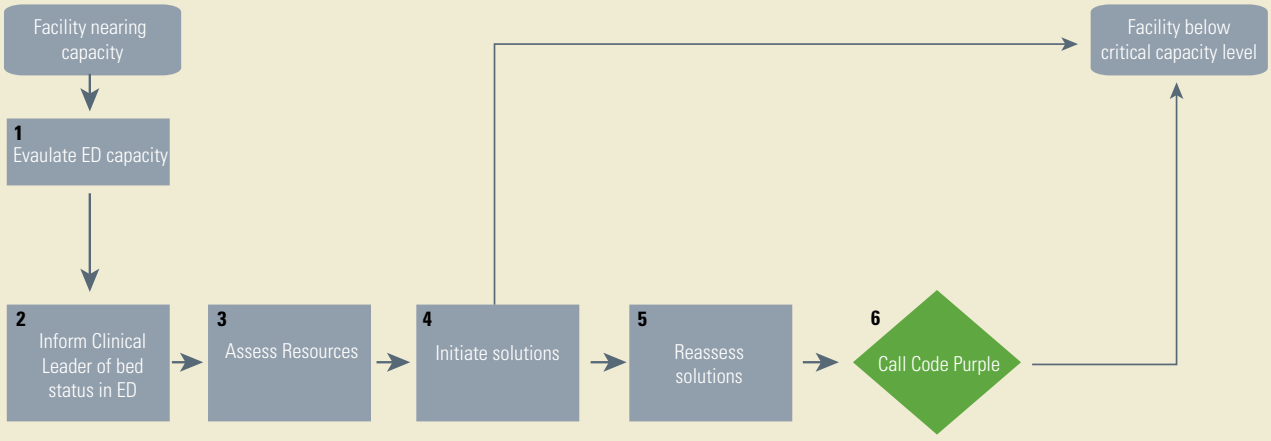


Figure 4. Revised process for managing capacity crisis in the emergency department (ED) at Valley Regional Hospital



Findings

Both Team Medication and Team Code Purple were surprised by the complexity and interrelatedness of the systems under analysis, which hospital staff used automatically and unquestioningly on a daily basis, and by the magnitude of the potential for harm within these complex processes.

Team Medication

Team Medication identified 78 potential failure modes within the various substeps for processing of medication orders. At one point, while considering the magnitude of the identified issues, one team member wondered aloud if anyone had actually designed the current system. A criticality score out of 100 was determined for each potential failure mode. The criticality scores ranged from 2 to 80, with a sum for all identified failure modes of 2,384 and an average of 31. Major themes discovered by Team Medication included communication, policy development, implementation of systems technology and general continuous quality improvement activities, as described below:

- Communication issues were found to be multidimensional. In particular, the FMEA highlighted concerns about communication between individuals as well as between departments.
- Development of and adherence to policies within the context of clinical activity was inconsistent. For example, the FMEA showed that allergy information was collected and documented in several places, but the information for a given patient was often contradictory.
- Investment in information systems technology was seen as key to solving many of the problems. For example, legibility of written orders can be problematic, and transcription of written orders by both nursing and pharmacy staff seems inappropriate in the context of a modern healthcare system.
- General continuous quality improvement activities, such as creating a double-check certification process for nursing staff, would assist in ensuring that double-checks are completed consistently.

Team Medication identified 78 potential failure modes within the various substeps for processing of medication orders.

Team Code Purple

Team Code Purple identified 31 potential failure modes with criticality scores ranging from 2 to 64 (sum 1,268; average 41). The highest-priority failure modes related to unpredictability of service demand, poor compliance with discharge criteria, inadequate documentation of patient care plans, lack of utilization and workload information systems and poorly understood and defined team roles for responding to a Code Purple. When the team recalculated criticality scores on the basis of full implementation of the recommended solutions, their sum dropped to 133 – a potential improvement of 90%!

Analysis of the failure modes and potential solutions identified by Team Code Purple revealed four themes: managing information, policy and procedure development, practice issues and communication.

- Managing information was a problem in several areas within the target hospital and across the provincial healthcare system. Specific concerns identified by the FMEA ranged from the lack of an electronic triage and workload measurement system in the local ED to the lack of a provincial bed-management system.
- The development of new policies and procedures is required at the board, executive, facility and unit levels. For example, policies are needed for determining district utilization of beds, creating clear trigger points for initiating certain processes and developing team, unit and individual expectations for responding to a Code Purple crisis.
- Practice-related issues identified by the FMEA included lack of documented care plans, problems with timeliness of physician rounds and response of all care providers to a Code Purple.
- Communication problems were found to affect various levels of the organization. For example, communication processes within the ED team, throughout the site and the district as well as communication of wait times to the public were complex, and varied depending on the time of day and day of the week.

Sharing of Information and Engaging the Organization

Senior leaders within Annapolis Valley Health were kept informed of the teams' progress in general terms throughout the course of the two projects. At the time of this writing, the two teams had completed their respective FMEAs but had not received administrative approval for full implementation of recommendations. The detailed findings will be presented at an upcoming meeting of key stakeholders. In the interim, improvements within the control of department leaders are being implemented.

The team leaders recognized the need to summarize the FMEA findings in a compact and meaningful way to assist the organization's leaders to understand both the findings and the recommendations. A summary sheet was developed to categorize and group related recommendations (Figure 5).

An unexpected positive benefit was that an enhanced understanding of the work of different team members resulted in a number of immediate quick fixes.

Lessons Learned

Team Process

A number of important lessons were learned regarding team dynamics:

- The commitment of team members is fundamental to success. The staff members who were invited to participate were genuinely interested in improving patient safety.
- Direct care staff must be involved in the process. Annapolis Valley Health was fortunate to have two physicians who were willing to participate in an activity that some would view as outside their scope of work.

Figure 5. Summary sheet for failure mode and effects analysis, Team Code Purple

Annapolis Valley Health

FMEA TEAM: CODE PURPLE

Dr. Lynne Harrigan; Kim Hutchison; Lynn Fudge; Kathie Swindell; Sue Hayes; Margie Jenkins

CEO
VP COM.
VP ACUTE
VP OPS
VP MED

Priority Code	
1	High Priority
2	Medium Priority
3	Low Priority
Time Period	
LT	Long Term (> 3 year)
MT	Medium Term (1 – 3 years)
ST	Short Term (1 year)
Resources	
Cap	Capital Costs
HR	Human resources/time
Bud	Budget impact

PC	TP	RES	FMEA ID	Action Area	Actions	Potential Account	Port-folio	Man. Concurrence	Deliver-able	Est. Time Frame
1	LT	HR	4B6;5A1;3B2; 3B1;3D3;3D2;3F1	Information Systems acquisitions	Lobby Province for: • A district day-day bed and provincial bed management/utilization system • A Provincial nursing workload system • An HR system to track competencies • A system to track equipment/physical resources such as pumps/ beds/monitors/isolatation rooms. This is sometimes part of a bed utilization system • Automated PT tracking system in ER	DOH & Dist Exec.	Exe. & CEO			
2	LT	Bud.	1B2; 4B7							
3	MT	Bud.	Criticality Score for this section 360 Range: 48-16							
3	LT									
3	MT	Bud.								
1	ST	HR	1F3;3C2;3C1;4A6 4B1;4B5;4B2;4B3; 4B4;5A4;1F4;4B5; 4B8;6A4;1E2	Exc. Level P7P Dev./ revision	• Always have the ability to clear two beds in ER. • Re-establish the original intent of CODE purple to decompress ER and call CODE purple off once this is done.	• Dist. ER Exec. & DMAC • Dist. ER & Site Man.	• VP Acute • VP Acute			
1	ST									

- The team needs to be supported as it negotiates its own rules and learns the process through experimentation and experience.
- The individual value of each team member must be recognized. Everyone's perspective is different, and the understanding of the process under analysis varied among individuals according to their role within that process. Revelations about how processes worked within and between departments improved the understanding of individual roles within the system.
- Team leaders and facilitators play a crucial role in maximizing the efficiency of the team and ensuring that documentation and background information are completed and available when needed.
- Having a defined "scribe" who records discussion notes that are not part of flow charts and spreadsheets is helpful for dealing with questions that arise later in the analysis.
- Teams need to celebrate small successes and have fun.

Teams need to celebrate small successes and have fun.

Additional Learning

Teams undertaking large-scale FMEA projects such as the ones described here should get early administrative sign-off on the

scope of the project and the associated resource requirements. Support by organizational leadership, as evidenced through the serious consideration of recommendations made by FMEA teams, is key to sustaining the efforts of individual staff for future FMEA projects. In retrospect, it would have been helpful to have followed a defined procedure for keeping decision-makers up to date on team activities.

Each team identified multiple opportunities for improvement; however, an unexpected positive benefit was that an enhanced understanding of the work of different team members resulted in a number of immediate quick fixes, some related to the processes under analysis and others for unrelated processes. For example, when nursing and pharmacy staff discussed medication process issues, they discovered that the delivery of narcotics could be improved by a simple change in timing. Some recommendations did not have an associated cost and could be implemented immediately by the charge person in the area. Planning for the implementation of each team's recommendations identified others within the organization who had to concur with recommendations and who could assist with implementation. The FMEA process helped the teams to consider additional solutions; for example, Team Code Purple asked the district's telecommunication and information services department to address the problem of urgently communicating information about ED overcrowding to family practitioners working in the community.

Use of Tools and Technology

The teams used technology as much as possible to minimize administrative activity. ISMP Canada provided electronic versions of spreadsheet tools. In addition, Visio software was used for electronic brainstorming of failure modes and for documenting related information. Some team members had the technical skills to use various types of software and to develop spreadsheets (e.g., the summary document shown in Figure 5), which was helpful. Use of colour for the complex summary documents improved readability and enhanced understanding. The summary document developed by the team also provided a visual representation of the amount of work completed.

Conclusions

To say that conducting an FMEA is time-consuming is an understatement; however, the value of this type of analysis lies in the fact that processes are deconstructed to a level of detail that allows full analysis of the potential opportunities for failure. This experience has convinced team members that attempting to shortcut the process through a less robust analysis would allow significant opportunities for harm to go undetected.

The findings of FMEA teams need to be widely shared within and outside individual organizations. This will help to sustain the momentum of the organization's quality improvement and risk management initiatives and will encourage action to implement recommendations. Furthermore, other facilities can learn not only from the specific process analysis and action plans but also from the personal experiences of other teams. HQ

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References

Canadian Council on Health Services Accreditation. 2007. *Patient Safety Goals and ROPs.* Ottawa: Author. Retrieved September 5, 2007. <http://www.cchsa.ca/default.aspx?page=139>.

Institute for Safe Medication Practices Canada. 2006. *Failure Mode and Effects Analysis Framework: A Tool for Proactively Identifying Risk in Health Care.* Toronto, ON: Author.

Joint Commission on Accreditation of Healthcare Organizations. 2002. *Failure Mode and Effects Analysis: Proactive Risk Reduction.* Oakbrook Terrace, IL: Joint Commission Resources.

McDermott, R., R. Mikulak and M. Beauregard. 1996. *The Basics of FMEA.* Portland, OR: Productivity, Inc.

Noseworthy, S.B. 2004. "Emergency Department Overcrowding: Waiting for Disaster." *Outlook Spring* 27-1, p. 12-17.

Physician Hospital Care Committee, a tripartite committee of the Ontario Hospital Association, Ontario Ministry of Health, Ontario Medical Association. 2006. *Improving Access to Emergency Care: Addressing Systems Issues.* Toronto: Ontario Medical Association.

Rowe, B.H., K. Bond, M.B. Ospina, S. Blitz, M. Schull, G. Innes, M. Afilalo, M. Bullard, S.G. Campbell, G. Curry, B. Holroyd, P. Toon and D. Sinclair. 2006. *Emergency Department Overcrowding in Canada: What Are the Issues and What Can Be Done?* (Technology Overview No. 21). Ottawa: Canadian Agency for Drugs and Technologies in Health.

Development of Canadian Safety Indicators for Medication Use

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Abstract

Reports of preventable illness due to medication errors are widespread in Canada. However, quantifying the magnitude of the problem has been hampered by a lack of measurement tools. Canadian-specific indicators, or performance measures, of safe medication use do not exist. The objective of this study was to develop a set of Canadian consensus-based indicators for the safe use of medication for both in-patient and outpatient settings.

A panel of 20 national experts was established from a convenience sample of experts representing medicine, nursing, pharmacy, research and decision-makers in hospitals and community settings across Canada. After creating a list of potential indicators from the literature, the final consensus set was chosen by the panel using a Delphi survey process via e-mail.

After three rounds, consensus was obtained on 20 medication-use safety indicators: seven indicators were related to systems of care, five to prescribing/ordering, three to monitoring/assessment, three to medication administration, one to preparation and dispensing and one to purchasing/inventory management. Seventeen of the indicators measure a process of care (in contrast to health outcome); at least 10 have applications outside the in-patient setting.

The resulting 20 medication-use safety indicators are diverse in scope and should be applicable in a variety of practice settings. These indicators may provide clinicians and decision-makers with valuable tools to assess the safety of medication-use systems.

Background

Patient safety is an area of increasing focus in Canada. Within this topic, safe use of medication has consistently been cited as a main area of concern; for example, both the Institute of Medicine report *To Err Is Human* (Kohn et al. 1999) and "The Canadian Adverse Events Study" (Baker et al. 2004) highlighted problems with adverse drug events. More recently, a special report on medication safety from the Institute of Medicine revealed that approximately 1.5 million preventable adverse drug events occur annually in the United States, resulting in a total cost of US$3.5 billion (Aspden 2006). Patients also recognize problems with the medication-use system. In the 2002 Commonwealth Fund survey, 11% of patients in Canada reported that they had been given the wrong medication at one time or another (Schoen et al. 2003).

Approximately 1.5 million preventable adverse drug events occur annually in the United States, resulting in a total cost of US$3.5 billion.

An indicator is a quantitative measure of some aspect of patient care that can be used to assess the quality of care being provided. Indicators are not direct measures of quality; they can be viewed as "alerts" to potential problems that require more detailed analysis (Nadzam 1991). Given the importance of medications in modern medicine, the fact that they are the fastest rising healthcare expenditure in Canada and that problems in their use have been widely documented, it is essential to use indicators to assess the medication-use system for both in-patient and outpatient settings.

The medication-use system encompasses the typical course of action related to drug therapy, including ongoing monitoring of patient care and progress (Ackroyd-Stolarz et al. 2005). The stages in the system include prescribing, dispensing, administering and monitoring. Currently, there is no set of indicators for assessing this system that are uniquely fitted to the Canadian environment. As a consequence, performance evaluation and benchmarking of medication safety based on quantitative data are difficult. Furthermore, Canadian medication safety experts should have the opportunity to suggest new indicators. Therefore, the objective of this study was to generate a Canadian set of medication-use safety indicators based on consensus among experts in patient and medication safety.

Methods

The following steps were used to generate a Canadian set of medication-use safety indicators: establishing an expert panel, developing a survey for the indicators and using the Delphi technique to achieve consensus on the indicators. These steps are outlined in detail below.

Expert Panel

The co-investigators and the partnering national organizations – Canadian Council on Health Services Accreditation, Canadian College of Health Service Executives, Canadian Institute for Health Information, Canadian Pharmacists Association, Canadian Society of Hospital Pharmacists and the Institute for Safe Medication Practices Canada – were responsible for identifying nationally recognized experts in the safety of the medication-use system. An attempt was made to ensure that the panel had representation from across the country and from a variety of health professions and backgrounds. The 20 potential panellists who were identified were initially contacted by e-mail; they received a brief description of the study and what would be required of participants. Panellists were selected based on their experience, willingness to participate and availability. All 20 potential panellists asked agreed to participate; the target size of 20 people was governed by resource constraints. The panel consisted of experts in medication safety representing medicine, nursing, pharmacy, research and decision-makers in hospital and community settings across Canada (Table 1).

Table 1. Demographic characteristics of the Canadian expert panel

Characteristic	Pharmacists (n = 7)	Physicians (n = 4)	Registered Nurses (n = 1)	Researchers (n =5)	Decision-Makers (n = 3)	Total (n = 20)
Gender (%)						
Female	6 (86)	–	–	2 (40)	1 (33)	9 (45)
Male	1 (14)	4 (100)	1(100)	3 (60)	2 (67)	11(55)
Primary practice setting (%)						
Tertiary hospital	1 (14)	2 (50)	–	1 (20)	2 (67)	6 (30)
Community hospital	–	–	1 (100)	–	–	1 (5)
Clinic	–	1 (25)	–	–	–	1 (5)
Community pharmacy	2 (29)	–	–	–	–	2 (10)
Academia	–	1 (25)	–	3 (60)	–	4 (20)
Regional health authority	1 (14)	–	–	–	1 (33)	2 (10)
National organization	1 (14)	–	–	1 (20)	–	2 (10)
Other	2 (29)	–	–	–	–	2 (10)
Region (%)						
Atlantic	1 (14)	1 (25)	1 (100)	–	1 (33)	4 (20)
Quebec	–	2 (50)	–	–	–	2 (10)
Ontario	1 (14)	1 (25)	–	4 (80)	–	6 (30)
Prairies	1 (14)	–	–	1 (20)	–	2 (10)
British Columbia	3 (44)	–	–	–	2 (67)	5 (25)
Northern territories	1 (14)	–	–	–	–	1 (5)
Education (%)						
MD	–	4 (100)	–	–	–	4 (20)
PhD	–	–	–	2 (40)	–	2 (10)
PharmD	1 (14)	–	–	2 (40)	1 (33)	4 (20)
MSc	2 (29)	–	–	1 (20)	1 (33)	4 (20)
BSc	4 (57)	–	1 (100)		1 (33)	6 (30)

Survey Development

The first step in the development of the survey was to search the literature. A MEDLINE search using the key words *patient safety* and *medication errors* produced 494 articles, which were reviewed by the lead author. Unpublished literature, which included information from organizations involved in medication safety, was also reviewed by the lead author. The indicators were developed by the two lead authors based on areas of concerns within the medication-use system discussed in both published and unpublished literature. The indicators were then classified according to stages in the medication-use system outlined by the Wisconsin Patient Safety Institute (2002). Indicators were assigned to one of the following six categories: prescribing/ordering, preparation and dispensing, administration, monitoring/assessment, purchasing/inventory management and systems of care (i.e., continuity of care after in-patient discharge). A draft survey instrument was created and pilot tested by the four co-investigators and five colleagues, who had the opportunity to comment on and suggest additional indicators. The co-investigators and colleagues consisted of experts in medication safety, physicians, nurses, pharmacists and researchers.

Consensus Building

We used the Delphi technique, which is a multiple iteration survey technique that enables anonymous, systematic refinement of expert opinion, to arrive at a combined or consensual opinion in a short period of time (Goodman 1987). It was first developed to prevent dominant personalities from taking over or intimidating others, as usually happens when groups of experts meet in person. The technique has been used extensively with expert panels to generate consensus on healthcare issues (Campbell and Cantrill 2001; Goodman 1987; Robertson and MacKinnon 2002). The experience of our research team suggests that in similar surveys using the Delphi technique, three or four rounds are typically required to reach consensus. In this study, the survey was distributed by e-mail; therefore, the participants never had the opportunity to meet in person, rendering the consensus process free of strong-personality coercion.

Criteria for Consensus

Surveys were distributed via e-mail. Participants were asked, "Should this indicator be included in a national set of medication safety indicators?" Each panellist ranked the potential indicators on a five-point Likert scale, where 1 = strongly disagree, 2 = disagree, 3 = unsure, 4 = agree and 5 = strongly agree. If the panellists chose 1 or 2, they were asked to explain why they did not think that indicator should be included. In round one, experts had the opportunity to comment on indicators and suggest additional ones, which were then added for the next round. The mean score for each indicator was calculated, and a second survey was prepared, rendering anonymous all comments and suggestions of panellists.

Consistent with the Delphi technique, surveys were individually tailored so that each respondent received his or her score for each indicator on the previous round as well as the mean score of the group. The cut-offs for rounds one, two and three were >4.0 (agree or strongly agree) for achieving consensus approval. The cut-off for achieving consensus dropped for round one was <2.0, for round two was ≤3.5 and for round three was ≤4.0. The rationale for the standard for achieving consensus dropped is outlined in the results.

Applications outside the in-patient setting are important as evidence shows that the rate of adverse events is four times higher in the community.

Results

From the literature review and after the pilot test, 53 potential indicators were chosen for inclusion in the first round of the survey. After the responses from round one were collated, 16 indicators had a mean score >4.0 and were thus deemed to be consensus approved. In round two, 70 indicators were presented, including new indicators created based on panellists' comments and new indicators suggested by the panellists. Of these, one indicator had a mean score >4.0 and was thus deemed to be consensus approved. The mean scores of the remaining indicators were between 2.0 and 4.0. Thus, to avoid repeating a

Table 2. Delphi rounds

Delphi Rounds*	No. of Indicators Evaluated	No. Achieving Consensus Approved	No. Achieving Consensus Dropped	No. Not Achieving Consensus Going to Next Round	No. New Indicators Suggested†
1	53	16	0	37	33
2	70	1	55	14	NA
3	14	3	11	0	NA

NA = not applicable.

*For all three rounds, the cut-off for achieving consensus approval was >4.0. The cut-off for achieving consensus dropped for round one was <2.0, for round two was ≤3.5 and for round three was ≤4.0.

†The expert panel only had the opportunity to suggest new indicators in the first round.

Table 3. The final medication-use safety indicators approved by consensus

Category and Indicator	Definition	Type	Source	Location of Data
Prescribing/Ordering				
1. Frequency of potentially dangerous medication abbreviations (based on Institute for Safe Medication Practices [ISMP]) (ISMP 2006a)	Number of prescriptions/medication orders using potentially dangerous medication abbreviations as a percentage of all prescriptions/medication orders	Process	Canadian Council on Health Services Accreditation (2006)	All*
2. Frequency of potentially dangerous dose abbreviations (based on ISMP) (ISMP 2006b)	Number of prescriptions/medication orders using potentially dangerous dose abbreviations as a percentage of all prescriptions/medication orders	Process	Canadian Council on Health Services Accreditation (2006)	All
3. Frequency of ambiguous prescription dosing instructions	Number of prescriptions/medication orders with "take as directed" as the only instruction for use as a percentage of all prescriptions/medication orders	Process	Wisconsin Patient Safety Institute (2002)	All
4. Frequency of incorrect prescription dose designation, e.g., 0.1 (rather than .1) or 1 (rather than 1.0)	Number of prescriptions/medication orders with incorrect leading and/or trailing zeros with decimal points as a percentage of all prescriptions/ medication orders	Process	Wisconsin Patient Safety Institute (2002)	All
5. Dosing for pediatric (patients <12 years) medications that have a narrow therapeutic index (e.g., prednisone, aminoglycosides, some antibiotics, chemotherapy)	Number of pediatric prescriptions for medications with a narrow therapeutic index with dose/weight calculations omitted as a percentage of all pediatric prescriptions for medications with a narrow therapeutic index	Process	Wisconsin Patient Safety Institute (2002)	All, except nursing homes
Preparation and Dispensing				
6. Documentation of allergy status	Number of patient profiles in which allergy status is documented before dispensing the first prescription/ medication order to the patient as a percentage of all patient profiles	Process	*2003/2004 Annual Report. Hospital Pharmacy in Canada: Medication Safety* (2004)	All
Administration				
7. Administering protocols for high-alert prescription medications (i.e., medications that bear heightened risk of causing significant patient harm when used in error, e.g., insulin and heparin)	Number of prescriptions/medication orders for high-alert medications using an administering protocol as a percentage of all prescriptions/medication orders for high-alert medications	Process	*2003/2004 Annual Report. Hospital Pharmacy in Canada: Medication Safety* (2004)	Hospitals and clinics
8. Verification of high-alert prescriptions	Number of prescriptions/medication orders for high-alert medications that are double-checked and documented (with initials) by pharmacist before administration as a percentage of all prescriptions/ medication orders for high-alert medications	Process	*2003/2004 Annual Report. Hospital Pharmacy in Canada: Medication Safety* (2004)	Hospitals and clinics
9. Machine-readable coding systems for administration	Number of doses administered with machine-readable coding (bar codes) as a percentage of all doses administered	Process	American Society of Health-System Pharmacists (2007)	Hospitals
Monitoring/Assessment				
10. Rate of ADE-related hospitalizations	Number of ADE-related hospitalizations as a percentage of all hospitalizations	Outcome	Mackinnon and McCaffery (2004)	Hospitals
11. Rate of ADE-related ER visits	Number ADE-related ER visits as a percentage of all ER visits	Outcome	Mackinnon and McCaffery (2004)	Hospitals

Table 3. The final medication-use safety indicators approved by consensus Cont'd

12. Monitoring and reducing ADEs by assigning pharmacists on rounds	Number of beds with daily pharmacist participation in interdisciplinary direct patient care as a percentage of all beds	Process	*2003/2004 Annual Report. Hospital Pharmacy in Canada: Medication Safety* (2004)	Hospitals
Purchasing/Inventory Management				
13. Differentiation of high-alert prescription medications (i.e., drugs that bear heightened risk of causing significant patient harm when used in error) (ISMP 2006b)	Number of high-alert prescription medications that are differentiated from other medications using flags, highlighting or some other system as a percentage of all high-alert prescription medications	Process	Wisconsin Patient Safety Institute (2002)	Hospitals and clinics
Systems of Care				
14. Medication histories for in-patients with complex high-risk regimens (i.e., challenging dosing schedule or route of administration; medication with documented and significant drug interactions polypharmacy; and medications with a narrow therapeutic index, insulin, antithrombotics, chemotherapy, etc.)	Number of in-patients with complex high-risk medication regimens whose medication history was recorded on admission as a percentage of all in-patients with complex high-risk medication regimens on admission	Process	American Society of Health-System Pharmacists (2007)	Hospitals, clinics and nursing homes
15. Medication reconciliation† rate	Number of unintentional medication order discrepancies (e.g., omission, commission, incorrect dose, incorrect frequency) as a percentage of all medication orders	Outcome	Canadian Council on Health Services Accreditation (2006)	Hospitals
16. Medication reconciliation† rate upon admission	Number of patients whose medication profiles are reconciled within 24 hours of admission as a percentage of admitted patients	Process	Canadian Council on Health Services Accreditation (2006)	Hospitals
17. Medication reconciliation† rate prior to discharge	Number of patients whose medication profiles are reconciled within 24 hours before hospital discharge as a percentage of discharged patients	Process	Canadian Council on Health Services Accreditation (2006)	Hospitals
18. Timeliness of discharge medication summary sent to community physicians	Number of discharge medication summaries sent to community physicians within 72 hours of hospital discharge as a percentage of discharged patients on medications	Process	Canadian Council on Health Services Accreditation (2006)	Hospitals
19. Timeliness of discharge medication summaries sent to community pharmacists	Number of discharge medication summaries sent to a community pharmacy within 72 hours of hospital discharge as a percentage of discharged patients on medications	Process	Canadian Council on Health Services Accreditation (2006)	Hospitals
20. Safety of compounding sterile medications	Number of hospitals that conduct an annual assessment of the processes used for compounding sterile medications (i.e., chemotherapy, intravenous medications) as a percentage of hospitals	Process	American Society of Health-System Pharmacists (2007)	Hospitals

ADE = adverse drug event; ER = emergency room.

*All refers to hospitals, clinics, community physician practices and offices, community pharmacies and nursing homes.

†A process that ensures the collection and communication of accurate patient/client medication information. The goal is to facilitate continuity of pharmaceutical care for patients/clients from admission to discharge or from beginning to end of service.

review of all 69 indicators, for round three, only the 14 indicators with a mean score between 3.5 and 4.0 were presented to the panel. Of these, only three had a mean score >4.0 and were thus deemed to be consensus approved. The remaining 11 indicators were dropped since most of the indicators had already been in the survey for two rounds. Since consensus was not achieved by that point, the two lead authors felt it would never be achieved. Therefore, 20 indicators in total were consensus approved (mean score >4.0) after three Delphi rounds (Table 2). Consensus was achieved over a two-month period.

Of the 20 approved indicators, seven are related to systems of care, five to prescribing/ordering, three to monitoring/assessment, three to medication administration, one to preparing and dispensing and one to purchasing/inventory management. Seventeen of the indicators measure a process of care (in contrast to a health outcome); at least 10 have applications outside the in-patient setting (Table 3).

Discussion

Although medication safety indicators can be found in the literature (*2003/2004 Annual Report. Hospital Pharmacy in Canada: Medication Safety* 2004; Agency for Healthcare Research and Quality 2005; American Society of Health-System Pharmacists 2007; Canadian Council on Health Services Accreditation 2006; MacKinnon and McCaffery 2004; Nadzam 1991; Robertson and MacKinnon 2002), there is clearly room for additional indicators, especially those developed specifically for the Canadian healthcare environment. The 20 final medication-use safety indicators on which our panel of experts agreed are quite diverse in scope and should be applicable in a variety of practice settings, including those outside the in-patient environment. The indicators generated in this study reflect the various stages in the medication-use system.

Safety is a concern at all these stages. Leape et al. (1995) found that most adverse drug events (ADEs) occur during the ordering and administration stages (39% and 38%, respectively); 12% occur during the transcription and verification stage and 11% during the pharmacy dispensing stage. Bates et al. (1995) had similar results: of the ADEs that were considered preventable, 49% occurred during the ordering stages, 26% during the administration stage, 11% during the transcription stage and 14% during the dispensing stage.

Our study focused on developing medication-use safety indicators that could be widely used in assessing quality of care in both hospital and community settings once they are validated. At least 10 of the indicators have applications outside the in-patient setting, which is important as evidence shows that the rate of adverse events is four times higher in the community (Gandhi et al. 2003). Forster et al. (2004) found that 23% of patients experienced an adverse event after discharge from hospital; 72% of these were attributable to medications. Nickerson et al. (2005) determined that patients averaged 3.5 drug-related problems at the time of hospital discharge. Thus, the indicators developed in this study reflect areas where problems occur in the delivery of medications and the ongoing monitoring of the patient in the community.

Limitations

The method used in this study has some limitations. The Delphi technique's ability to achieve consensus results, at least in part, from group interactions that occur anonymously, thus preventing domination by one or a few individuals, role playing or intimidation (Campbell and Cantrill 2001; Goodman 1987). Although this is clearly a strength of the technique, at times, we felt that some in-depth discussion, perhaps via videoconferencing or face-to-face meetings, would have been valuable. For example, consensus was deemed to have been achieved based on mean scores, but, occasionally, some experts' comments contradicted the mean scores (i.e., the majority agreed, but there was not absolute group agreement). Follow-up group interaction to resolve these discrepancies would have been interesting.

Conclusion

This study developed a set of 20 consensus-based medication-use safety indicators. In a second phase, a subset of these indicators will be tested for feasibility, reliability and validity in four health authorities in Atlantic Canada. If these indicators are found to be feasible, reliable and valid, the national partnering organizations will be involved in a comprehensive dissemination and knowledge-transfer strategy to ensure that the indicators are widely used, providing clinicians and decision-makers alike with a valuable tool to assess the safety of the medication-use system in Canada. HQ

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References

2003/2004 Annual Report. Hospital Pharmacy in Canada: Medication Safety. 2004. Toronto: Eli Lilly Canada Inc. Retrieved December 26, 2006. <www.lillyhospitalsurvey.ca/hpc2/content/rep_2004_toc.asp>.

Ackroyd-Stolarz, S., N. Hartnell and N.J. MacKinnon. 2005. "Approaches to Improving the Safety of the Medication Use System." *Healthcare Quarterly* 8: 59–64.

Agency for Healthcare Research and Quality. 2005. *AHRQ Quality Indicators: Guide to Patient Safety Indicators* (V. 2.1, Revision 3. Publication No. 03-R203). Rockville, MD: Author. Retrieved December 27, 2006. <www.qualityindicators.ahrq.gov/archives/psi/psi_guide_rev3.pdf>.

American Society of Health-System Pharmacists. 2007. *ASHP Health-System Pharmacy 2015 Initiative Self-Assessment Tool*. Bethesda, MD: Author. Retrieved January 11, 2007. <www.ashp.org/s_ashp/quart1.asp?CID=218&DID=255>.

Aspden, P., ed. 2006. *Preventing Medication Errors.* Washington: Institute of Medicine. Retrieved January 9, 2007. <www.iom.edu/Object.File/Master/35/943/medication%20errors%20new.pdf>.

Baker, G.R., P.G. Norton, V. Flintoft, R. Blais, A. Brown, J. Cox, E. Etchells, W.A. Ghali, P. Hebert, S.R. Majumdar, M. O'Beirne, L. Palacios-Derflingher, R.J. Reid, S. Sheps and R. Tamblyn. 2004. "The Canadian Adverse Events Study: The Incidence of Adverse Events among Hospital Patients in Canada." *Canadian Medical Association Journal* 170(11): 1678–86.

Bates, D.W., D.J. Cullen, N. Laird, L.A. Petersen, S.D. Small, D. Servi, G. Laffel, B.J. Sweitzer, B.F. Shea, R. Hallisey et al. 1995. "Incidence of Adverse Drug Events and Potential Adverse Drug Events: Implications for Prevention. ADE Prevention Study Group." *Journal of the American Medical Association* 274(1): 29–34.

Campbell, S.M. and J.A. Cantrill. 2001. "Consensus Methods in Prescribing Research." *Journal of Clinical Pharmacy and Therapeutics* 26(1): 5–14.

Canadian Council on Health Services Accreditation. 2006. *CCHSA Patient Safety-Canadian Performance Measures Consensus Survey: Summary Report for Participating Organizations.* Ottawa: Author.

Forster, A.J., H.D. Clark, A. Menard, N. Dupuis, R. Chernish, N. Chandok, A. Khan and C. van Walraven. 2004. "Adverse Events among Medical Patients after Discharge from Hospital." *Canadian Medical Association Journal* 170(3): 345–49. Retrieved December 27, 2006. <www.cmaj.ca/cgi/content/full/170/3/345>.

Gandhi, T.K., S.N. Weingart, J. Borus, A.C. Seger, J. Peterson, E. Burdick, D.L. Seger, K. Shu, F. Federico, L.L. Leape and D.W. Bates. 2003. "Adverse Drug Events in Ambulatory Care." *New England Journal of Medicine* 348(16): 1556–64.

Goodman, C.M. 1987. "The Delphi Technique: A Critique." *Journal of Advanced Nursing* 12(6): 729–34.

Institute for Safe Medication Practices. 2006a. *ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations.* Huntingdon Valley, PA: Author. Retrieved December 29, 2006. <www.ismp.org/Tools/errorproneabbreviations.pdf>.

Institute for Safe Medication Practices. 2006b. *ISMP's List of High-Alert Medications.* Huntingdon Valley, PA: Author. Retrieved December 29, 2006. <www.ismp.org/Tools/highalertmedications.pdf>.

Kohn, L.T., J.M. Corrigan and M.S. Donaldson, eds. 1999. *To Err Is Human: Building a Safer Health System*. Washington, DC: Institute of Medicine, National Academy Press.

Leape, L.L., D.W. Bates, D.J. Cullen, J. Cooper, H.J. Demonaco, T. Gallivan, R. Hallisey, J. Ives, N. Laird, G. Laffel et al. 1995. "Systems Analysis of Adverse Drug Events. ADE Prevention Study Group." *Journal of the American Medical Association* 274(1): 35–43.

MacKinnon, N.J. and K.J. McCaffery. 2004. *Health System Performance Indicator as a Tool for Maximizing Health Gains in Canada: Where Do Pharmaceuticals Fit?* Kirkland, QC: Merck Frosst Canada Ltd.

Nadzam, D.M. 1991. "Development of Medication-Use Indicators by the Joint Commission on Accreditation of Healthcare Organizations." *American Journal of Hospital Pharmacy* 48(9): 1925–30.

Nickerson, A., N.J. MacKinnon, N. Roberts and L. Saulnier. 2005. "Drug-Therapy Problems, Inconsistencies and Omissions Identified during a Medication Reconciliation and Seamless Care Service." *Healthcare Quarterly* 8: 65–72.

Robertson, H.A. and N.J. MacKinnon. 2002. "Development of a List of Consensus-Approved Clinical Indicators of Preventable Drug-Related Morbidity in Older Adults." *Clinical Therapeutics* 24(10): 1595–613.

Schoen, C., C. DesRoches and D. Downey. 2003. *The Canadian Health Care System: Views and Experiences of Adults with Health Problems.* New York: The Commonwealth Fund.

Wisconsin Patient Safety Institute. 2002. *Maximizing Patient Safety in the Medication Use Process: Practice Guidelines and Best Demonstrated Practices.* Madison, WI: Author.

Medication Safety in the Operating Room: Teaming Up to Improve Patient Safety

Rozina Merali, Beverley A. Orser, Alexandra Leeksma, Shirley Lingard, Susan Belo and Sylvia Hyland

Abstract

A medication safety project for operating rooms (ORs) was initiated under the leadership of the Departments of Anesthesia and Nursing with a representative from the Canadian Anesthesiologists' Society and the Institute for Safe Medication Practices Canada. The aims of the collaborative project were twofold: (1) to identify areas of exposure to risk and make recommendations to enhance medication safety within the hospital and (2) to inform the development of a medication safety checklist specific to the OR setting. The strategies developed and implemented during this project were aimed at reducing the risk of injury induced by medications. Attempts were made to use feasible best practices and managerial support systems for defined areas – in this case, medication-use systems for the ORs and associated patient care areas. The learning from this project will also inform the development of a medication safety checklist for use by other hospitals and OR settings.

Several studies have suggested that medication error is a leading cause of adverse events during anesthesia. For example, in an analysis of critical events during anesthesia, Cooper et al. (1984) demonstrated that the total number of medication-related events (including syringe swaps, drug ampoule swaps, overdoses and incorrect drug choices) far exceeded the next most frequent problem, disconnection of the breathing circuit. In a large Australian survey, Webster et al. (2001) estimated the incidence of drug administration errors in anesthesia on the basis of a large, prospective set of data. Overall, one drug administration error was reported for every 133 anesthetics administered. A survey of 687 anesthesiologists (representing a 30% response rate) (Orser et al. 2001) revealed that 85% of the respondents had experienced at least one drug error or near miss. A variety of factors contribute to increases in the risk of medication error in patients undergoing anesthesia, including the use of potent drugs that carry a risk of serious injury or death when administered in excessive doses or without adequate patient support; the dynamic, complex environment of the operating suite; and the fact that one person is responsible for prescribing, dispensing and administering the anesthetic and

monitoring the patient. Safeguards that are present in hospital nursing units (e.g., review of medication orders by nurses or pharmacists) are lacking. In addition, the administration of several high-risk drugs over a short period of time likely increases the likelihood of errors (Orser 2000).

The Project

In January 2005, patient safety was adopted as a priority for a large teaching hospital in Ontario. The hospital's board of trustees approved an Accountability for Patient Safety Policy, which created a framework for all staff, volunteers and physicians, emphasizing shared responsibility to ensure that systems of care were as safe as possible.

A medication safety project for operating rooms (ORs) was initiated under the leadership of the Departments of Anesthesia and Nursing. The Institute for Safe Medication Practices Canada (ISMP Canada) was invited to be a team member. The aims of the collaborative project were twofold: (1) to identify areas of exposure to risk and make recommendations to enhance medication safety within the hospital and (2) to inform the development of a medication safety self-assessment specific to the OR setting and related patient care areas, as part of a collaborative project with the Canadian Anesthesiologists' Society. The project was funded through the Ontario Ministry of Health and Long-Term Care.

On March 15 and 16, 2005, an interdisciplinary team of consultants from ISMP Canada, along with a representative from the US-based ISMP, performed a targeted system review of medication use in the OR and related patient care areas at the hospital. The review team observed the environments in which medications were prescribed, stored, transcribed, prepared, dispensed and administered. Areas of direct observations included the same-day surgical ward, individual ORs and the post-anesthesia care unit. Physicians (surgeons and anesthesiologists), nurses, respiratory therapists, perfusionists, pharmacy technicians, educators and representatives from

Table 1. Examples of findings and recommendations of the review team

Finding	Recommendation	Status of Change
Patient Information		
Incomplete and inconsistent medication history in patient charts Lack of sufficient prompts to ensure routine assessment of allergy information	Consistently document and complete preoperative medication history for all patients Add prompts to pre-admission records	New forms to prompt for medication and allergy history have been instituted. Medication reconciliation initiative has been started in associated patient care areas.
Drug Information		
Pharmaceutical care not provided routinely in OR, PACU and SDS areas	Provide enhanced pharmacist support	Approval has been granted for one permanent full-time equivalent pharmacist for the OR, PACU and SDS areas.
Communication of Drug Orders and Information		
Large number of abbreviations used on preprinted forms and in medication communications (verbal and written)	Eliminate use of dangerous abbreviations and dose expressions	Revisions have been made to preprinted forms.
Dose, frequency and route information inconsistently written on handwritten and preprinted orders	Incorporate computerized physician order entry into strategic planning	Computerized physician order entry, integrated with clinical decision support, is planned.
Drug Labelling, Packaging and Nomenclature		
Medication brands change without the knowledge of surgical teams or technicians	Enhance communication mechanisms	This is currently in progress.
Anesthetic cart trays not standardized; quantities not based on usage patterns	Standardize anesthetic cart trays and consider usage patterns	This has been completed.
Practitioner-prepared solutions, basins and syringes are inconsistently labelled, both on and off the sterile field	Require labelling of all medications and solutions up to the point of use Standardize labelling procedures	Policy, checklists and standardization of labelling are in development.

Finding	Recommendation	Status of Change
Drug Standardization, Storage and Distribution		
Hazardous chemicals found in close proximity to products designated for patient use	Evaluate need for, and then clearly identify and segregate, hazardous products	This has been completed.
Selected medications prepared in the unit with limited checking and sterility safeguards	Increase provision of premixed solutions	Opioids for epidural administration are now prepared by pharmacy; additional medications are under consideration for premixing.
Neuromuscular blocking agents not adequately segregated in storage areas	Segregate and label storage areas for neuromuscular blockers	This has been completed.
Use of bulk bottles for medication supplies, poor design of medication supply area, incomplete documentation	Budget for increased use of unit-dose products; consider acquisition of profiled automated dispensing cabinets for OR, PACU and SDS; incorporate bar-coding into strategic planning	One automated dispensing cabinet has been installed, and its evaluation is in progress.
Environment and Workflow		
Top of anesthesia carts cluttered	Minimize advance preparation of syringes for later administration and segregate them from the immediate workspace Return or remove unused medications from the work cart	Ongoing monitoring of the environment has been implemented.
Staff Competency and Education		
Medication "stashes" found in selected areas; other "workarounds" identified	Investigate, evaluate and educate staff about the dangers associated with workaround practices	Systems for review of practices are being explored.
Patient Education		
Inconsistent preoperative teaching of patients	Provide enhanced education materials for preoperative patients Consider pharmacy involvement in same-day assessment	These enhancements are in progress.
Quality Processes and Risk Management		
Limited voluntary reporting, a "siloed" error-analysis process and limited feedback	Encourage reporting (including near misses) by all practitioners Consider monitoring use of trigger drugs (e.g., naloxone and other reversal agents)	Hospital-wide electronic incident reporting program is being implemented. Patient safety rounds are held regularly.
Inconsistent system of double-checks	Consistently employ independent double-checks for hospital-selected "high-alert" drugs	Checklist development for high-risk procedures and disease management is currently under review by several departments.

PACU = post-anesthesia care unit; SDS = same-day surgery.

surgical management were interviewed. The team also toured the pharmacy. Various supporting documents (e.g., protocols, policies, procedures, order sets, drug guidelines, error reports and educational materials) were reviewed during the assessment process. System weaknesses were identified, and 75 specific recommendations were made to enhance medication safety.

Hospital managers reviewed and endorsed the recommendations (examples of which are listed in Table 1), and the Pharmacy Department received funding to hire an OR pharmacist to lead the implementation of the recommendations. Deliverables for this pharmacist included developing an implementation team, leading the implementation of selected recommendations over the short term and helping to develop plans for the implementation of selected long-term recommendations. Many of the changes that have already been made or are currently in progress are being considered for hospital-wide implementation.

Discussion

Published analyses of the underlying causes of medication errors suggest that many of these errors stem from basic ergonomic flaws in medication systems and the hospital environment (Leape et al. 1991; Silver and Antonow 2000). Systems approaches to deal with these ergonomic flaws and to thus reduce or intercept medication errors encompass standardization, simplification, the institution of double-check systems, restriction of access, the reduction of the reliance on memory and the creation of redundancies for critical functions. Incorporation of these principles into the design of work processes reduces the likelihood of error and increases the chances that any errors that do occur will be intercepted before patient harm occurs (Massachusetts Hospital Association 1999).

The teaching hospital that undertook this project recognized a need to address safety issues and to expand the knowledge base on medication safety. Although the efficacy of the recommendations in Table 1 has not yet been proven by formal research, it has been argued that many medication safety practices involve common sense and are well supported by human-factors literature in other industries (Leape et al. 2002). As such, the medication safety team feels that their implementation is reasonable. The carefully constructed implementation plan and agenda, the provision of education sessions and the creation of ongoing opportunities for input from different professional groups helped move the initiative forward and ensured that this collaborative project would provide knowledge translation for hospital staff. Nonetheless, achieving continued steady improvement will depend on adequate resources being sustained over an extended period.

Conclusions

Enhancing working relationships among anesthesiologists, pharmacists and nurses is pivotal for safe medication practices in the OR setting. The strategies developed and implemented during this project were aimed at reducing the risk of injury induced by medication errors. Attempts were made to use feasible best practices and managerial support systems for enhanced medication-use systems in the ORs and associated patient care areas. The learning from this project will also inform the development of a medication safety checklist for use by other hospitals. HQ

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References

Cooper, J.B., R.S. Newbower and R.J. Kitz. 1984. "An Analysis of Major Errors and Equipment Failures in Anesthesia Management: Considerations for Prevention and Detection." *Anesthesiology* 60(1): 34–42.

Leape, L.L., D.M. Berwick and D.W. Bates. 2002. "What Practices Will Most Improve Safety? Evidence-Based Medicine Meets Patient Safety." *Journal of the American Medical Association* 288(4): 501–7.

Leape, L.L., T.A. Brennan, N.M. Laird, A.G. Lawthers, A.R. Localio, B.A. Barnes, L. Hebert, J.P. Newhouse, P.C. Weiler and H. Hiatt. 1991. "The Nature of Adverse Events in Hospitalized Patients. Results of the Harvard Medical Practice Study II." *New England Journal of Medicine* 324(6): 377–84.

Massachusetts Hospital Association. 1999. *MHA Best Practice Recommendations to Reduce Medication Errors.* Executive Summary. Burlington, MA: Massachusetts Coalition for the Prevention of Medical Errors. Retrieved April 30, 2006. <http://www.macoalition.org/documents/Best_Practice_Medication_Errors.pdf>.

Orser, B.A. 2000. "Medication Safety in Anesthetic Practice: First Do No Harm [Editorial]." *Canadian Journal of Anesthesia* 47(11): 1051–4.

Orser, B.A., R.J.B. Chen and D.A.Y. Yee. 2001. "Medication Errors in Anesthetic Practice: A Survey of 687 Practitioners." *Canadian Journal of Anesthesia* 48(2): 139–46.

Silver, M.P. and J.A. Antonow. 2000. "Reducing Medication Errors in Hospitals: A Peer Review Organization Collaboration." *Joint Commission Journal on Quality Improvements* 26(6): 332–40.

Webster, C.S., A.F. Merry, L. Larsson, K.A. McGrath and J. Weller. 2001. "The Frequency and Nature of Drug Administration Error during Anesthesia." *Anaesthesia and Intensive Care* 29(5): 494–500.

Survey of Nursing Perceptions of Medication Administration Practices, Perceived Sources of Errors and Reporting Behaviours

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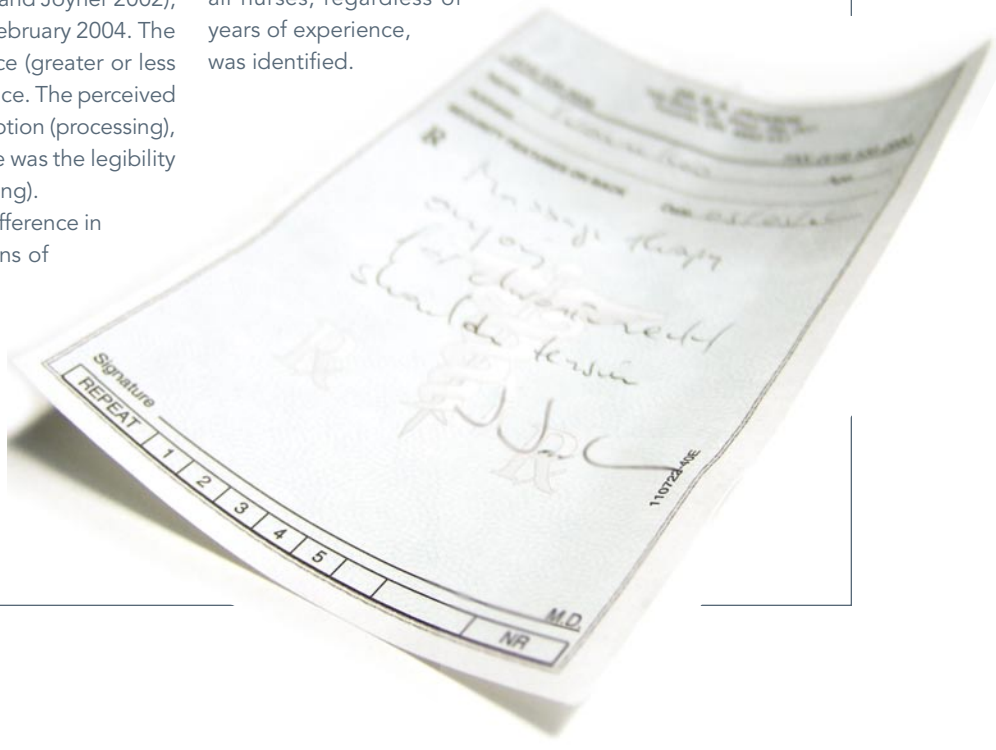
Abstract

In January 2003, St. Mary's Hospital Center in Montreal, Quebec, established an interdisciplinary Committee on the Systematic Approach to Medication Error Control to review the whole process of medication administration within the hospital and to develop a systematic approach to medication error control. A cross-sectional survey on medication administration practices, perceived sources of errors and medication error reporting of nurses, adapted from a nursing practice survey and medication variance report (Sim and Joyner 2002), was conducted over a two-week period in February 2004. The results were analyzed by years of experience (greater or less than five years) and patient care unit of practice. The perceived source of error most often cited was transcription (processing), and the second most frequently cited source was the legibility of handwritten medication orders (prescribing).

The results demonstrate no significant difference in medication safety practices or in perceptions of errors by years of experience. Nurses appear to adapt to the safety culture of the unit rather quickly, certainly within their first five years on the unit. Good medication error reporting behaviour was noted, with no differences between all comparative groups within both years of experience and unit of practice. Quality improvement initiatives to improve the safety of medication administration practices have included the development of a nursing medication administration handbook, the revision of policies and procedures related to medication administration safety, the standardization of solutions and limited variety of high-risk medication dosages and the reduction of handwritten reorders. The need for ongoing education and information sessions on policies and procedures specific to safe medication practices for all nurses, regardless of years of experience, was identified.



St. Mary's Hospital Center, located in Montreal, Quebec, is a 316-bed acute care, university-affiliated community hospital, with 65 beds designated for long-term care and a very large outpatient and family medicine program. The hospital has approximately 1,800 full-time and part-time employees, including about 618 registered nurses. In addition, there are roughly 254 active and 104 associate physicians practising at St. Mary's Hospital. The hospital provides a wide variety of acute, critical, emergency, cancer, mental health, maternal-child, surgical, medical care and diagnostic services, in addition to an active clinical teaching program.

The medication administration process, including the reporting and management of medication errors, was identified in 2002 by the hospital's Quality and Risk Management Coordinating Committee as a priority area for quality improvement. Starting in the spring of 2002, in-service education sessions were offered to every nurse on every shift to encourage the reporting of all adverse healthcare services–related events and, in particular, medication errors. In 2003–2004, 20% of all reported incidents and accidents were medication related; this percentage has fluctuated between 22 and 26% over the past three years. In 2003–2004, 732,902 medication orders were processed and administered; this increased to 767,829 (a 4.8% increase) by 2006–2007.

In January of 2003, a Committee on the Systematic Approach to Medication Error Control was established and mandated to review the whole process of medication administration within the hospital and to develop a systematic approach to medication error control, as outlined by Anderson and Webster (2001) and Kohn et al. (1999). This committee was composed of a physician, a nurse, a nurse manager, the chief pharmacist and a quality analyst. As part of this mandate, a cross-sectional survey of nurses on medication administration practices was conducted in February 2004. The objectives of the survey were to (1) describe nurses' perceptions of medication administration practices, reporting of errors and sources of medication errors and (2) describe the relationships between nurses' perceptions and their years of experience and the patient care unit on which they worked.

Prior research has addressed responses to observed medication errors (Kazaoka 2007; McBride-Henry and Foureur 2006; Nicholson 2006), incident reporting (Cohen et al. 2003; Mayo and Duncan 2004), safety practices in medication administration (Cohen et al. 2003; O'Shea 1999; Sim and Joyner 2002; Winson 1991), perceived sources of errors (Hicks et al. 2004; Leape et al. 1995; Mayo and Duncan 2004; Osborne 1999) and the impact of mentorship programs on new nurses (Casey et al. 2004; Duchscher and Cowin 2006; Stewart and Kreuger 1996; Thomka 2001; Thomka 2007). Literature has shown that senior nurses, as preceptors, may take risks as a result of their comfort or familiarity with the medication process, and junior nurses, as "preceptees," may feel pressured to emulate the practices of the senior nurses, thus quickly adopting and fitting into the culture of the patient care unit (Thomka 2007). To our knowledge, no studies have examined both nursing perceptions and medication safety practices by years of experience.

Methods

All registered nurses regardless of status or shift and in all patient care areas where nurses administer medications were asked to participate. Nurse managers, supervisors, liaison nurses and nurses working in areas where no medications are administered were excluded from the study. From the initial total of 618 registered nurses, 508 qualified for the study. Of these, 122 were excluded as they were on a leave of absence, sick leave or vacation, unavailable, participated in the pretest or refused. The final number of questionnaires distributed was 386 and, of these, 205 were returned. The information collected was non-nominative, ensuring the anonymity of respondents.

In December 2003, the survey was pretested in a focus group consisting of 10 members of the Professional Nurses Practice Committee (PNPC). Based on their feedback, the survey was revised to improve clarity and ensure anonymity of the respondents. Over a two-week period in February 2004, all unit PNPC representatives were given questionnaires to distribute in their own patient care unit or clinical area. All nurses were approached at work to complete the survey. The PNPC representative recorded distribution data. A self-addressed return envelope was attached to each questionnaire. Each unit or area was canvassed several times over a two-week period to maximize distribution over weekends and all shifts.

The questionnaire consisted of multiple-choice and open-ended questions (Figure 1) directed toward current practice, perceptions of sources of error, error reporting practices and demographic information. Eight questions on current practice were adapted and expanded from a seven-question medication administration practice survey developed by a community hospital in the United States (Sim and Joyner 2002). Possible responses were always, frequently, about half the time, rarely and never. For the analyses, these responses were coded from one to five, respectively, for good/favourable medication practices (questions 1, 3, 4, 5, 7 and 8); responses for two questions (questions 2 and 6; see Figure 1) were reverse-coded for poor/unfavourable practices. Medication error reporting behaviour was examined through the use of a single multiple-choice question with a five-point response scale from always to never.

Nurses were then asked to select what they perceived as the six most common sources of error from a checklist of 16 specific causes of errors. They also had the opportunity to list three other causes of errors. When possible, the other causes of errors mentioned by nurses were recoded into the 16 specified causes within the survey. The perceived sources of medication errors

Figure 1. Medication administration survey In an effort to understand the current medication practices, this survey is being circulated to all the RNs o

Current Practice

Thinking of the medications that you have administered during the last month, how frequently:

1	Do you check the patient's armband prior to administering medications? ☐ Always ☐ Frequently ☐ About Half the Time ☐ Rarely ☐ Never
2	Do you prepare and carry medications for more than two patients with you at a time? ☐ Always ☐ Frequently ☐ About Half the Time ☐ Rarely ☐ Never
3	Do you label the medication cup with the patient's name and room number? ☐ Always ☐ Frequently ☐ About Half the Time ☐ Rarely ☐ Never
4	Do you bring your MAR/medication sheet with you? ☐ Always ☐ Frequently ☐ About Half the Time ☐ Rarely ☐ Never
5	Do you label syringes and bags with the medication, name, patient name and room number? ☐ Always ☐ Frequently ☐ About Half the Time ☐ Rarely ☐ Never
6	Do you administer medications that another nurse has prepared? ☐ Always ☐ Frequently ☐ About Half the Time ☐ Rarely ☐ Never
7	Do you have heparin doses double-checked by another nurse? (exclude heparin flush) ☐ Always ☐ Frequently ☐ About Half the Time ☐ Rarely ☐ Never
8	Do you have insulin doses double-checked by another nurse? ☐ Always ☐ Frequently ☐ About Half the Time ☐ Rarely ☐ Never

Sources of Error: In your opinion, what are the six main causes of error? Please check only 6 of the following:

☐	a) computer entry error (processing)	☐	k) miscalculation (administering)
☐	b) transcription error (processing)	☐	l) procedure/policy not followed (administering)
☐	c) no order sent to/received by pharmacy (processing)	☐	m) filled incorrectly (dispensing)
☐	d) error checking MAR/medication sheet (processing)	☐	n) mislabelled (dispensing)
☐	e) legibility (prescribing)	☐	o) names of meds look alike (dispensing)
☐	f) incorrect order (prescribing)	☐	p) labels of meds look alike (dispensing)
☐	g) confusing order/instructions (prescribing)	☐	q) other, specify:_____
☐	h) misunderstood verbal order (prescribing)	☐	r) other, specify:_____
☐	i) knowledge deficit (administering)	☐	s) other, specify:_____
☐	j) distractions (administering)		

Reporting Errors: I report medication errors using the Incident/Accident form (AH223). Please check one response.

☐ Always ☐ Frequently ☐ About Half the Time ☐ Rarely ☐ Never

Demographics: Please indicate the area where you usually work:

☐	Psychiatry / OPD Clinic	☐	5 Main/ONC Clinic	☐	5 North
☐	Family Medicine Center	☐	7 Main	☐	8 Main
☐	6 North/6 South	☐	5 South	☐	Dialysis
☐	4 Main/Women's CI/Nursery/Case room	☐	ICU/CCU/MDC	☐	RR/SDC/OR
☐	Emergency				

Years of practice as RN: ☐ 5 or less ☐ more than 5

CCU = Coronary Care Unit; ICU = Intensive Care Unit; MAR = medication administration record; MDC = Medical Day Center; ONC Clinic = Oncology Clinic; OPD Clinic = Out-Patient Clinic; OR = Operating Room; PNPC = Professional Nurses Practice Committee; RN = Registered Nurse; RR = Recovery Room; SDC = Surgical Day Center; Women's CI = Women's Clinic.

were then grouped into five categories: processing (four specific causes), prescribing (four causes), administering (four causes), dispensing (four cause) and other (three causes). The proportions of errors in the first four categories were calculated for each nurse as the sum of errors in that category divided by the total potential causes in the category.

Further details about the methods used are presented in Appendix A.

Results

Among the 205 questionnaires received, 144 with complete data on medication practices, years of experience and hospital unit were retained for the principal components analysis (Table 1). Two factor solutions emerged from the principal components analysis, named "dosage care" (with three items) and "right patient" (with four items), and two single items assessed "preparing/carrying medications" and "error reporting."

"Error reporting" had the lowest mean (1.7 on a scale from one to five), indicating the most favourable medication practice (Table 2). At the other extreme, "preparing/carrying medications" showed the worst level (mean of 3.5). Work unit was significantly associated with "dosage care," "right patient" and "preparing/carrying medications," whereas years of experience was not associated with any of the four behaviour scales. After applying Bonferroni correction, "dosage care" had more favourable scores in the maternal-child and surgical units and less favourable scores in the critical care, emergency and medical units. On the other hand, "right patient" had significantly more favourable scores in the emergency, medical and surgical units and less favourable scores in the maternal-child unit. The mean score for "preparing/carrying medications" was more favourable in the critical care and maternal-child units and less favourable in emergency, medical and surgical units.

Errors related to transcribing were the most frequently reported, followed by errors involving legibility and distractions.

The top three perceived sources of errors were transcribing (processing), legibility (prescribing) and distractions (administering) (Table 3). For the category "administering," there were no significant differences for results between patient care units (Table 4). However, for perceived transcribing errors (processing), the maternal-child unit responded more favourably than did the medical and surgical units.The perception of legibility (prescribing) being an important source of error was significantly stronger in the emergency unit than in the medical units. As shown in Table 4, the perception that medication processing and prescribing were sources of errors was associated with patient care units. After applying the Bonferroni correction, the maternal-child unit had a significantly lower mean score on medication processing than did the medical and surgical units. The medical unit had a significantly lower mean score on medication prescribing than did the emergency unit. Years of nursing experience was not associated with perceived sources of error.

Table 1. Results of principal components analysis and internal consistency (N = 144)

Items from Medication Questionnaire by Sub-scale	Factor Loading	Cronbach Coefficient Alpha (Standardized)
Sub-scale 1: dosage care (% of variance explained = 21.1%)		
Q6 Administering medications another nurse has prepared	0.63	.65
Q7 Having heparin doses double-checked	0.85	
Q8 Having insulin doses double-checked	0.77	
Sub-scale 2: right patient (% of variance explained = 18.4%)		.54
Q1 Checking patient's armband prior to administering	0.66	
Q3 Labelling medication cup with patient's name and room number	0.50	
Q4 Bringing MAR/medication sheet with you	0.70	
Q5 Labelling syringes and bag with medication, name, patient name and room number	0.60	
Sub-scale 3: preparing/carrying medications		
Q2 Preparing or carrying medications for more than two patients at a time	n.a.	n.a.
Sub-scale 4: error reporting A280		
S4 Using incident/accident form to report errors	n.a.	n.a.

MAR = medication administration record; n.a. = not applicable.

Discussion

This cross-sectional survey among nurses in a university-affiliated general community hospital investigated self-reported medication practices and sources of error. Using sub-scales and items

Table 2. Results of medication report practices outcomes by unit and nurse experience

		Sub-scale 1: Dosage Care		Sub-scale 2: Right Patient Identification		Sub-scale 3: Preparing/Carrying Medications		Sub-scale 4: Reporting Errors	
	n	Mean (SD)*	p Value†	Mean (SD)*	p Value†	Mean (SD)*	p Value†	Mean (SD)*	p Value†
Overall (N)	144	2.2 (1.0)		2.0 (0.8)		3.5 (1.4)		1.7 (0.9)	
Unit			<.001		<.001		<.001		.199
Critical care	14	3.0 (1.3)		2.2 (0.8)		1.8 (1.3)		1.4 (0.6)	
Emergency	22	2.8 (1.0)		1.6 (0.6)		3.5 (1.4)		1.8 (1.2)	
Medicine	40	2.3 (0.7)		1.6 (0.5)		4.3 (1.0)		1.9 (1.0)	
Maternal-child	29	1.4 (0.6)		2.7 (0.6)		2.8 (1.4)		1.4 (1.2)	
Surgery	15	1.6 (0.6)		1.5 (0.5)		4.3 (1.0)		1.9 (0.8)	
Others‡	24	2.7 (1.1)		2.6 (1.0)		3.8 (1.2)		1.5 (0.7)	
Years of experience			.066		.432		.819		.579
<5	38	1.9 (1.0)		1.8 (0.6)		3.8 (1.4)		1.8 (1.0)	
>5	106	2.4 (1.0)		2.1 (0.9)		3.4 (1.4)		1.6 (0.9)	

*All the outcomes scores are between 1 (most favourable) and 5 (least favourable). †Two-way analysis of variance. ‡Dialysis, mental health, family medicine, long-term care or oncology.

assessing different aspects of practice (dosage care, right patient, preparing/carrying medications and reporting errors) we were able to identify areas where practices may need improvement. Errors related to medication processing (transcribing) were the most frequently reported, followed by errors involving prescribing (legibility) and administering medications (distractions). Dispensing errors were the least frequent. This ranking of perceived causes of error differed minimally from results in the Mayo and Duncan (2003) study, where illegible handwriting (prescribing) ranked the highest, followed by distraction (administration).

Differences among patient care units were found both in medication practices and perceived sources of error. These are likely explained by differences in the patient population and the types and number of medications used on particular patient care units. For example, the maternal-child care unit uses fewer medications than do other patient care units, with more standardized medications being prescribed. Patients within the maternal-child care unit are also less acute and, generally, a healthier population. These factors probably account for the more favourable scores on "dosage care." Maternal-child care units seldom use insulin or heparin. Interestingly, on some patient care units where nurses were more likely to prepare more than one patient medication at the same time, they took greater safety measures for patient identification. Notably, no relationships were found between medication practices or perceived sources of error by years of experience. This result is similar to results in both the Mayo and Duncan (2003) and the Osborne et al. (1999) studies, where no significant differences were noted in perceptions related to age and years of practice and medication errors. This study highlights the need for ongoing education programs on medication safety for all nurses, regardless of years of experience.

Since the administration of this survey, numerous measures have been put in place to facilitate medication administration and to reduce the probability of incidents or accidents involving the medication administration process. These include the generalized use of the seven-day computerized medication administration record (MAR) on almost all in-patient care units, with the exceptional use of the 24-hour MAR on the critical care and surgical units. In 2006–2007, 282,740 new orders were automatically transcribed through the use of the computerized MAR, thereby eliminating manual transcriptions by nurses of medication orders. The use of mediplan®, used by nurses, on the patient care units and the medipharm® computerized medication reordering processes, used by pharmacists, has eliminated the legibility concerns for reorders. However, legibility concerns remain for new orders, which continue to be handwritten. Since 2006, intravenous heparin solution bags have been sent prepared from the pharmacy to the patient care units.

Table 3. Proportion of medication errors, per nurse, per category (N = 144)

Error and Items	Rank	n	%
Processing			
Processing: transcription error	1	106	73.6
Processing: no order sent to/received by pharmacy	2	60	41.7
Processing: error checking MAR/medication sheet	3	57	39.6
Processing: computer entry error	4	38	26.4
Mean proportion of processing errors = 0.45 (SD = 0.27)*			
Prescribing			
Prescribing: legibility	1	71	49.3
Prescribing: confusing order/instructions	2	68	47.2
Prescribing: incorrect order	3	27	18.8
Prescribing: misunderstood verbal order	4	19	13.2
Mean proportion of prescribing errors = 0.32 (SD = 0.26)*			
Administering			
Administering: distractions	1	81	56.3
Administering: miscalculation	2	49	34.0
Administering: procedure/policy not followed	3	25	17.4
Administering: knowledge deficit	4	19	13.2
Mean proportion of administering errors = 0.30 (SD = 0.23)*			
All dispensing			
Dispensing: labels of medications look alike	1	19	13.2
Dispensing: names of medications look alike	2	17	11.8
Dispensing: mislabelled	3	16	11.1
Dispensing: filled incorrectly	4	15	10.4
Mean proportion of dispensing errors = 0.12 (SD = 0.18)*			

MAR = medication administration record.

*Adjusting for the total numbers of opportunity.

Notably, no relationships were found between medication practices or perceived sources of error by years of experience.

The PNPC has developed a medication administration guidelines handbook for all nurses, as well as a two-volume comprehensive booklet titled Medication Administration (phases I and II). Both documents reinforce safe medication administration practices and review related policies and procedures as well as the incident/accident reporting process for medication errors. Policies and procedures were revised to better address safety issues in medication administration.

Furthermore, the previously existing mentorship program for the training of new nurses was standardized and improved to include an evaluation of the new employees' knowledge of the medication administration procedures. This allowed for a tailoring of the mentorship to each individual's needs while providing comprehensive training covering the essential elements common to all areas.

Frequent in-service education sessions are being offered to all nurses on all shifts to encourage reporting of healthcare services–related incidents and accidents, possibly explaining the favourable scores overall on "error reporting." The systems approach to reducing errors was introduced at St. Mary's in 2002 and has been found to be an effective means to encourage incident/accident reporting.

Limitations

There were two identified limitations to this study. The first limitation was the grouping of practice experience into the broad categories of less than or more than five years, originally designed to ensure anonymity. A more graduated scale with a larger sample size to maintain anonymity may be more sensitive and helpful in determining the impact of practice experience on perceptions and actual practice.

The second limitation involved the use of a questionnaire survey which may have had an impact on the reporting of current practices and error reporting behaviours (sub-scales one to four). Direct observation has been found to be a more sensitive method for detecting medication administration behaviours. A subsequent study of medication administration practices comparing perceptions with observed behaviours and actual reported incidents may yield a more accurate portrait of current practices.

Conclusions

In spite of the limitations outlined above, this study demonstrates the need for more education for all nurses, taking into consideration the role adjustment period for new nurses as well as the time associated with preceptorship programs. The

Table 4. Results of perceived sources of error outcomes by unit and nurse experience

		Processing		Prescribing		Administering		Dispensing	
	n	Mean (SD)*	p Value†	Mean (SD)*	p Value†	Mean (SD)*	p Value†	Mean (SD)*	p Value†
Overall (N)	144	0.45 (0.3)		0.32 (0.3)		0.30 (0.2)		0.12 (0.2)	
Unit			.001		.0002		.049		.624
Critical care	14	0.33 (0.2)		0.30 (0.2)		0.38 (0.2)		0.16 (0.2)	
Emergency	22	0.39 (0.2)		0.51 (0.3)		0.27 (0.3)		0.09 (0.1)	
Medicine	40	0.54 (0.3)		0.23 (0.2)		0.23 (0.2)		0.13 (0.2)	
Maternal-child	29	0.34 (0.2)		0.39 (0.2)		0.33 (0.2)		0.15 (0.2)	
Surgery	15	0.57 (0.3)		0.33 (0.2)		0.25 (0.2)		0.12 (0.2)	
Others‡	24	0.51 (0.3)		0.23 (0.3)		0.41 (0.3)		0.06 (0.13)	
Years of experience			.067		.912		.923		.524
<5	38	0.42 (0.3)		0.30 (0.2)		0.29 (0.3)		0.13 (0.2)	
>5	106	0.46 (0.3)		0.33 (0.3)		0.31 (0.2)		0.11 (0.2)	

*All the outcomes scores (rate) are between 0 and 1 (higher: more sources of error).

†Two-way analysis of variance.

‡Dialysis, mental health, family medicine, long-term care or oncology.

authors acknowledge that more research is needed on the impact of senior nurses, preceptorship programs and patient care unit safety culture on the medication safety practices of junior nurses. Future research should use a more graduated scale for the years of experience and an observational approach to error reporting and practice behaviours.

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Bibliography

Anderson, D.J. and C.S. Webster. 2001. "A Systems Approach to the Reduction of Medication Error on the Hospital Ward." *Nursing and Health Care Management Issues – Journal of Advanced Nursing* 35(1): 34–41.

Casey, K., R. Fink, M. Frugman and J. Propst. 2004. "The Graduate Nurse Experience." *The Journal of Nursing Administration* 34(6): 303–11.

Cohen, H., E.S. Robinson and M. Mandrack. 2003. "Getting to the Root of Medication." *Nursing* 33(9): 36–45.

Cohen, M.R. 1999. "Causes of Medication Errors." In M.R. Cohen, ed., *Medication Errors.* Washington, DC: American Pharmacists Association.

Duchscher Boychuk, J.E. and L.S. Cowin. 2006. "The New Graduate's Professional Inheritance." *Nursing Outlook* 54(3):152–8.

Haw, C., J. Stubbs and G. Dickens. 2007. "An Observational Study of Medication Administration Errors in Old-age Psychiatric Inpatients." *International Journal of Quality in Health Care* 19(4): 210–16.

Hicks, R.W., S.C. Becker, D. Krenzischeck and S.C. Beyea. 2004. "Medication Errors in the PACU: A Secondary Analysis of MEDMARX Findings." *Journal of PeriAnesthesia Nursing* 19(1): 18–28.

Huber, D. 2002. "Nevada Nurses Participate in Medication Errors Survey." *Nevada RN Information* 11(3): 18–9.

Kazaoka, T., K. Ohtsuka, K. Ueno and M. Mori. 2007. "Why Nurses Make Medication Errors: A Simulation Study." *Nurse Education Today* 27(4): 312–7.

Kohn, L.T., J.M. Corrigan and M.S. Donaldson, eds. 1999. *To Err Is Human: Building a Safer Health System.* Washington, DC: National Academy Press.

Leape L.L., D.W. Bates, D.J. Cullen, J. Cooper, H.J. Demonaco, T. Gallivan, R. Hallisey, J. Ives, N. Laird and G. Laffel. 1995. "Systems Analysis of Adverse Drug Events. ADE Prevention Study Group." *Journal of the American Medical Association* 274: 35–43.

Manun'Ebo, M., S. Cousens, P. Haggerty, M. Calengaie, A. Ashworth and B. Kirkwood. 1997. "Measuring Hygiene Practices: A Comparison of Questionnaires with Direct Observations in Rural Zaire." *Tropical Medicine and International Health* 2(11): 1015–21.

Mayo, A.M. and D. Duncan. 2004. "Nurse Perception of Medication Errors. What We Need to Know for Patient Safety." *Journal of Nursing Care Quality* 19(3): 209–17.

McBride-Henry, K. and M. Foureur. 2006. "Medication Administration Errors: Understanding the Issues." *Australian Journal of Advanced Nursing* 23(3): 33–41.

Nicholson, D., W. Hersh, T.K. Gandhi, S.N. Weingart and D.W. Bates. 2006. "Medication Errors: Not Just a Few Bad Apples." *Journal of Clinical Outcomes Management* 13(2): 114–5.

Osbourne, J., K. Blias and J. Hayes. 1999. "Nurses' Perceptions: When Is It a Medication Error?" *Journal of Nursing Administration* 29(4): 33-38.

O'Shea, E. 1999. "Factors Contributing to Medication Errors: A Literature Review." *Journal of Clinical Nursing* 8(5): 496–504.

Sahlberg-Blom, E., B.-M. Ternestedt and J.-E. Johansson. 2001. "Is Good 'Quality of Life' Possible at the End of Life? An Explorative Study of the Experiences of a Group of Cancer Patients in Two Different Care Cultures." *Journal of Clinical Nursing* 10(4): 550–62.

Sim, T.A. and J. Joyner. 2002. "A Multidisciplinary Team Approach to Reducing Medication Variance." *Joint Commission Journal on Quality Improvement* 28(7): 403–9.

Song, Y. and G.-J. Knapp. 2007. "Quantitative Classification of Neighborhoods: The Neighborhoods of New Single-Family Homes in the Portland Metropolitan Area." *Journal of Urban Design* 12(1): 1–24.

Spouce, J. 2001. "Bridging Theory and Practice in the Supervisory Relationship: A Sociocultural Perspective." *Journal of Advanced Nursing* 33(4): 512–22.

Stewart, B.M. and L.E. Krueger. 1996. "An Evolutionary Concept Analysis of Mentoring in Nursing." *Journal of Professional Nursing* 12(5): 311–21.

Thomka, L.A. 2001. "Graduate Nurses' Nurses' Experiences of Interactions with Professional Nursing Staff during Transition to the Professional Role." *The Journal of Continuing Education in Nursing* 32(1): 15–9.

Thomka, L.A. 2007. "Mentoring and Its Impact on Intellectual Capital: Through the Eyes of the Mentee." *Nursing Administration Quarterly* 31(1): 22–6.

Winson, G. 1991. "A Survey of Nurse's Attitudes towards Single Administration of Medications." *Nursing Practice* 4(3): 20–3.

Appendix A

Information on the usual patient care unit where the nurse worked and years of practice (five years or less, and more than five years) was collected. Principal components analysis was used to reduce the questions into a smaller number of sub-scales that account for most of the variance in the data. All components associated with an eigenvalue greater than one were first selected. A varimax rotation was then applied to the chosen components to obtain more interpretable sub-scales (Stevens 1996). Questions with the greatest factor loadings, >0.50, and in the same direction, were included in each sub-scale. The internal consistency of each sub-scale thus derived was estimated using Cronbach's alpha statistic. The score for each sub-scale was estimated as the average score for that sub-scale.

Both mean sub-scale scores of medication practice behaviours and mean rates of perceived sources of medication errors were compared across categories for two occupational characteristics (years of experience and work unit) using two-way analysis of variance (ANOVA) models. Patient care units were coded according to the following categories: critical care, emergency, medicine, maternal-child, surgery and other (units with seven or fewer respondents, including mental health, dialysis, oncology, family medicine and long-term care). The interaction between years of experience and work unit was tested and found not significant (using alpha of .1) for all two-way ANOVA models. Bonferroni contrasts were used to compare units. All analyses were performed using the SAS 9.1 software package (SAS 2007). In the interpretation, the p value of a two-sided test was considered statistically significant when less than .05.

References

SAS Institute Inc. 2007. SAS Online Doc, Version 9.1. Cary, NC: SAS Institute Inc. Retrieved September 3, 2007. <http://www.sas.com>.

Stevens, J.P. 1996. *Applied Multivariate Statistics for the Social Sciences.* Hillsdale, NJ: Lawrence Erlbaum Associates.

Communication and Relationship Skills for Rapid Response Teams at Hamilton Health Sciences

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Abstract

Rapid response teams (RRT) are an important safety strategy in the prevention of deaths in patients who are progressively failing outside of the intensive care unit. The goal is to intervene before a critical event occurs. Effective teamwork and communication skills are frequently cited as critical success factors in the implementation of these teams. However, there is very little literature that clearly provides an education strategy for the development of these skills. Training in simulation labs offers an opportunity to assess and build on current team skills; however, this approach does not address how to meet the gaps in team communication and relationship skill management. At Hamilton Health Sciences (HHS) a two-day program was developed in collaboration with the RRT Team Leads, Organizational Effectiveness and Patient Safety Leaders. Participants reflected on their conflict management styles and considered how their personality traits may contribute to team function. Communication and relationship theories were reviewed and applied in simulated sessions in the relative safety of off-site team sessions. The overwhelming positive response to this training has been demonstrated in the incredible success of these teams from the perspective of the satisfaction surveys of the care units that call the team, and in the multi-phased team evaluation of their application to practice. These sessions offer a useful approach to the development of the soft skills required for successful RRT implementation.

Critical events such as cardiac, respiratory and neurological events are common and serious complications among hospitalized patients. Despite advances in the treatment for cardiac arrest, only 17% of patients survive to discharge (Naeem and Montenegro 2005). Further, 64–80% of patients who experience cardiac arrest show identifiable signs of deterioration six to eight hours prior to their arrest (Franklin and Matthew 1994; Schein et al. 1990). Rapid Response Teams (RRTs) (also known as medical emergency teams and critical care outreach teams) are rapidly becoming an important patient safety strategy in the prevention of death in patients who are progressively failing outside of intensive care units. RRTs are composed of critical care registered nurses, physicians and/or registered respiratory therapists and can be summoned to assist with the care of an acutely ill patient *before* a critical event occurs. The team can begin treatment immediately, initiate a transfer to

a higher level of care or communicate a treatment plan to the patient's most responsible physician. Studies have shown that this approach results in fewer cardiac arrests, increased survival rates for those who have a cardiac arrest and shorter lengths of stay post-arrest both in the intensive care unit and in the hospital overall (Bellomo et al. 2003).

Successful critical care outreach teams focus considerable energy on creating a collaborative culture that supports anyone who requests their help.

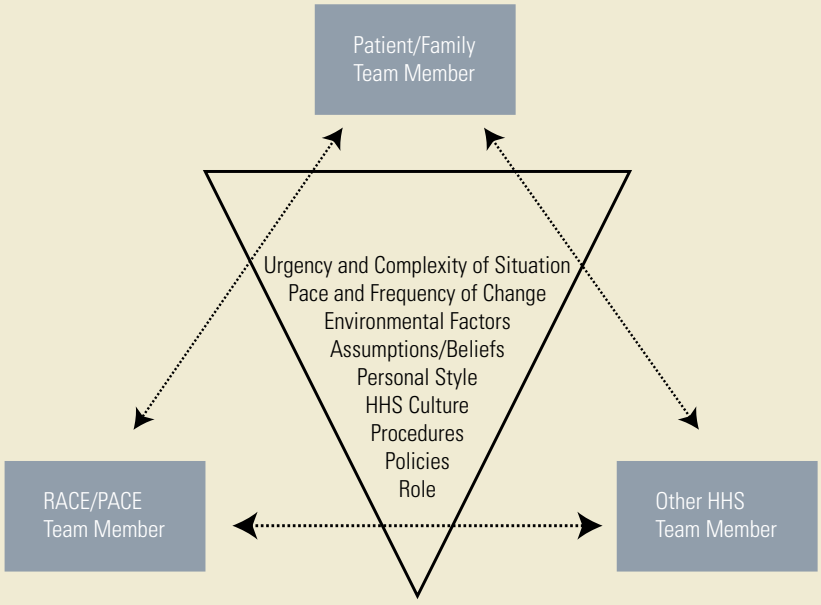
Hospitals in Australia and the United Kingdom have adopted this patient safety strategy. In Canada, in May 2006, the Ontario Ministry of Health and Long-Term Care (MOHLTC) provided funding for CCOTs at 22 sites. In addition, MOHLTC funded four pediatric pilot sites. Hamilton Health Sciences (HHS) received funding to provide 24/7 services at Hamilton General Hospital and McMaster Children's Hospital. Known as the RACE (rapid assessment of critical events) team at the Hamilton General Site and PACE (pediatric assessment of critical events) team at the Children's Hospital, the teams are composed of a critical care registered nurse, a registered respiratory therapist and a physician. Registered nurses and registered respiratory therapists underwent a rigorous selection process and educational program prior to working on the RACE and PACE teams.

Significant clinical skills training including simulation laboratory experiences were provided to all team members. However, it was recognized at the outset that effective team communication and relationship skills are as important as critical care skills and would be crucial success factors in the implementation of these teams. Successful CCOTs focus considerable energy on creating a collaborative culture that supports anyone who requests their help (Institute for Healthcare Improvement 2006), and they recognize that optimal care delivery is dependent on the ability of team members to work and communicate effectively together (Mistry et al. 2006). There is, however, a paucity of literature that clearly provides education strategies for the development of these skills. Training in simulation laboratories offers an opportunity to assess and build on current team skills, but it does not address how to meet the gaps in team communication and relationship skills and knowledge. The final step to prepare RACE and PACE team members to be effective in their roles was participation in a two-day communication and relationship skills workshop.

Inclusive Design Approach

A collaborative and systems approach was required to design an effective workshop that met the requirements from various perspectives (Barbazette 2001; Cranton 1992; Dzik-Juasz 2006; Furjanic and Trotman 2000). Once the project teams decided to implement a workshop, a working group was established. The sessions were designed, developed and implemented internally by the HHS Organizational Effectiveness team (quality, organizational development and patient safety specialists) in collaboration with the RACE/PACE team leads. The structure of the design team created synergy, collaboration and the alignment of content with process expertise. This ensured a systems perspective for the overall design of the workshop. Two-day action learning workshops were held during November 2006 for 29 PACE and RACE team members to enhance the interpersonal and communication skills required to be an effective member of the teams. The workshops provided participants with necessary

Figure 1. Factors influencing communications



HHS = Hamilton Health Sciences; PACE = pediatric assessment of critical events; RACE = rapid assessment of critical events.
Source: From the HHS workshop Teaming Up! The DNA of Working Together for Patient Care.

knowledge and skills and allowed them to apply the information obtained through practical scenarios in the areas of communication and relationship management.

An inclusive participative process was used that ensured the working group continuously communicated with the PACE and RACE Steering Committees and Senior Leadership team. By extending the development of the program content to a wider group within the organization, the workshop content was enriched and the *buy-in* for conducting the program within the organization was positively influenced (Barbazette 2001; Furjanic and Trotman 2000). The team communication workshop was created using a five-phase process: analysis, design, development, implementation and evaluation (Barbazette 2001; Furjanic and Trotman 2000). Overall, the inclusive design approach assisted in producing an effective workshop that met the needs of the project teams, healthcare professionals within the teams and, ultimately, patients.

Figure 2. Workshop learning goal and objectives

Learning goal: To enhance the interpersonal and communication skills required to be an effective member of the PACE and RACE teams, resulting in the provision of safe and optimum care for patients.

Learning objectives: Upon completion of the learning session, each participant will:

- understand his or her communication/interpersonal style and how that style influences others;
- learn and understand how to use a structured communication technique to facilitate effective communication between various members of the healthcare team;
- understand the principles and benefits of situational awareness and take a systems approach to enhance team performance and patient care;
- enhance critical-thinking skills related to communication, relationship building and conflict management; and
- increase his or her awareness level of the internal resources available at HHS to assist the PACE and RACE teams with their day-to-day roles and responsibilities.

HHS = Hamilton Health Sciences; PACE = pediatric assessment of critical events; RACE = rapid assessment of critical events.

Source: From the HHS workshop Teaming Up! The DNA of Working Together for Patient Care.

Complexities at the professional, organizational, team, personal and patient levels can create conflicting priorities and communication challenges.

Workshop Content

According to Hill (1996), technical competence in the workplace is not enough. Success also depends on interpersonal skills and the ability to develop effective work relationships with key individuals. Today's healthcare environment consists of complexities related to systems, processes, culture and behaviours. These complexities influence communication and relationships, which, in turn, can impact quality of care and of the workplace.

Figure 1 identifies the factors that influence communication between the interrelated team members, including the patient and family members, PACE and RACE team members and other HHS team members.

Healthcare teams face many kinds of communication challenges on a day-to-day basis. Complexities at the professional, organizational, team, personal and patient levels can create conflicting priorities and communication challenges. Patient safety literature identifies that communication and teamwork affect quality and safety and are responsible for a large percentage of sentinel events (Leonard et al. 2004). The content of the HHS workshop predominantly consisted of self-awareness activities related to personal style and communication skills. Theories, concepts and applications for effective team communication with a focus on communication approaches, team interaction and relationship management were included (Figure 2).

When considering the content for the workshop, a systems approach consisting of the process, task and people factors for teams provided the foundational framework (Table 1).

Various learning approaches were used to enhance the learner's ability to remember the content and apply the newly acquired information and skills within day-to-day activities (Barbazette 2001; Cranton 1992; Dzik-Juasz 2006; Farbstein 2003; Furjanic and Trotman 2000). An action learning approach was employed so that participants could explore and examine behaviours and actions to enhance performance levels (Dzik-Jurasz 2006; Kieren and Kalliath 2005). The use of lecturettes, case simulations, group exercises and discussions, feedback opportunities and a behavioural style inventory, Personality Dimensions – True Colors, fostered an open and participative learning environment. Participants were given time to interact and share knowledge, which enhanced the learning and experience.

By combining the content for each team and various learning approaches, a workshop was created that provided both behavioural and technical applications to support the PACE and RACE roles. Best practices, a standardized approach, user-friendly applications, participant learning styles and HHS values were principles used during the creation of the content and materials for the workshop.

Level 1 and 2 Training Evaluations

Level 1 and 2 training evaluations were conducted to capture

the participants' reactions to the training sessions and the learning that was acquired over the two-day period. Level 1 evaluations measured the reaction of the students, that is, what they thought and felt about the training. Level 2 evaluations measured the students' learning, that is, the resulting increase in knowledge or capability (Kirkpatrick 1994). A summary of level 1 and 2 training evaluations indicated that participants felt the workshop reaffirmed the importance of effective communication skills, teamwork and conflict-resolution skills in the provision of quality patient care. Participants gained an understanding of personal styles and the SBAR (Situation-Background-Assessment-Recommendation) approach for effective, structured communication, and they learned new communication and conflict-resolution techniques, including how to communicate assertively. They identified an increased self-awareness in relation to listening, body language, tone and being less judgmental. Overall, the evaluations indicated that the participants found that the sessions were informative, were relevant to practice, helped to build confidence and met learning needs with respect to communication.

Best practices, a standardized approach, user-friendly applications, participant learning styles and HHS values were principles used in the workshop.

Level 3 Evaluation: Transfer of Learning to Behaviour

In May 2007, all PACE and RACE team members completed a level 3 training evaluation. The level 3 evaluation measured the extent to which the students applied the learning and changed their behaviours (Kirkpatrick 1994). Participants were asked if they were applying the skills they acquired from the team communication and relationship workshops within their PACE or RACE role. This six-month evaluation consisted of quantitative and qualitative components. Responses were collated and summarized. Response rates were 100% for both the PACE and RACE teams. Participants were asked to respond to 11 items and indicate the level of frequency and effectiveness they have had with each item since participating in the training program. Participants were asked to use a scale to rate the 11 items; the scale ranged from 1 = not at all, to 5 = greatly. Participants asked themselves, "Overall, how much did the team communications workshop improve my performance in the role of PACE/RACE?" Average response rates were 3.9 for the PACE team and 3.7 for the RACE team. Three major themes were identified when participants were asked to complete the following sentence: "As a result of participating in the team communication workshop, I have been able to …":

1. use SBAR effectively. Participants demonstrated an understanding of the importance of using SBAR as a consistent and concise approach for communication between team members and physicians. They indicated that they were applying SBAR during verbal and written communications.
2. improve my communication skills. Participants indicated that they had an increased self-awareness in relation to active listening, body language and tone of voice. They also noted that they had become more assertive and less aggressive with their approach when interacting with others.
3. gain insight into behaviour of self and others. Participants have learned to recognize individual personal styles in themselves and others. They understand these styles, individual preferences and temperament types and the impact that personal style has within the workplace and within teams. Many stated that, as a result, they appreciate others' differences and have

Table 1. Factors of the workshop's foundational framework

Process Factors	Task Factors	People Factors
• The functions and elements of high-performance teams • Complexities and challenges of healthcare teams • Communication principles and effective techniques; e.g., internal and external factors influencing listening, critical language, cycle of assertion, SBAR communication techniques, situational analysis, safety briefings, team debriefing • Conflict resolution and relationship management practices and strategies	• Roles and responsibilities of PACE and RACE team members for the organization, the team and the patient • HHS internal support mechanisms, including human resources, chaplaincy, Ethics Consultation team, human rights specialist, etc. • PACE and RACE situations through role-playing and case study activities	• Understanding of self and others using a personal style inventory, Personality Dimensions – True Colors • Organizational and personal factors influencing psychological safety and conflict • Building trust for effective communication and relationship building • Critical thinking and emotional intelligence to enhance patient safety and individual and team performance

HHS = Hamilton Health Sciences; PACE = pediatric assessment of critical events; RACE = rapid assessment of critical events; SBAR = Situation-Background-Assessment-Recommendation.

been able to adapt appropriate communication styles and improve interpersonal relations.

Satisfaction Survey

To further affirm that communication on the RACE and PACE teams is effective and helps promote the provision of safe and optimum care for patients, a satisfaction survey for end-users (care unit staff) was developed. The results to date for both the RACE and PACE teams specifically related to communication and relationship management have been overwhelmingly positive. Care unit staff reported that the team members are approachable, take the time to answer questions, share their knowledge and communicate clearly regarding next steps and monitoring. It is also clear from these evaluations that care unit staff believe the teams have made a positive contribution to patient care and outcomes. It is important to note, however, that this method of evaluation has some limitations. A full assessment of the intervention would also require a study of the changes in team behaviour in practice, through observation or a case-control design.

Lessons Learned

As a result of this experience, five key lessons were learned that others should consider when designing a workshop to assist with team communications within the healthcare environment. First, it is important to understand the behavioural perspectives that influence team dynamics and the performance levels of the team for patient care (Gordon 2002; Katzenback and Smith 1993; Leonard et al. 2004). Second, the use of case simulations builds an individual's awareness of his or her communication patterns and provides a structured opportunity to practise and obtain feedback. This allows the learner to observe communication from a distance and then safely participate and test more effective ways to talk and behave (Farbstein 2003). Evidence of the benefits of case simulations was displayed throughout the interactive exercises.

The third lesson learned pertained to the challenges when translating lecture material to hands-on simulations. Time and effort need to be taken to do this effectively so that the case studies provide real-life examples for the participants to relate to and learn from. Fourth, one must consider the importance of standardized processes and practices. Since a number of disciplines are critical for the optimal care of patients, there exists a challenge in coordinating and communicating under stress (Small et al. 1999). The employment of standardized tools and behavioural approaches during the workshop can greatly enhance safety within the workplace, for these tools can effectively bridge the differences in communication style and practices between nurses, physicians and others (Leonard et al. 2004), thereby improving the teams' effectiveness.

Finally, we learned that individual performance is not sufficient to achieve optimum safety and good team functioning. There is a need to enhance individuals' and teams' communication skills to establish effective teams and to contribute to safer patient care. Teams need to be provided with the behavioural awareness and skill development necessary for success in addition to procedural and technical skills. Simply identifying gaps in communication and teamwork is not enough – it is essential to address them in a structured approach.

Recommendations, Next Steps and Sustainability

The HHS Organizational Effectiveness team designed and implemented an effective structured action learning approach to address gaps in communication and team-based skills. The workshops were an effective strategy to meet these critical success factors for CCOTs. The care unit satisfaction survey results indicate that team members have consistently demonstrated effective communication and relationship management skills and have been perceived as approachable and friendly. Further work is needed to refine communication practices using the SBAR format for verbal and written communications. A RACE/PACE communication forum has been established to address ways to standardize communication practices including SBAR across all HHS sites.

PACE and RACE team members appreciated the opportunity to share experiences and learn from each other during the combined workshops. Opportunities for ongoing learning and sharing between the two teams will be explored. One idea is to revisit and build on the learning that occurred during the workshops as a regular component of the quarterly educational review process for the teams. Our critical care physician partners were unable to participate in the two-day workshops. However, preliminary discussions are under way to offer a repeat workshop to new team members that will include the PACE and RACE physicians. HQ

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References

Barbazette. 2001. *The Trainer's Support Handbook.* New York, NY: McGraw Hill.

Bellomo, R., D. Goldsmith, S. Uchino, J. Buckmaster, G.K. Hart, H. Opdam, W. Silvester, L. Doolan and G. Gutteridge. 2003. "A Prospective Before-and-After Trial of a Medical Emergency Team." *Medical Journal of Australia* 179: 283–7.

Cranton. 1992. *Working with Adult Learners.* Toronto, ON: Wall & Emmerson, Inc.

Dzik-Juasz. 2006. "Supporting Sustainable Change." *Nursing Management* 13(4): 26–9.

Farbstein, K. 2003. "Role Playing Case Simulations: A Tool to Improve Communication and Enhance Safety." *Joint Commission Journal on Quality and Safety* 29(5): 260–2.

Franklin, C. and J. Matthew. 1994. "Developing Strategies to Prevent In-Hospital Cardiac Arrest: Analyzing Responses of Physicians and Nurses in the Hours before the Event." *Critical Care Medicine* 22(2): 244–7.

Furjanic and Trotman. 2000. *Turning Training into Learning.* New York, NY: AMACOM.

Gordon. 2002. "A Perspective on Team Building." *Journal of the American Academy of Business* 2(1): 185.

Hill. 1996. *Building Effective One-on-one Work Relationships.* Harvard Business School Technical Notes, 9-497-028.

Institute for Healthcare Improvement. 2006. *Rapid Response Teams: Reducing Codes and Raising Morale.* Cambridge, MA: Author. Retrieved September 15, 2006. <http://www.ihi.org>.

Katzenback and Smith. 1993. *The Wisdom of Teams.* New York, NY: Harvard Business School Press.

Kieren and Kalliath. 2005. "Action Learning: Developing a Learning Culture in an Interdisciplinary Rehabilitation Team." *Organizational Development Journal* 23(3): 39–51.

Kirkpatrick. 1994. *Evaluating Training Programs.* San Francisco, CA: Berrett-Koehler Publishers, Inc.

Leonard, Frankel and Simmonds. 2004. *Achieving Safe and Reliable Healthcare.* Chicago: Health Administrative Press.

Mistry, K., J. Turi, R. Hueckel, J. Mericle and J. Meliones. 2006. "Pediatric Rapid Response Teams in the Academic Medical Center." *Clinical Pediatric Emergency Medicine* 7(4): 241–7.

Naeem, N. and H. Montenegro. 2005. "Beyond the Intensive Care Unit: A Review of Interventions Aimed at Anticipating and Preventing In-Hospital Cardiopulmonary Arrest." *Resuscitation* 67(1): 13–23.

Schein, R.M., N. Hazday, M. Pena, B.H. Ruben and C.L. Sprung. 1990. "Clinical Antecedents to In-Hospital Cardiopulmonary Arrest." *Chest* 98: 1388–92.

Small, S., R. Wuerz, R. Simon, N. Shapiro, A. Conn and G. Setnik. 1999. "Demonstration of High-Fidelity Simulation Team Training for Emergency Medicine." *Emergency Medicine* 6(4): 312–23.

Effectiveness of an Adapted SBAR Communication Tool for a Rehabilitation Setting

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Abstract

Effective communication and teamwork have been identified in the literature as key enablers of patient safety. The SBAR (Situation-Background-Assessment-Recommendation) process has proven to be an effective communication tool in acute care settings to structure high-urgency communications, particularly between physicians and nurses; however, little is known of its effectiveness in other settings. This study evaluated the effectiveness of an adapted SBAR tool for both urgent and non-urgent situations within a rehabilitation setting.

In phase 1 of this study, clinical staff, patient and family input was gathered in a focus-group format to help guide, validate and refine adaptations to the SBAR tool. In phase 2, the adapted SBAR was implemented in one interprofessional team; clinical and support staff participated in educational workshops with experiential learning to enhance their proficiency in using the SBAR process. Key champions reinforced its use within the team. In phase 3, evaluation of the effectiveness of the adapted SBAR tool focused on three main areas: staff perceptions of team communication and patient safety culture (as measured by the Agency for Healthcare Research and Quality Hospital Survey on Patient Safety Culture), patient satisfaction (as determined using the Client Perspectives on Rehabilitation Services questionnaire) and safety reporting (including incident and near-miss reporting).

Findings from this study suggest that staff found the use of the adapted SBAR tool helpful in both individual and team communications, which ultimately affected perceived changes in the safety culture of the study team. There was a positive but not significant impact on patient satisfaction, likely due to a ceiling effect. Improvements were also seen in safety reporting of incidents and near misses across the organization and within the study team.

Background

Communication failures have been cited as the leading cause of inadvertent patient harm (Joint Commission on Accreditation of Health Care Organizations 2004; Leape et al. 1995; Sutcliffe et al. 2004; Wilson et al. 1995). Communication failures include issues such as insufficient information, faulty exchanges of existing information, ambiguous and unclear information and lack of timely and effective exchange of pertinent information (Leonard et al. 2004; Sutcliffe et al. 2004) and result from individual, interpersonal and systemic factors. Increasing recognition of these issues has made improving teamwork and communication a priority for advancing patient safety and quality of care (Baker and Norton 2001; Canadian Council of Health Services Accreditation 2004; Health Council of Canada 2005; Joint Commission on Accreditation of Health Care Organizations 2004; Leggat and Dwyer 2005). Effective interaction between team members has been associated with greater efficiency and decreased workloads, improved clinical outcomes, reduced adverse drug events, reduced patient morbidity, improved job satisfaction and retention and improved patient satisfaction (Aiken 2001; Borrill et al. 2000; D'Amour et al. 2005; Gittell et al. 2000; Leape et al. 1999; Shortell et al. 1994; Zwarenstein et al. 2005).

Standardized tools and behaviours from the aviation industry such as SBAR can greatly enhance safety by helping to set expectations for what is communicated and how communication is handled.

Methods and tools from high-reliability industries are potential sources of innovation for healthcare teams (Leonard et al. 2004). Standardized tools and behaviours from the aviation industry such as Situation-Background-Assessment-Recommendation or SBAR (SBAR Technique for Communication: A Situational Briefing Model 2005), appropriate assertion, critical language and situational awareness can greatly enhance safety by helping to set expectations for what is communicated and how communication is handled among team members (Leonard et al. 2004). To date, successful implementation in healthcare of the SBAR technique has been demonstrated in high-risk settings, including perinatal care, operating rooms, intensive care and emergency departments, with improvements seen in staff and patient satisfaction, clinical outcomes, team communication and patient safety culture (Leonard et al. 2004; McFerran et al. 2005; Uhlig et al. 2002).

Most of the work examining healthcare communication and teamwork and associated strategies has focused on acute care settings and nurse-physician relationships (Storch 2005). There has been little focus within the rehabilitation literature on the use of structured communication tools for enhanced teamwork and patient safety. Rehabilitation offers a unique setting, differing from acute care in the types of clinical issues faced, team composition and interaction, the higher involvement of rehabilitation professionals and the greater involvement of patients and family members within a client-centred care model.

Purpose of the Study

This study had three distinct phases: phase 1, adaptation of the SBAR communication tool to the rehabilitation setting; phase 2, implementation of the adapted SBAR tool into an interprofessional rehabilitation team for both urgent and non-urgent safety issues; and phase 3, evaluation of the effectiveness of the adapted SBAR tool related to staff perceptions of team communication and patient safety culture, patient satisfaction and safety reporting. This article focuses on the results of the evaluation phase of this pilot study. More in-depth details and results of phases 1 and 2 will be reported elsewhere (A. Andreoli, personal communication).

Study Design

Phase 1: Adaptation of the SBAR Tool

Input from clinical staff and from former in-patients and family members was gathered in a focus-group format to help guide, validate and refine adaptations to the SBAR tool. As well, clinical scenarios were developed based on examples raised in these focus groups and from previous research work conducted within our institution; these were later used as teaching tools for the adapted SBAR. Experts in the area of communication and patient safety were also consulted regarding changes made to the original tool. (See Appendix 1 for the adapted SBAR tool.)

Phase 2: Implementation of the Adapted SBAR Tool

The implementation phase took place in one clinical unit within a rehabilitation and complex continuing care hospital over a six-month period. The Stroke Rehabilitation Unit was selected as the team had demonstrated ability in the past to successfully implement process and practice innovations. In addition, service delivery in stroke rehabilitation is available nationwide; thus, study results could be transferable to many settings.

All full-time and part-time clinical and support staff (n = 43) and leaders of the Stroke Rehabilitation Unit were offered the opportunity to take part in this demonstration project intervention. A series of three workshops totalling four hours were scheduled for staff members, physicians and leaders and offered at varying times of the day to maximize attendance. The didactic and interactive workshops highlighted a number of topics related to communication, safety and the adapted SBAR tool. The use of real case examples helped to illustrate how SBAR may be implemented and applied within a rehabilitation context.

Phase 3: Evaluation of the Adapted SBAR Tool

A pre-post test design was used for this study. Data collection, outcome measures and analysis are described below for each of the three main outcomes of this project: staff perceptions of team communication and patient safety culture, patient satisfaction and safety reporting.

Staff Perceptions of Team Communication and Patient Safety Culture

Prior to the implementation of the adapted SBAR (T1) and approximately six months following the implementation phase (T2), we administered the Hospital Survey for Patient Safety Culture (Westat 2004). The survey was distributed to all clinical and non-clinical hospital staff (n = 1,520) at T1 and again approximately 12 months later (n = 1,451). There were two waves of distribution at both time points. The survey was first distributed attached to pay stubs for all employees. Four weeks later, managers of all clinical units and departments distributed the survey to staff and encouraged their response. A self-addressed stamped envelope was included in survey packages, and respondents were assured anonymity.

The Hospital Survey on Patient Safety Culture (Westat 2004) was developed with the support of the Agency for Healthcare Research and Quality (AHRQ) in the United States (http://www.ahrq.gov/qual/hospculture/). The 42-item survey uses a five-point Likert scale to assess safety culture facility-wide or for specific units; 18 questions are reverse worded and coded accordingly. The survey can also be used to track changes in patient safety over time and to evaluate the impact of patient safety interventions. It is intended for all types of hospital staff, ranging from housekeeping and security to nurses and physicians. This survey has been widely used in American hospitals and has been found to be reliable and valid (Westat 2004). It covers 12 unit-specific and hospital-wide patient safety domains, including those specific to communication and teamwork.

Survey data were analyzed to compare staff members' perceptions across time, both within the study unit and across the hospital. The survey developers suggest using a 5% difference as a rule of thumb when comparing results; that is, results must be at least 5% higher to be considered "better" or at least 5% lower to be considered "worse." This rule of thumb was suggested in regard to comparing hospital results to the benchmark, which is the average of results from 382 American hospitals. The authors assume that a 5% difference is likely to be statistically significant for most hospitals, given the number of responses per hospital (i.e., several hundred responses), and is thus a meaningful difference to consider (Westat 2004). As well, using SPSS software, we conducted critical ratio tests to compare the pre-post Stroke Rehabilitation Unit responses as well as the responses from the Stroke Unit versus those from staff in the rest of the hospital at T1 and T2. Unpaired t-tests were also conducted to compare Stroke Unit data at T1 and T2.

Patient Satisfaction

We used two cross-sectional cohorts of patients: those patients who were discharged from the Stroke Rehabilitation Unit six months prior to the implementation phase and those who were discharged six months following the implementation of the adapted SBAR tool. Upon discharge from our facility, all patients are sent the Client Perspectives of Rehabilitation Services (CPRS) questionnaire. Patient responses are sent directly to an external survey firm that houses all CPRS (and other) data provincially. Through our quality and performance measurement team, we obtained the data for the Stroke Rehabilitation Unit for the six months prior to the implementation phase. Due to system difficulties, data for patient satisfaction could only be obtained for four months following the implementation phase (rather than six months).

The CPRS contains seven domains that measure client-centred care from the clients' perspective using a five-point Likert scale (Cott et al. 2003, February 20). The tool has been found to be valid and reliable in rehabilitation populations (Cott et al. 2003, February 20) and is sent to all clients discharged from designated rehabilitation beds in Ontario. Results are reported in *Hospital Report: Rehabilitation* published by the Ontario Ministry of Health and Long-Term Care. We anticipated that several domains would be positively impacted by improved team communication: client participation in decision-making, education from the clients' perspective, family involvement, emotional support and coordination and continuity of care. We compared responses from the two cohorts, analyzing percentages of respondents who answered the two highest ratings ("excellent" and "very good").

Safety Reporting

Incidents and near-miss reporting are tracked on a quarterly basis through the risk manager. Currently, we use an on-line reporting system that captures both incidents and near-miss situations. From our quality and performance measurement team, we obtained the incident and near-miss reports for the six months prior to the implementation of the adapted SBAR and for the six months following the end of the implementation period. We anticipated that with improved team communication and patient safety culture, staff on the Stroke Rehabilitation Unit would feel encouraged to report safety issues in an open and comfortable environment. As a result, we predicted that reporting of incidents and near misses would increase following the implementation phase of the study.

Results

Results of the evaluation phase are described below.

Staff Perceptions of Team Communication and Patient Safety Culture

Overall Response Rates and Demographics

There were 415 usable surveys returned in T1, for a response rate of 27% – 32 were from the Stroke Unit, for a study team response rate of 74% (32/43). In T2, 319 surveys were returned hospital-wide (response rate = 22%). The Stroke Unit had a response rate of 62% (27/43). Of the respondents in T1, 86% were clinical staff hospital-wide; in T2, 87% were clinical staff. In both T1 and T2, the majority of clinical staff included nurses (36% and 33%), physicians (3% and 6%) and other healthcare providers (36% and 37%).

Stroke Unit: Results Pre- and Post-implementation

From T1 to T2, the Stroke Unit showed improvement of >5% (as per the 5% rule of thumb) in eight dimensions: overall perceptions of safety, frequency of events reported, organizational learning–continuous improvement, teamwork within units, feedback and communication about error, staffing, hospital management support for patient safety and teamwork across hospital units. However, when analyzed using critical ratio tests, no dimensions were found to be statistically significant. As the percentage difference for a number of dimensions exceeded 10%, we decided to continue statistical analysis with unpaired t-tests; five dimensions were found to be statistically significant ($p < .05$) (organizational learning–continuous improvement, communication openness, feedback and communication about error, staffing and hospital management support for patient safety). See Table 1 for details.

Stroke Unit versus Rest of Hospital: Results Pre- and Post-implementation

Using the 5% rule of thumb, prior to the intervention, the Stroke Unit scored higher than the rest of the hospital in three of the 12 dimensions (organizational learning–continuous improvement, feedback and communication about error and staffing) and lower than the rest of the hospital in five dimensions (overall perceptions of safety, frequency of events reported, teamwork within units, teamwork across hospital units and hospital handoffs and transitions). Following the implementation phase, the Stroke Unit made significant gains and scored higher (>5%) than the rest of the hospital in seven dimensions; however, only two of these dimensions showed statistical significance using the critical ratio test (organizational learning–continuous improvement and feedback and communication about error) (Table 2).

Table 1. Stroke Rehabilitation Unit: comparison of results pre- and post-intervention

Dimension	Pre-intervention (%)	Post-intervention (%)	Difference (%)	Critical Ratio Test $z > 1.96$	t-Test $p < .05$
Overall perceptions of safety	50	60	10	1.312	.22
Frequency of events reported	44	55	11	1.100	.08
Supervisor/manager expectations and actions promoting patient safety	67	69	2	0.151	.28
Organizational learning–continuous improvement	72	85	13	1.680	.03
Teamwork within units	69	77	8	1.131	.08
Communication openness	56	60	4	0.316	.04
Feedback and communication about error	57	71	15	1.688	.00
Non-punitive response to error	39	40	0	–0.126	.24
Staffing	53	61	7	0.899	.05
Hospital management support for patient safety	67	78	11	1.323	.02
Teamwork across hospital units	48	56	8	0.920	.26
Hospital handoffs and transitions	38	40	2	0.087	.39

Legend:

Significantly better | No difference | Significantly worse

Table 2. Stroke Unit versus rest of hospital: comparison of results pre- and post-intervention

	Pre-intervention				Post-intervention			
Dimension	**Stroke Unit (%)**	**Rest of Hospital (%)**	**Difference (%)**	**Critical Ratio Test z > 1.96**	**Stroke Unit (%)**	**Rest of Hospital (%)**	**Difference (%)**	**Critical Ratio Test z > 1.96**
Overall perceptions of safety	50	56	–6	0.832	60	55	5	0.730
Frequency of events reported	44	53	–9	1.462	55	50	5	0.557
Supervisor/manager expectations and actions promoting patient safety	67	68	–1	0.117	69	71	–2	0.269
Organizational learning–continuous improvement	72	65	7	1.033	85	68	17	2.610
Teamwork within units	69	74	–5	1.038	77	76	1	0.210
Communication openness	56	52	4	0.557	60	53	7	0.921
Feedback and communication about error	57	51	6	1.227	71	50	21	3.088
Non-punitive response to error	39	40	–1	–0.092	40	44	–4	0.472
Staffing	53	48	5	0.159	61	51	10	1.051
Hospital management support for patient safety	67	65	2	0.194	78	70	8	1.104
Teamwork across hospital units	48	56	–8	2.332	56	57	–1	0.200
Hospital handoffs and transitions	38	43	–5	2.054	40	43	–3	0.408

Legend:

Significantly better | No difference | Significantly worse

Patient Satisfaction

Preliminary analysis of this data shows marginal improvement within the study team in overall quality of care and in two of the seven domains of patient satisfaction when comparing cohorts six months prior to the implementation of the adapted SBAR communication tool (n = 42) and four months following its implementation (n = 24) (Figure 1).

Safety Reporting

Figure 2 shows safety reporting levels for incidents over the 18-month study period. There are trends to increasing incident reporting across both the organization and within the study unit, and to an increase in near-miss reporting across the organization. However, the overall numbers are quite small, particularly for the study team.

Discussion

Results from this pilot study appear promising, particularly within the study team's perceptions of team communication and patient safety culture. The SBAR tool was used primarily between professional staff and occasionally with team physicians to discuss changes in the patient care plan, discharge planning and specific safety issues, both urgent (e.g., changes in status) and non-urgent (e.g., team debriefing following a challenging admission). The most statistically significant changes seen in the communication domains (e.g., teamwork within units, feedback and communication about error) have been a result of how the tool was used within the study team. Being the selected team for the pilot study may have positively influenced domains related to organization learning–continuous improvement and hospital management support for patient safety by reinforcing the perception of organizational support for ongoing professional learning.

Figure 1. Patient satisfaction results pre- and post-implementation for Stroke Rehabilitation Unit

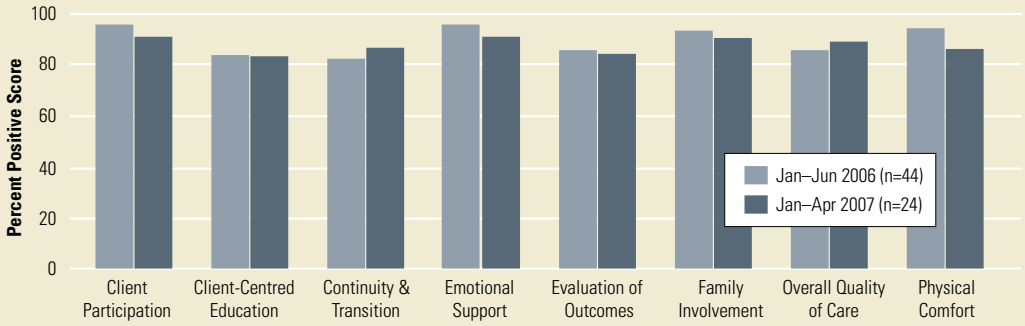
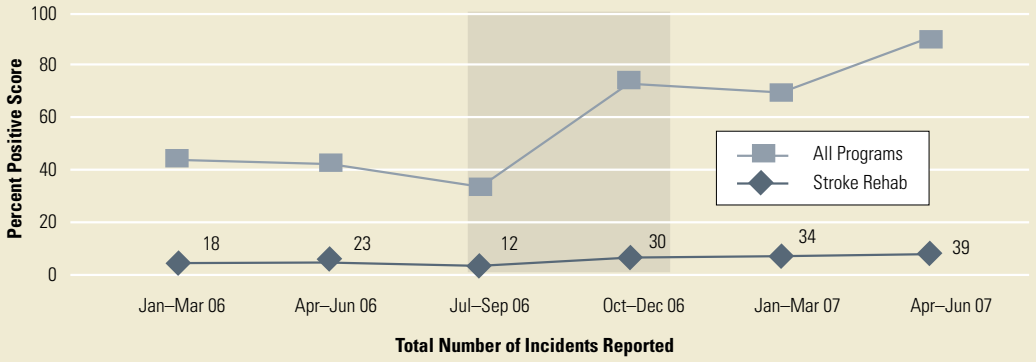


Figure 2. Total number of incidents reported



Post-intervention, the Stroke Rehabilitation Team showed improvement over the rest of the hospital in seven dimensions. Two of these dimensions showed a statistically significant improvement – organizational learning–continuous improvement and feedback about communication and error. Again, this indicates the perceived improvement of ongoing learning and staff perceptions that the SBAR tool enhanced the pilot team's communication, particularly related to discussions of error and safety concerns.

Study Limitations

Although the use of the survey developers' suggested 5% rule revealed encouraging results, these must be interpreted with caution as the rule was meant to be used with larger sample sizes. The small sample size of the study team, in particular, was a limitation in this demonstration project that affected the statistical power to detect differences when examining the AHRQ culture survey scores. While the Stroke Team did appear to make some positive changes in the overall quality of care for patient satisfaction and also within two of seven domains of the CPRS (continuity and transition, emotional support), the percent change is small and not significant as the sample size was too small to elicit any power. As well, the pre-implementation scores of the Stroke Team were already high in most domains, indicating that there may have been a ceiling effect.

The measurement of safety reporting in this project showed itself to be a proxy measure only. While there was an increased trend in reporting of incidents and near misses, again, the numbers during the study period are quite small and are not significant. As well, any increases cannot be attributed specifically to the implementation of this one pilot project but, rather, to part of an overall series of initiatives aimed at changing safety culture across the organization as a whole. For example, new initiatives such as Safety Walkabouts with the senior leadership team, leader engagement and training related to safety culture, safety communications from the chief executive officer and staff training regarding the online reporting system have all increased awareness of safety within our hospital and the need to report near misses and incidents. These hospital-wide initiatives may also have positively affected the domain related to hospital management support for safety in the AHRQ culture survey, both across the organization and within the study team (which showed the greatest change).

The most statistically significant changes seen in the communication domains have been a result of how the tool was used within the study team.

Future Research Directions

We recommend broadening the use of the adapted SBAR tool across our organization and into other rehabilitation and complex continuing care centres to allow for a more robust evaluation beyond the limits of this pilot study. There may be great

value in targeting the use of the adapted SBAR to specific safety situations that are known to occur within rehabilitation facilities (e.g., falls interventions) to allow further uptake in defined situations across all teams. With a targeted use of the SBAR, the evaluation of its effectiveness may also be more specific and show more change across other domains (e.g., teamwork across teams and handoffs and transitions). We also need to consider how an adapted SBAR tool may be used to engage patients and family members to help structure their own safety concerns. As well, further consideration needs to be given as to how best to measure and evaluate the effectiveness of such a tool.

Conclusion

The effectiveness of the adapted SBAR communication tool has shown early promise in improving the patient safety culture within the pilot study unit. This study has expanded the use of the SBAR tool from its original purpose of physician-nurse communications in high-urgency situations to be used in a myriad of healthcare situations between a variety of team members. The expansion of the use of the SBAR tool beyond its acute care roots has the potential to enhance interprofessional team communication in a rehabilitation context and is a valuable contribution to safety research and practice. HQ

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References

Aiken, L.H. 2001. "Evidence-Based Management: Key to Hospital Workforce Stability." *Journal of Health Administration Education Special Issue*: 117–25.

Baker, G.R. and P. Norton. 2001. "Making Patients Safer! Reducing Error in Canadian Healthcare." *Healthcare Papers* 2(1): 10–31.

Borrill, C., M.A. West, D. Shapiro and A. Rees. 2000. "Team Working and Effectiveness in Health Care." *British Journal of Health Care* 6(8): 364–71.

Canadian Council of Health Services Accreditation. 2004. *Patient Safety Goals and Required Organizational Practices* (Communique No. 2). Ottawa: Author. Retrieved July 14, 2005. <http://www.cchsa-ccass.ca/pdf/PSCommunique2.pdf>.

Cott, C.A., G. Teare, K. McGilton, S. Lineker and G. Ibram. 2003, February 20. *The Client-Centred Rehabilitation Questionnaire: Development and Pilot Testing*. Presented at GTA Rehab Best Practice Day.

D'Amour, D., M. Ferrada-Videla, L. San Martin-Rodrigues and M.D. Beaulieu. 2005. "The Conceptual Basis for Interprofessional Collaboration: Core Concepts and Theoretical Frameworks." *Journal of Interprofessional Care* 19(Suppl. 1): 116–31.

Gittell, J.H., K.M. Fairfield, B. Bierbaum, W. Head, R. Jackson, M. Kelly, R. Laskin, S. Lipson, J. Siliski, T. Thornhill, J. Zuckerman. 2000. "Impact of Relational Coordinator on Quality of Care, Postoperative Pain and Functioning, and Length of Stay: A Nine-Hospital Study of Surgical Patients." *Medical Care* 28(8): 807–19.

Health Council of Canada. 2005. *Health Care Renewal in Canada: Accelerating Change*. Toronto, ON: Author.

Joint Commission on Accreditation of Health Care Organizations. 2004. *Root Causes of Sentinel Event*s, *1995–2004*. Oakbrook Terrace, IL: Author. Retrieved July 14, 2005. <http://www.jcaho.org/accredited+organizations/ambulatory+care/sentinel+events/root+causes+of+sentinel+event.htm>.

Leape, L.L., D.W. Bates, D.J. Cullen, J. Cooper, H.J. Demonaco, T. Gallivan, R. Hallisey, J. Ives, N. Laird, G. Laffel et al. 1995. "Systems Analysis of Adverse Drug Events. ADE Prevention Study Group." *Journal of the American Medical Association* 274(1): 35–43.

Leape, L.L., D.J. Cullen, M.D. Clapp, E. Burdick, H.J. Demonaco, J.I. Erickson and D.W. Bates. 1999. "Pharmacist Participation on Physician Rounds and Adverse Drug Events in the Intensive Care Unit." *Journal of the American Medical Association* 283(3): 267–70.

Leggat, S. and J. Dwyer. 2005. "Improving Hospital Performance: Culture Change Is Not the Answer." *Healthcare Quarterly* 9(2): 60–5.

Leonard, M., S. Graham and D. Bonacum. 2004. "The Human Factor: The Critical Importance of Effective Teamwork and Communication in Providing Safe Care." *Quality and Safety in Health Care* 13: 85–90.

McFerran, S., J. Nunes, D. Pucci and A. Zuniga. 2005. "Perinatal Patient Safety Project: A Multicenter Approach to Improve Performance Reliability at Kaiser Permanente." *Journal of Perinatal and Neonatal Nursing* 19(1): 37–45.

Ontario Ministry of Health and Long-Term Care. 2007. *Hospital Reports 2001–2007*. Toronto: Author. Retrieved January 9, 2008. <http://www.hospitalreport.ca/downloads/year.html>.

SBAR Technique for Communication: A Situational Briefing Model. 2005. Cambridge, MA: Institute for Healthcare Improvement. Retrieved July 7, 2005. <http://www.ihi.org/IHI/Topics/PatientSafety/SafetyGeneral/Tools/SBARTechniqueforCommunicationASituationalBriefingModel.htm>.

Shortell, S.M., J.E. Zimmerman, D.M. Rousseau, R.R. Gillies, D.P. Wagner, E.A. Draper, W.A. Knaus and J. Duffy. 1994. "The Performance of Intensive Care Units: Does Good Management Make a Difference?" *Medical Care* 32(5): 508–25.

Storch, J.L. 2005. "Patient Safety: Is It Just Another Bandwagon?" *Nursing Leadership* 18(2): 39–55.

Sutcliffe, K.M., E. Lewton and M.M. Rosenthal. 2004. "Communication Failures: An Insidious Contributor to Medical Mishaps." *Academic Medicine* 79(2): 186–94.

Uhlig, P.N. et al. 2002. "Reconfiguring Clinical Teamwork for Safety and Effectiveness." *Focus on Patient Safety* 5(3): 1–2.

Westat, R. 2004. *Hospital Survey on Patient Safety Culture* (AHRQ Publication No. 04-0041). Rockville, MD: Agency for Healthcare Research and Quality. Retrieved July 14, 2005. <http://www.ahrq.gov/qual/hospculture/>.

Wilson, R.M., W.B. Runciman, R.W. Gibberd, B.T. Harrison and J.D. Hamilton. 1995. "Quality in Australian Health Care Study." *Medical Journal of Australia* 63: 458–71.

Zwarenstein, M., S. Reeves and L. Perrier. 2005. "Effectiveness of Pre-licensure Interprofessional Education and Post-licensure Collaborative Intervention." *Journal of Interprofessional Care* 19(Suppl. 1): 148–65.

Appendix 1. Adapted SBAR tool

<table>
<tr><td>S</td><td colspan="2">Situation
My name is_____. I work on the _____service.
☐ I need to talk to you about an urgent safety issue regarding (name of client).
☐ I need to talk to you about a quality of care issue regarding (name of client).
☐ I need about … minutes to talk to you; if not now, when can we talk?
I need you to know about:
☐ changes to a patient status
☐ changes to treatment plan, procedures or protocols
☐ environmental/organizational issues related to patient care</td></tr>
<tr><td>B</td><td colspan="2">Background (as related to the specific situation only)
What background information do you need? Are you aware of…?
The patient is … years old and has a primary diagnosis of … as well as … She/He was admitted on … and is scheduled for discharge on … His/Her treatment plans related to this issue to date include … She/He is being monitored by … (specialist) … and has appointments for…(procedures) …
This patient/family/staff are requesting that …</td></tr>
<tr><td rowspan="2">A</td><td colspan="2">Assessment
I think the key underlying problem/concern is …
The key changes since the last assessment related to the specific concern are:</td></tr>
<tr><td>Person Level Changes
☐ Vital signs/GI/cardio/respiratory
☐ Neurological
☐ Musculoskeletal/skin
☐ Pain
☐ Medications
☐ Psychosocial/spiritual
☐ Sleep
☐ Cognitive/mental status/behavioural
☐ Nutrition/hydration</td><td>Activity/Participation/Functional Changes
☐ ADLs
☐ Transfers
☐ Home/community safety

Environmental Changes
☐ Organizational/unit protocols/processes
☐ Discharge destination
☐ Social/family supports</td></tr>
<tr><td>R</td><td>Recommendations
Based on this assessment, I request that:
☐ we discontinue/continue with …
☐ we prepare for discharge or extend discharge date
☐ you approve recommended changes to treatment plan/goals including …
☐ you reassess the patient's …
☐ the following tests/assessments be completed by ...
☐ the patient be transferred out to … /be moved to …
☐ you inform other team members/family/patients about change in plans
☐ I recommend that we modify team protocols in the following ways …</td><td>To be clear, we have agreed to … Are you OK with this plan?
☐ I would like to hear back from you by …
☐ I will be in contact with you about this issue by …</td></tr>
</table>

Communities of Practice: Creating Opportunities to Enhance Quality of Care and Safe Practices

Debbie White, Esther Suter, I. John Parboosingh and Elizabeth Taylor

Abstract

A Communities of Practice (CoPs) approach was used to enhance interprofessional practice in seven clinical sites across Alberta. Participating staff were free to decide the area of practice to focus on and the actions to be implemented. All practice changes implemented by the CoPs related to either improving communications (e.g., introduction of joint care meetings) or information transfer (e.g., streamlining of admission and discharge processes). The practice changes contributed to more effective communication of information and more effective transitions of patients between providers, hence potentially reducing errors.

The present study demonstrates that CoPs can enhance interprofessional communication and patient safety in traditional care delivery units. In contrast to more structured safety initiatives, sites were able to choose their area of focus. This ensures buy-in and enhances sustainability, making CoPs an interesting option for patient safety initiatives.

Team learning, practitioner competencies, a shared vision and system thinking are elements critical to patient safety (Dekker 2006; Sheps 2006). Furthermore, creating safe places for discussing errors and latent conditions for patient harm are vital to advancing a culture of safety (Morath and Leary 2004). Communication that reduces risk and improves safety in patient care focuses on the ability to share near misses or "no harm" events that caregivers experience at work and the structures and processes that influence these events. High trust levels between professionals are required for successful communication of "dare to share" issues. This type of trust needs to be developed over time.

A number of mechanisms have emerged that help create safe collaborative environments that provide opportunities for health providers to exchange information and discuss experiences. The benefits of safety teams in reducing errors and improving quality of care have been recognized in a number of studies (Boddington et al. 2006; Firth-Cozens 2001; West 2001). (Although safety teams and safety action teams are similar, safety teams in patient literature are seen as broader collaboratives than those teams defined as safety action teams. Here, we refer only to safety teams.) Clinical microsystems (Barach and Johnson 2006)

transcend disciplinary boundaries, providing an opportunity to impact both micro and system-wide improvements in patient safety and quality care. Because of their inter-professional focus, they provide a conceptual and practical mechanism to understand the core processes of care and influence redesign of care (i.e., facilitate effective transitions for patients).

Communities of practice (CoPs) are frequently discussed in the context of knowledge management (Hildreth and Kimble 2004; Hindmarsh and Pilnick 2002; O'Hara and Brown 2001; Seidler-de Alwis and Hartman 2004) and are characterized by shared learning and teaching, collegial relationships, non-hierarchical structures and commitment to change. CoPs are not unlike safety teams (Morath and Leary 2004) and provide a structure and collaborative culture where improvements in patient safety and quality can occur (Firth-Cozens 2001). CoPs have been employed in the business world to connect stakeholders across departments and improve information sharing (e.g., St. Onge and Wallace 2003). However, they have not been extensively explored in the healthcare context. The present project, funded through Health Canada's Interprofessional Education for Collaborative Patient-Centred Practice initiative, used a CoP approach to enhance inter-professional practice in clinical sites.

Methods

Seven healthcare sites across three large healthcare regions in Alberta were approached for participation in the project. The sites were purposefully chosen to represent a range of services provided, populations served, size and geographical locations to provide a rich context for the study. The sites were approached through the site managers; presentations to site staff were held to explain the project, expectations and timelines and to answer questions. The following sites participated: a geriatric psychiatry ward, a rural in-patient rehabilitation unit, a geriatric day centre, a geriatric day centre with 24/7 care, a management team for outreach services, an acute care unit and acute and community care departments in a rural hospital.

Staff at participating sites were asked to focus on collaboration across health professions (i.e., inter-professional practice) using a CoP approach. Essential to CoPs are three elements: (1) the community, which consists of a self-motivated and voluntary group of people who find innovative and dynamic ways to generate knowledge (including tacit knowledge), (2) the domain, or area of interest that creates a sense of identity and cohesiveness for the community or group and (3) the practice, which is the common knowledge (including tools, protocols, etc.) that the community or group develops to work together effectively (Wenger 1998; Wenger et al. 2002). The area of practice to focus on and the actions that were implemented to improve practice were at the discretion of participating staff. At each site, CoP members from different health professions met face to face to discuss their current practice and to identify areas for improvement. During those meetings, the CoP members also jointly decided what kind of practice changes they wanted to design and who would be responsible for implementing them. Each site had a project facilitator assigned who worked with site members over a period of six months to support CoP development and the implementation of inter-professional practice.

Data Collection and Analysis

After three and six months, semi-structured interviews were conducted with CoP members at the different sites to examine how the project was progressing and how it impacted individual learning, professional practice, team functioning and organizational climate. In addition, the evaluation monitored how the inter-professional CoPs were created, including the successes and challenges. Facilitators assisted with the recruitment of interview participants. If not all CoP members were available for interviews, facilitators ensured that a representative sample of individuals at each site (i.e., both core and peripheral CoP members from as many disciplines as possible) were interviewed. Interviews were taped using digital recorders and transcribed. Interviews lasted approximately 60 minutes. Informed consent was provided.

Transcribed interview data were stored and managed using QSR N6 computer software. Interview transcripts were coded for themes; themes across participants and CoPs were then identified and categorized by one researcher and verified by additional researchers. Differences in interpretation were discussed and reconciled.

Results

A total of 74 health professionals from the seven participating sites (40 at the midpoint, 34 at the end of the six months) were interviewed. Practice changes and main challenges are discussed here.

An example of a change to improve communication was the introduction of the purple pen.

Practice Changes

Across all sites, practice changes implemented by the CoPs could be categorized as improving either communications or information transfer. A number of the CoPs instituted joint meetings as a way of improving communication. Depending on the site, these joint meetings were organized between nursing and other staff, between acute care and rehabilitation teams or between two sets of program staff that were physically located at different centres. An example of a change to improve communi-

cation was the introduction of the purple pen – physiotherapy staff used the purple pen to leave notes on the white board to alert other providers to their care concerns. According to a staff nurse, this made a significant difference to communication and the continuity of patient care:

> "On the white report board, physio uses purple. So that's their concerns for that patient; then it's integrated into the care we give during that day or there may be something that says what to do over the weekend. So that doesn't fall behind with the progress the patient is making with them. So it's been good for communication that way."

Other changes implemented by CoPs included clarification with relevant providers around the services the program offers and identification of anticipated outcomes:

> "The other thing that happened was group meetings with others around [clinical applications and treatments] that were causing confusion, miscommunication and just clarifying when those programs will be done, when they will not be done; that type of thing. So that is something that has changed and I think is working well."

This clarification was required as many of the treatments this clinic provides are time sensitive with respect to subsequent rehabilitation interventions. Prior to the project, these time-sensitive windows were missed due to misunderstandings or lack of communication, leading to suboptimal patient care.

Many of these communication changes emerged because CoP members realized how important clear communication is to an inter-professional team, including communication around the roles and responsibilities of different professional groups. Improvements to communication processes, internally or externally, created a greater sense of being informed. Staff also felt that the changed communication processes improved the relationships between staff members and led to greater team cohesion.

Streamlining admissions and discharge processes to improve information flow and continuity was another common practice change implemented by the CoPs. This was achieved by consolidating patient intake forms from different health professionals to avoid duplications and eliminate out-of-date and unnecessary documentation, by developing a discharge form or by designating an intake person to reduce the initial involvement of multiple professionals in admissions:

> "The process already is working better. Having [professional's name] as our triage person instead of front-loading every professional with an admission has been really beneficial."

There were a number of positive results for both patients and providers as a result of the CoPs. For staff involved, the CoPs provided increased opportunities to prioritize, examine client issues and engage in shared decisions. As a result, staff reported that they felt more connected as a team and enjoyed better working relationships. Participants commented on the impact of these practice changes on patient care, such as reduced assessment times, reduced burden for patients by minimizing "front-loading" and eliminating repetition of admission questions, and greater patient care continuity.

Main Challenges for the Clinical Sites

Initially, some sites found it difficult to grasp the CoP concept and to find a domain or focus to work on. This resulted in a slow start for many of the sites and the need for the facilitators to carefully explore the concepts with site participants within the unique context of each site. Once staff were able to more fully understand the nature of CoPs and how to use them to enhance inter-professional practice, CoP development progressed more smoothly and practice changes rapidly emerged.

Various time and environmental constraints were also discussed. These included finding staff time and space for meetings as well as difficulty implementing the changes. It was difficult for sites to identify local champions or leaders to move the project forward; this was perhaps not unrelated to time constraints. The support from the facilitators was widely appreciated, as was the flexibility of the CoP participatory approach. Each site had the opportunity to tailor the project to their individual site needs and to seek assistance as needed from the facilitator to improve their project experience. In addition to the flexible approach, sites reported that the opportunity for reflection on existing processes and the provision of "permission" to explore were beneficial. The importance of organizational support was also emphasized.

Discussion

When presented with the challenge to improve inter-professional practice, each of the seven participating sites determined that changes in the style and type of communication were the primary focus for practice change. Although CoPs during their exploratory stage discussed many different options for practice improvement, there seemed to be a general recognition that clear, effective communication is an essential prerequisite for successful collaboration. CoP members were skilled in identifying information and communication gaps or redundancies and in finding creative solutions to improving communication flow, such as the purple pen. CoPs have helped create more opportunities for staff to talk about their work, exchange information, listen respectfully and build relationships while engaged in shared decision-making.

Significant gains in quality of patient care can be achieved by

enhancing communication processes. Although no patient outcomes were captured in this study, the practice changes implemented contributed to more effective communication of information – hence, there was a potential reduction in errors. Streamlining admission and discharge processes led to perceptions of more effective transitions of patients between providers and across various practice settings and facilitated appropriate monitoring and surveillance of the patient, further reducing the potential for failure-to-rescue events.

CoPs have not been extensively used in healthcare primarily due to the lack of understanding of the concept. This project demonstrated that the use of CoPs can be an effective approach to initiate discussions among health providers and explore opportunities for practice change. In contrast to more rigorous and prescribed communication and practice interventions, the CoP approach has multiple benefits; it is a self-directed and flexible approach that can be adapted to various contexts. CoP members consist of all levels of staff, who jointly decide what is important and what adds value to their practice. This creates a sense of ownership and buy-in. Given the time pressures and initiative burnout experienced in some healthcare settings, staff buy-in is essential for the success of an intervention.

Organizational change literature stresses the importance of including front-line professionals, patients and senior leaders for successful organizational change (Alton et al. 2006; Odwazny et al. 2005). Furthermore, the need for dedicated structures and multiple tactics to support sustainable change and share organizational learnings has been highlighted (Dixon and Schofer 2006; Woodward 2006). The CoP approach is flexible enough to allow for ongoing modifications and adaptations as needed. Mature CoPs have also demonstrated that significant culture change can be effected. While this project's duration was too short to show pronounced culture changes, indications of emerging shifts were evident through staff perceptions of improved working relationships and team cohesiveness.

CoPs might be one vehicle for creating new mechanisms for staff to relate to each other, sharing tacit knowledge and contributing to organizational learning (Gherardi and Nicolini 2000). In addition to sharing problems and creating solutions, exchanging emotions, values and meaning are important components of communication of both CoPs and safety teams. For example, story telling has been shown to be an effective way of communicating and building trust (Clandinin and Connelly 2000; Denning 2006) as well as to share tacit knowledge and practical wisdom about how to work not only as individuals but within an interprofessional context (Czarniawska 2007). Healthcare leaders have to see the value of relationships in enhancing patient safety and be prepared to invest in CoPs. CoPs are similar to patient safety collaboratives in that, when supported and resourced by the organization, they provide excellent opportunities for health professionals to develop and implement care processes and structures that enhance both quality and safety (Leape et al. 2006). "Effective communication [among a CoP or safety team] is a critical factor in ensuring the delivery of effective health services and avoiding error and adverse events" (Lingard et al. 2006).

The present study has provided insight on the usefulness of CoPs and their potential for enhancing inter-professional communication and patient safety in traditional care delivery units. In contrast to other more structured safety initiatives, in

CoPs sites were able to choose their area of focus, ensuring buy-in and enhancing sustainability, which makes CoPs an interesting option for patient safety initiatives. HQ

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Bibliography

Alton, M., J. Mericle and D. Brandon. 2006. "One Intensive Care Nursery's Experience with Enhancing Patient Safety." *Advances in Neonatal Care* 6(3): 112–9.

Barach, P. and J. Johnson. 2006. "Understanding the Complexity of Redesigning Care around the Clinical Microsystem." *Quality and Safety in Health Care* 15(Suppl.): 10–16.

Boddington, R., H. Arthur, D. Cummings, S. Mellor and D. Salter. 2006. "Team Resource Management and Patient Safety: A Team Focused Approach to Clinical Governance." *Clinical Governance: An International Journal* 11(1): 58–68.

Clandinin, D.J. and F.M. Connelly. 2000. *Narrative Inquiry: Experience and Story in Qualitative Research*. San Francisco: Jossey-Bass.

Czarniawska, B. 2007. "Narrative Inquiry in and about Organizations." In D.J. Clandinin, ed., *Handbook of Narrative Inquiry Mapping as a Methodology.* London: Sage.

Dekker, S.W.A. 2006. "Resilience Engineering: Chronicling the Emergence of Confused Consensus." In E. Hollnagel, D. Woods and N. Levenson, eds., *Resilience Engineering: Concepts and Precepts.* Aldershot, United Kingdom: Ashgate Publishing.

Denning, S. 2006. "Effective Storytelling: Strategic Business Narrative Techniques." *Strategy and Leadership* 34(1): 42–8.

Dixon, N. and M. Schofer. 2006. "Struggling to Invent High-Reliability Organizations in Health Care Settings: Insights from the Field." *Health Services Research* 41(4): 1618–32.

Firth-Cozens, J. 2001. "Cultures for Improving Patient Safety through Learning: The Role of Teamwork." *Quality in Health Care* 10(Suppl. 2): 26–31.

Gherardi, S. and D. Nicolini. 2000. "The Organizational Learning of Safety in Communities of Practice." *Journal of Management Inquiry* 9: 7–18.

Hildreth, P. and C. Kimble. 2004. *Knowledge Networks: Innovation through Communities of Practice.* London: Idea Group Publishing.

Hindmarsh, J. and A. Pilnick. 2002. "The Tacit Order of Teamwork: Collaboration and Embodied Conduct in Anesthesia." *The Sociological Quarterly* 43: 139–64.

Leape, L., G. Rogers, D. Hanna, P. Griswold, F. Federico, C. Fenn, D. Bates, L. Kirle and B. Claridge. 2006. "Developing and Implementing New Safe Practices: Voluntary Adoption through Statewide Collaboratives." *Quality and Safety in Health Care* 15: 289–95.

Lingard, L., G. Regehr, S. Espin and S. Whyte. 2006. "A Theory Based Instrument to Evaluate Team Communication in the Operating Room: Balancing Measurement Authenticity and Reliability." *Quality and Safety in Health Care* 15: 422–6.

Morath, J. and M. Leary. 2004. "Creating Safe Spaces in Organizations to Talk about Safety." *Nursing Economics* 22(6): 344–54.

Nieva, V.F. and J. Sorra. 2003. "Safety Culture Assessment; a tool for improving patient safety in healthcare organizations." *Quality and Safety in Health Care* 12: 17–23.

Odwazny, R., S. Hasler, R. Abrams and R. McNutt. 2005. "Organizational and Cultural Changes for Providing Safe Patient Care." *Quality Management Health Care* 14(3): 132–43.

O'Hara, K. and B. Brown. 2001. *Designing CSCW Technologies to Support Tacit Knowledge Sharing through Conversation Initiation.* Bonn, Germany: ECSCW. Retrieved April 16, 2007. <http://www.hpl.hp.com/personal/Kenton_Ohara/papers/tacitkw_ECSCW.pdf>.

Seidler-de Alwis, R. and E. Hartman. 2004. "The Role of Tacit Knowledge in Innovation Management." In B. Bekavac, J. Herget and M. Rittberger, eds., *Information Zwischen Kultur und Marktwirtschaft.* Chur, Switzerland: Proceedings ISI.

Sheps, S. 2006. "Reflections on Safety and Interprofessional Care: Some Conceptual Approaches." *Journal of Interprofessional Care* 20(5): 545–8.

St. Onge, H. and D. Wallace. 2003. *Leveraging Communities of Practice for Strategic Advantage*. Burlington, MA: Butterworth-Heinemann.

Wenger, E. 1998. C*ommunities of Practice: Learning, Meaning and Identity.* Cambridge, UK: Cambridge University Press.

Wenger, E., R. McDermott and W. Snyder. 2002. *Cultivating Communities of Practice: A Guide to Managing Knowledge.* Boston: Harvard Business School Press.

West, E. 2001. "Management Matters: The Link between Hospital Organization and Quality of Patient Care." *Quality and Safety in Health Care* 10: 40–8.

Woodward, S. 2006. "Learning and Sharing Safety Lessons to Improve Patient Care." *Nursing Standard* 20(18): 49–53.

Illustration by Eric Hart.

Giving Back the Pen

Disclosure, Apology and Early Compensation Discussions after Harm in the Healthcare Setting

Rob Robson and Elaine Pelletier

" If you take my pen and say you are sorry and don't give me back my pen, nothing has happened."
– attributed to Bishop Desmond Tutu.

Abstract

In her recently published book *After Harm*, Nancy Berlinger shares a story about Bishop Desmond Tutu as he comments on the importance of restitution or compensation after an event that has led to harm. Transparency and disclosure are very much on the healthcare agenda in Canada. The increased interest in training providers for difficult conversations and disclosure is a positive sign. Using honest disclosure and apology as important interventions, organizations are beginning to adopt a more open approach to the concept of rebuilding trust after a patient has been harmed. But there continues to be significant reluctance to take the next logical step to solidify the fiduciary relationship between provider and patient – the willingness to enter into early discussions about compensation, non-monetary and otherwise.

The Winnipeg Regional Health Authority has developed, with the participation of the facility insurers, a process to identify those cases in which it would be appropriate not only to offer an apology of responsibility but also to initiate discussions around the questions of restitution and compensation. The article describes the steps that led to the development of a detailed process map for such cases and shares the algorithm that has been adopted. As well, the potential challenges associated with such an approach when there are multiple liability and insurance providers are discussed.

In a recently published book on the ethics of forgiveness after medical error has harmed a patient, *After Harm* (Berlinger 2005), the author shares comments attributed to Bishop Desmond Tutu: "If you take my pen and say you are sorry and don't give me back my pen, nothing has happened." (page 61). This story was one of several influences that led the Winnipeg Regional Health Authority (WRHA) to review its approach to patients harmed as a result of breakdowns in the provision of care provided to the population it serves. In essence, it provided the philosophic stance from which to develop consensus on this question. This article describes the process developed by WRHA and reflects on some of the issues central to the question of compensating patients after harm.

Background

Dr. Lucian Leape, a pediatric surgeon and leader in the patient safety movement in North America, wrote an article on the question of disclosure and apology following patient harm (Leape 2006). In the article, he identified four key issues to be considered. He suggested that leaders should do the following:

> First, set expectations. Hospital policy should be clear and unequivocal (and in writing): patients are entitled to a full and compassionate explanation when things go wrong.
>
> Second, doctors and nurses, as well as risk managers and other support personnel, need training in communicating with patients after adverse events. They also need training on how to support colleagues when they are "second victims."
>
> Third, support systems need to be developed for all parties. Patients need help after an event, including after discharge from the hospital … And we need to help these second victims deal with their emotional trauma. Professional and peer support systems must be developed.
>
> Finally – and this is the tough part – after enlisting full support of the board of trustees, hospital leaders need to insist that liability carriers provide early settlements for injured patients. (Leape 2006: 18)

These four principles were accepted by the senior management group at WRHA in the summer of 2006. The WRHA Board of Directors approved the proposals in principle and asked staff to operationalize the concepts. The board also wrote to the minister of health to encourage the passage of an Apology Act, similar to that implemented in British Columbia (Oppal 2006).

Berlinger and Leape were not the first to raise the issues of disclosure and apology after harm. An excellent review of the subject has been written by a psychiatrist (Lazare 2005, 2006), and many penetrating analyses in the preceding decades (Sharpe 2000, 2004) have raised similar issues. Clearly though, a certain "tipping point" was being reached, or at least approached, with the proposal to move ahead expeditiously, as outlined by Leape (2006).

Adopting a Clear Position about Disclosure of Harm

The proclamation of Bill 17 (Legislative Assembly of Manitoba 2005) on November 1, 2006, created a positive legal duty for healthcare facilities in Manitoba to inform patients and/or family members, in a timely manner, of the facts surrounding critical incidents. The legislation also created legal privilege for the work of committees that are mandated to investigate the factors that led to a given patient being unintentionally harmed. This created a secure place to examine all aspects of a critical incident without fear that the discussions, opinions and speculation could surface during litigation or some other form of legal proceeding. In the past, this fear has been a notorious barrier to effective investigation of such events.

Coincidentally, the existing WRHA policy on disclosure was due for periodic revision. In the spring of 2007, a new policy was adopted, WRHA Policy 10.50.030 (WRHA 2007). The policy mandates the disclosure of pertinent clinical information, not only following critical incidents but in other situations, as part of normal patient-centred high-quality clinical care. While policy alone rarely leads to permanent changes in behaviour, the revision satisfies the first of Leape's four concerns – WRHA now has a clear policy and process for the disclosure to patients of the facts surrounding a critical incident.

Providing Training for All Levels of Providers

Patient safety colleagues from the Calgary Health Region shared their experience working with the US Institute for Healthcare Communication (IHC, http://www.healthcarecomm.org/; see also IHC-Canada at http://www.ihcc.ca/). The IHC had been extremely helpful in organizing train-the-trainer sessions in Alberta, with content that was adapted to the Canadian experience. Dan O'Connell (O'Connell and Reifsteck 2004) was the main contact and, in January 2007, 20 WRHA physicians, nurses and other managers participated in a three-day session.

The IHC course Disclosing Unanticipated Outcomes and Medical Errors emphasizes how to make effective disclosures with patients and family members (see http://www.healthcarecomm.org/index.php?sec=courses&sub=faculty). The Canadian version of the workshop is titled Disclosure of Unanticipated Medical Outcomes (DUMO; see http://www.ihcc.ca/workshops.asp). A distinction is made between those cases in which the standard of care was met and those cases in which the care was ultimately deemed to be unreasonable or substandard. The distinction is important in terms of the steps to be taken by the care providers involved in the disclosure and the type of apology to be provided.

An expression of sympathy or regret is appropriate in all cases of unanticipated patient harm.

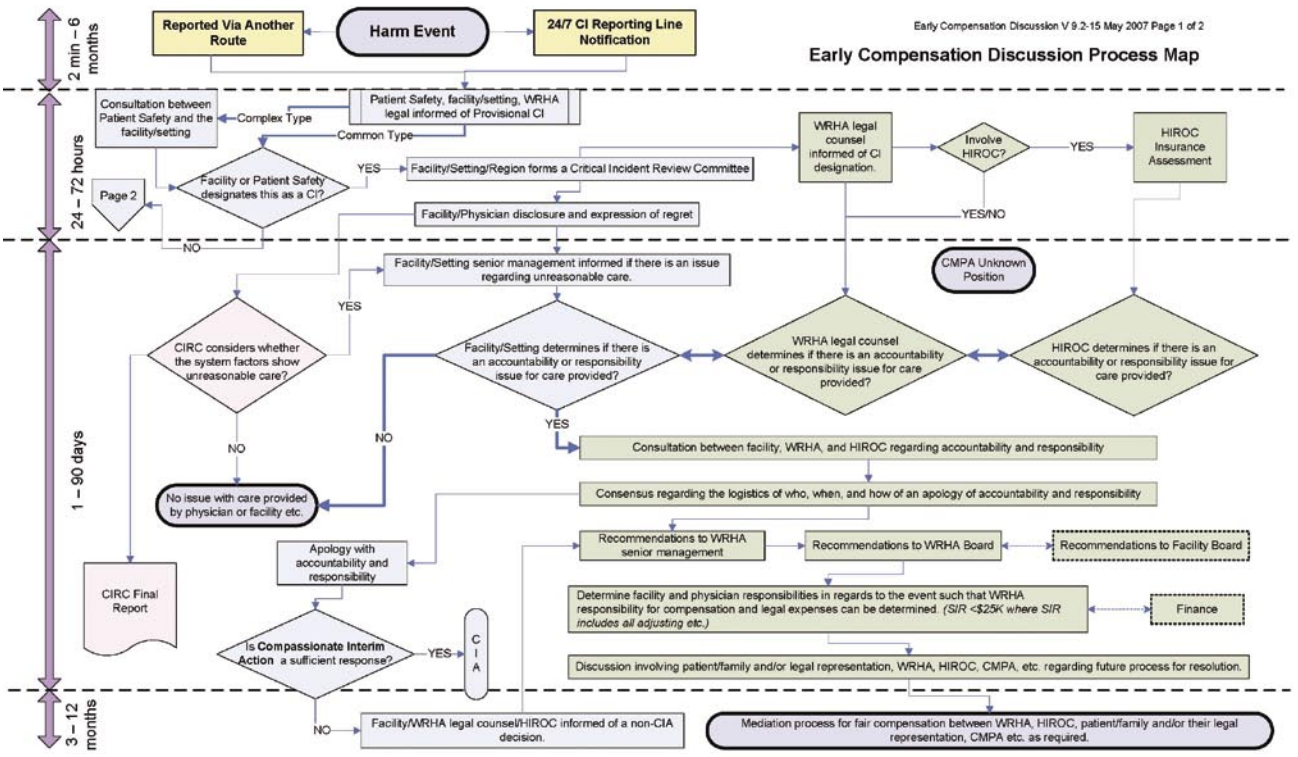
The DUMO workshop teaches that an expression of sympathy or regret is appropriate in all cases of unanticipated patient harm. When the care is also felt to be substandard or unreasonable, a more robust apology of responsibility is appropriate. This distinction is germane to the subject of this article as the analytic process proposed by IHC through DUMO helps to identify cases in which early discussion of compensation should be considered.

DUMO provides a framework for difficult disclosure conversations as well as concrete operational direction for the individuals involved. The half-day workshops have been provided more than 5,600 times in the past several years reaching 70,000 clinicians all over North America, and have been found effective in training more than 8,000 physicians associated with the Kaiser Permanente system in the United States (Boyle et al. 2006; O'Connell et al. 2003). Within Canada, the Health Quality Council of Alberta (see http://www.hqca.ca/index.php?id=58) and the Calgary Health Region (http://www.calgaryhealthregion.ca/) have been leaders in training large numbers of staff in the delivery of the DUMO workshop and have delivered it to more than 500 providers in the past year. WRHA now has 14 certified DUMO trainers and plans to offer the course frequently.

Providing Support for Staff and Patients following Critical Incidents

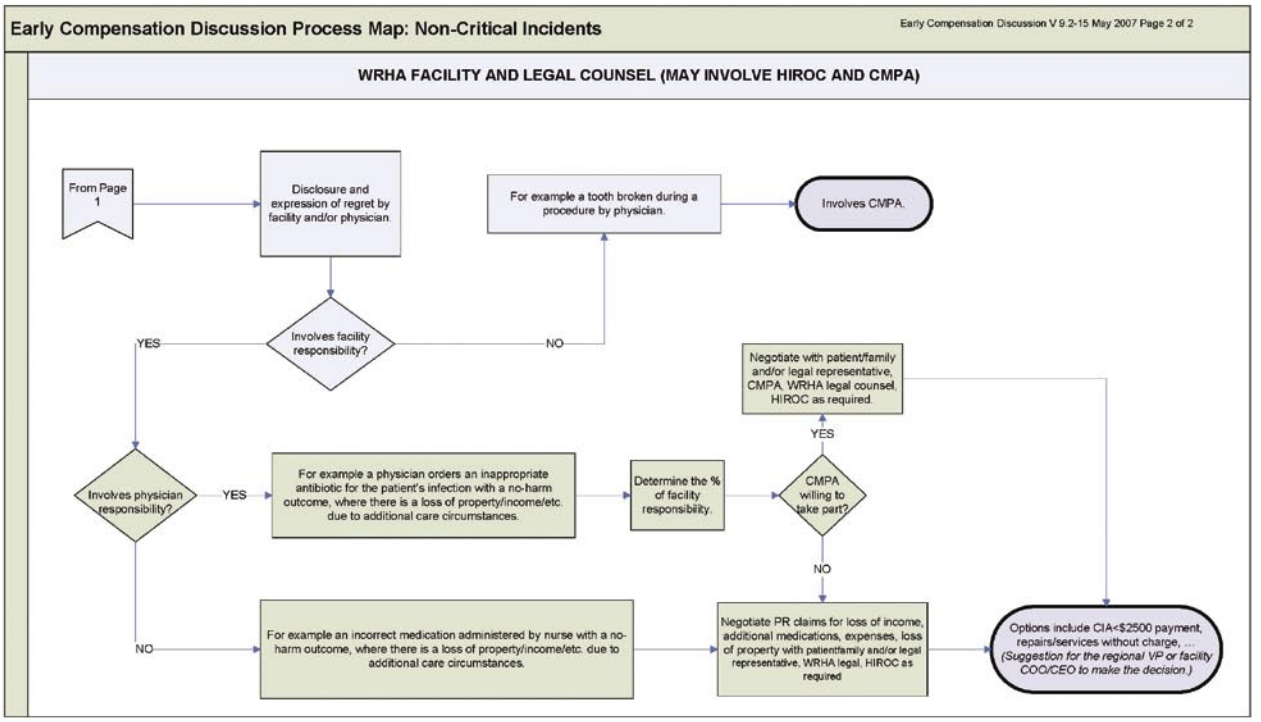
Providing support for staff and patients after critical incidents is a challenging and important issue. Patients and family members are not the only ones harmed following unanticipated medical outcomes. The concept of the "second victim" has been explored in some depth (Wu 2000) in recognition of the significant impact that critical incidents can have on providers, of all

Figure 1. Page one of the early compensation process map, addressing the process for critical incidents



CI = critical incident; CIA = Compassionate Interim Action; CIRC = Critical Incident Review Committee; CMPA = Canadian Medical Protective Association; HIROC = Hospital Insurance Reciprocal of Canada; SIR = Self Insured Retention; WRHA = Winnipeg Regional Health Authority.
Source: Winnipeg Regional Health Authority.

Figure 2. Page two of the early compensation process map, addressing the process for non-critical incidents



CEO = chief executive officer; COO = chief operating officer; CIA = Compassionate Interim Action; CMPA = Canadian Medical Protective Association; HIROC = Hospital Insurance Reciprocal of Canada; PR = Public Relations; VP = vice-president; WRHA = Winnipeg Regional Health Authority.

Source: Winnipeg Regional Health Authority.

kinds. It is also clear that the harm is not restricted to physical harm – significant psychological, emotional and stress-related symptoms appear after a critical incident.

The issue of harm inflicted on the provider-patient relationship as a distinct third level of harm has also been explored (Berlinger 2005). This recognition of a holistic and systemic level of harm is important in appreciating the fiduciary nature of the relationship between patients and providers/facilities. By better understanding the link between trust and healing, it becomes clearer why a comprehensive approach to disclosure, apology and compensation discussions is essential to advancing patient safety.

WRHA does not presently have a comprehensive approach to providing support in these difficult situations. At times, colleagues rise to the occasion and address the issues in a sensitive and humane manner, with both providers and patients. At other times, there is awkwardness, avoidance and a reluctance to face the implications that lie behind the harm arising from complex (albeit well-intentioned) healthcare delivery systems.

The origins of the discomfort that providers experience are explored by Dekker (2005, 2006). The perspective of a healthcare system that may be fundamentally unsafe is commonly rejected in favour of the belief that failures arise primarily from the actions of individuals rather than from combinations of systemic contributing factors. The belief that any one of us, as providers, in the same circumstances could easily have been involved in a similar critical incident is not easy to accept and may very well explain our reticence to support other colleagues involved in one of these events.

How would the distinction between reasonable and unreasonable care be accomplished?

Early Compensation Discussions

A number of practical issues arose as soon as serious consideration was given to developing a process for WRHA. We were unaware of any precedent in Canada that had attempted

to address the question of compensating patients for harm following healthcare system breakdowns, outside of the formal litigation system. While a number of examples existed in the United States (Berlinger 2005; Boothman 2006; Kraman and Boothman 2007; Kraman and Hamm 1999), there are significant differences between both the medical and legal environments in the two countries.

The issue of case identification was also challenging. Clearly, this could not proceed on the basis of sympathy or other subjective concerns. While the DUMO training program offered some hints, how would the distinction between reasonable and unreasonable care be accomplished? In what forum could such evaluations reasonably develop?

Finally, the issue of determining appropriate levels of compensation presented special difficulties. Compensation in such instances is traditionally provided by insurers. To what extent would such a new process be considered a fundamental undermining of the operating principles of such groups or companies? And how would the sharing of responsibility (and therefore compensation) be resolved when there are multiple insurers involved?

While WRHA and all its facilities are insured by the not-for-profit Hospital Insurance Reciprocal of Canada (HIROC; see http://www.hiroc.com/) most privately owned clinics are not insured by HIROC. Most of the physicians with privileges in WRHA facilities receive liability protection through the Canadian Medical Protective Association (http://www.cmpa-acpm.ca/); however, some do not. In a given case, there could be several parties in the compensation discussion. This would make for challenging discussions.

Some General Principles

After more than 10 meetings with representatives from HIROC in Toronto, WRHA in-house counsel, WRHA patient safety representatives and local HIROC provincial counsel, a process map was developed (see Figures 1 and 2) that addresses the fourth issue raised by Lucian Leape's 2006 article and fulfills the direction from WRHA's Board of Directors to operationalize the concepts outlined above. This was greatly facilitated by the convergence of several factors, including the newly proclaimed legislation from the Manitoba Government, the vision of patient safety leaders like Lucian Leape, the clearer understanding of the role of apology and early compensation discussions as means of promoting and reinforcing patient safety initiatives and, finally, the determined leadership within the WRHA to operationalize the concepts of trust and respect.

The concrete steps in the process include the following:

1. Early identification of all potential cases, initially applying the legislated definition of a critical incident to identify cases in which harm resulted from breakdowns in the healthcare system. The 24/7 call centre system in place for notification of potential new critical incidents provides an easy way to find appropriate cases.
2. Parallel evaluations of the care provided by two distinct and protected streams – by the Critical Incident Review Committee (CIRC – mandated by legislation to undertake safety reviews of critical incidents) and by WRHA in-house counsel (with participation of legal representatives of the insurer). In the case of the CIRC, the ability to consult clinical experts in a legally protected environment allows for an independent evaluation of the reasonableness of care provided.
3. Once a specific case is identified (through a consensus process) that fulfills the definition of a critical incident and is due at least in part to conditions under the control of the WRHA, notification of the chief executive officer or chief operating officer of the involved facility to arrange for an appropriate apology of responsibility. To the extent that this may involve the actions of individuals not under the direct control of WRHA (e.g., most physicians), an invitation to participate in the apology will be extended to all parties who may be involved.
4. At this point, there is divergence of the two streams: (1) CIRC continues its primary function of identifying systemic contributing factors that led to the critical incident in the first place and (2) the insurer's provincial counsel, with participation of WRHA in-house counsel, refines the potential issues of compensation (monetary and non-monetary) and considers the reasonable share between the various parties.
5. Before any other steps are taken, a final verification with the WRHA Board of Directors takes place. If there is agreement to proceed, efforts are made to involve all parties and insurers in discussions with the patient and legal representatives.

Clearly these discussions will be most effective if all parties are present and participating in good faith. Initially, the new process will be "field tested" on a range of simpler cases to identify process issues that may not have been anticipated by the original design group.

The Evaluation Process

An evaluation process will be developed to closely monitor the cases that follow this process map. The evaluation will examine not only the financial results of the process at several levels but will also seek feedback from all the participants, using an array of qualitative methods to assess the overall impact of introducing this process.

While it is reassuring that more than 50 organizations and facilities in the United States have embarked on analogous processes in recent years (Berlinger 2005), and several have published preliminary results, they have significant differences

compared with the situation in Canada. The WRHA evaluation will need to reflect the particular circumstances and objectives of the healthcare system in Canada as it strives to promote safer quality care for its patients.

Of course, the ultimate goal of patient safety programs and initiatives is to avoid "taking the pen" in the first place.

Conclusion

This article has described the factors that led WRHA to develop a process to identify cases involving patient harm following critical incidents in the healthcare system. As well, it describes the main steps that would lead to early compensation discussions with patients in those cases when preventable contributing factors were under the control of WRHA.

This may represent one way to begin "giving back the pen" to patients who have been harmed. Of course, the ultimate goal of patient safety programs and initiatives is to avoid "taking the pen" in the first place. We believe this process is unique within healthcare in Canada, and we will carefully monitor the results of our work. HQ

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References

Berlinger, N. 2005. *After Harm: Medical Error and the Ethics of Forgiveness.* Baltimore, MD: Johns Hopkins University Press.

Berlinger, N. and A.W. Wu. 2005. "Subtracting Insult from Injury: Addressing Cultural Expectations in the Disclosure of Medical Error." *Journal of Medical Ethics* 31: 106–8.

Boothman, R.C. 2006. *Medical Justice: Making the System Work Better for Patients and Doctors.* Testimony of Richard C. Boothman, Chief Risk Officer, University of Michigan Health System before the United States Senate Committee on Health, Education, Labor and Pensions, Thursday, June 22, 2006. Retrieved January 10, 2008. <http://help.senate.gov/Hearings/2006_06_22/boothman.pdf>.

Boyle, D., D. O'Connell, F.W. Platt and R.K. Albert. 2006. "Disclosing Errors and Adverse Events in the Intensive Care Unit." *Critical Care Medicine* 34(5): 1532–7.

Dekker, S.W.A. 2005. *Ten Questions about Human Error: A New View of Human Factors and System Safety.* Mahwah, NJ: Lawrence Erlbaum Associates, Inc.

Dekker, S.W.A. 2006. *The Field Guide to Understanding Human Error.* Aldershot, United Kingdom: Ashgate Publishing Co.

Kraman, S. and R. Boothman. 2007. "Sorry Doesn't Work Alone." Glen Carbon, IL: Sorry Works. Retrieved January 10, 2008. <http://www.sorryworks.net/article31.phtml>.

Kraman, S.S. and G. Hamm. 1999. "Risk Management: Extreme Honesty May Be the Best Policy." *Annals of Internal Medicine* 131: 963–7.

Lazare, A. 2005. *On Apology.* New York, NY: Oxford University Press.

Lazare, A. 2006. "Apology in Medical Practice: An Emerging Clinical Skill. American Medical Association." *Journal of the American Medical Association* 296(11): 1401–4.

Leape, L. 2006 "Full Disclosure and Apology: An Idea Whose Time Has Come." *Physician Executive* 32(2): 16–18.

Legislative Assembly of Manitoba. 2005. *Bill 17, The Regional Health Authorities Amendment and Manitoba Evidence Amendment Act.* Winnipeg, MB: Manitoba Government. Retrieved January 10, 2008. <http://web2.gov.mb.ca/laws/statutes/2005/c02405e.php>.

O'Connell, D. and S.W. Reifsteck. 2004. "Disclosing Unexpected Outcomes and Medical Error." *Journal of Medical Practical Management* 19(6): 317–23.

O'Connell, D., M.K. White and F.W. Platt. 2003. "Disclosing Unanticipated Outcomes and Medical Errors." *Journal of Clinical Outcomes Management* 10(1): 25–9.

Oppal, W. 2006. Bill 16 – 2006. *Apology Act.* Victoria, BC: Queen's Printer. Retrieved January 10, 2008. <http://www.leg.bc.ca/38th2nd/amend/gov16-2.htm>.

Sharpe, V.A. 2000. "Behind Closed Doors: Accountability and Responsibility in Patient Care." *Journal of Medicine and Philosophy* 25(1): 28–47.

Sharpe, V.A., ed. 2004. *Accountability for Patient Safety: Medical Error and Policy Reform.* Washington, DC: Georgetown University Press.

Winnipeg Regional Health Authority. 2007. WRHA policy 10.50.030. Winnipeg, MB: Author. Retrieved January 10, 2008. <http://www.wrha.mb.ca/about/files/policy/10.50.030.pdf>.

Wu, A.W. 2000. "Medical Error: The Second Victim. The Doctor Who Makes the Mistakes Needs Help Too." *BMJ* 320: 726–7.

"It's Safe to Ask": Promoting Patient Safety through Health Literacy

Jan Byrd and Laurie Thompson

Abstract

The Manitoba Institute for Patient Safety launched "It's Safe to Ask" in January 2007. The communication and health literacy initiative is aimed at Manitoba's vulnerable populations and their primary care providers. Phase 1 includes a poster and brochure for patients and a toolkit for providers/organizations, pilot tested in six sites in Manitoba. Posters will serve as a symbol that dialogue is encouraged. Tools, available in 15 languages, provide patients and family members with three key questions to ask in healthcare interactions, tips on how to ask questions, and room for notes and listing of medications. The initiative will promote involvement in healthcare by patients, stronger communication between patient and provider, and reduction of risk for adverse events. "It's Safe to Ask" has been implemented in over 65 sites across Manitoba. A formal evaluation is underway. Phase 2 and 3 will enhance key tools and include interventions with specific populations.

What Is the Problem?

Patients who visit the doctor expect to leave knowing what their health problem is, what they need to do about it and why. But for patients with low health literacy, this is rarely the case. The 2003 Adult Literacy and Life Skills Survey found that 42% of Canadian adults lacked sufficient literacy skills to cope with the demands of life and work in our society ("Literacy and Health in Canada" 2006). Over 43% of American adults are unable to read, understand and act on basic health information (Institute of Medicine Committee on Health Literacy 2004; Schwartzberg 2005). Healthcare information and instructions that patients receive may be complex, illegible, poorly designed, poorly written and delivered in a way that does not match the patients' literacy and language levels (Baker 2005; Rudd 2005).

Over 43% of American adults are unable to read, understand and act on basic health information.

Patients with low health literacy have less knowledge about their health problems (Weiss et al. 2005) and are more likely to be confused or inadequately informed about their condition and the processes of care needed to manage it (Shillinger et al. 2004). They have more difficulty identifying their medication, describing their treatment (Wolf et al. 2005) and reading medication labels, and thus may take medications incorrectly (Perrin 1998). Healthcare professionals often make incorrect assumptions about individuals' ability to read, ask questions and comprehend health information (Institute of Medicine Committee on Health Literacy 2004). Fear, embarrassment, shame and limited skills keep patients with low health literacy from asking important questions of healthcare providers and clarifying the answers (Speros 2005). When low health literacy is invisible, communication is not adjusted to meet the level of the patients (Safer and Keenan 2005).

Low health literacy is a serious threat to patient safety, promoting misunderstandings, miscommunication, errors, increased hospital admissions, longer hospitalizations, poor health outcomes and higher healthcare costs.

Although frequently overlooked, low health literacy is a serious threat to patient safety, promoting misunderstandings, miscommunication, errors, increased hospital admissions, longer hospitalizations, poor health outcomes and higher healthcare costs (Baker 2005; Rudd 2005; Schwartzberg 2006; Weiss et al. 2005; Wolf et al. 2005). Low health literacy increases hospital admission rates by up to 30% and may cost as much as US$73 billion annually in the United States (Institute of Medicine Committee on Health Literacy 2004).

What Do We Need to Do?

Presenting health information in clear, plain language, ensuring written patient materials are presented at no higher than a grade five reading level (Mayer and Villaire 2004; Safer and Keenan 2005) and supplementing text with graphics, cartoons and photos (Baker 2005; Davis and Wolf 2004; Delp and Jones 1996; Kickbusch 2001; Rudd 2005; Schwartzberg 2005) are steps to improving health literacy. However, better educational materials for patients need to correspond with improved communication between professionals and their patients. A clear conversation in the doctor's office, hospital or pharmacy is the only way to confirm that patients understand information they have received, know how to act on it and understand why they should do so. Patients need to ask the questions that will provide them with necessary information; healthcare providers need to recognize the signs of low health literacy and adjust their communication accordingly (Hixon 2004; Kleinbeck 2005).

Why Do We Need to Do This?

Increasingly, patients are asked to engage in decision-making, information seeking and monitoring of their own health (Institute of Medicine Committee on Health Literacy 2004). Low health literacy is most common among the elderly, minorities, persons with limited English proficiency, immigrants and those with low incomes (Baker 2005; Faguy 2004). Seniors are particularly likely to have low health literacy; they are also more frequent users of the healthcare system and take more medications (Centre for Literacy 2001). Many seniors overestimate their literacy skills (Centre for Literacy for Quebec 2001) and are reluctant to ask for health information because of their respect for the doctor-patient relationship and their socialization patterns; the potential for medication errors in this group is great. Health literacy is also a particular concern for Aboriginal Manitobans, 45–70% of whom have less than a grade nine education (Statistics Canada 2001). As treatment regimes become more complex, with many patients managing their health at home (via multiple medications, inhalers or devices to monitor blood sugar), low health literacy is an increasing problem.

The Canadian Council on Health Services Accreditation (CCHSA) includes communication and patient involvement as one of 21 required organizational practices for patient safety in their organizational accreditation surveys. As an example of an initiative that corresponds with this required organizational practice, CCHSA has included links to It's Safe to Ask.

Introducing *It's Safe to Ask*

US-based Partnership for Clear Health Communication developed Ask Me 3 to encourage patients to ask three basic questions about their healthcare. Preliminary research showed that where Ask Me 3 was implemented, patients were indeed more likely to ask three simple questions about their healthcare (Allison-Ottey 2006).

It's Safe to Ask is a Manitoba Institute for Patient Safety (MIPS) initiative, patterned on Ask Me 3, that encourages patients to ask three simple questions:

1. What is my health problem?
2. What do I need to do?
3. Why do I need to do this?

The initiative's goals are to raise awareness of health literacy issues, improve health literacy and enhance communication between professionals and patients. It's Safe to Ask tools include patient brochures and display posters, with information presented at a grade four reading level. Materials are available for free at www.safetoask.ca in 15 languages: Amharic, Arabic, Chinese, Cree, English, Eritrean, French, German,

Korean, Ojibwa, Oji-Cree, Punjabi, Russian, Spanish and Tagalog. All materials were reviewed by literacy experts and focus tested with community user groups. MIPS also worked with healthcare providers to create tools for them, including information on low health literacy and its impact on patients' experiences, strategies for effective communication with patients and families and an implementation guide.

A pilot test period was held from June to November 2006 in six healthcare settings across Manitoba: an inner-city community clinic, a French healthcare centre, three community pharmacies and a Labour, Delivery, Recovery and Post Partum ward at a teaching hospital. Participants' feedback was used to refine and improve the initiative. Leading up to the province-wide launch on January 9, 2007, and coinciding with Canadian Patient Safety Week 2006, 19,000 pharmacists, nurses and physicians across Manitoba received It's Safe to Ask information and a poster and brochure. The official public launch began a four-month public awareness campaign that included billboards in Winnipeg and surrounding urban and rural areas, Winnipeg transit bus ads, public service announcements (in six languages), community newspaper articles and a dedicated website, www.safetoask.ca. Twenty-two sites in Winnipeg and various sites across other Regional Health Authorities were early implementers of It's Safe to Ask. There have been close to 140,000 hits to the website since the launch.

A formal evaluation of It's Safe to Ask is under way with funding from the Manitoba Medical Services Foundation and the Winnipeg Foundation. The evaluation focuses on assessing awareness, examining implementation and learning about ways in which patients and providers are using Its Safe to Ask across Manitoba. Results are expected in early 2008.

Well over 80 Manitoba sites have requested tools for patients and healthcare providers, and each will determine the best possible way to integrate the initiative at their site.

Well over 80 Manitoba sites have requested tools for patients and healthcare providers, and each will determine the best possible way to integrate the initiative at their site. Early learning indicates that a planned, sustained effort, with continued education and assistance by site champions and expressed support from senior leadership, is key to the successful implementation of It's Safe to Ask. At any site, there needs to be a person devoted to quality improvement and patient safety who "owns" It's Safe to Ask – this person communicates with existing and new staff about its use and benefits, replenishes brochures and helps to integrate It's Safe to Ask into existing processes, such as discharge planning. Making any new initiative "the way we do business here" is difficult work, and inviting patients to be involved in this way needs ongoing, explicit support from executives, directors and managers. Ongoing discussion among staff within teams about how to work with patients with low health literacy is important. If a site loses its "champion," the initiative can become very passive, with little noticeable change in patient behaviour. Posters need to be kept in good repair and in view of both patients and staff. Participating organizations should add to their website a link to the It's Safe to Ask website.

Further research will explore the relationship between the use of It's Safe to Ask and increased patient satisfaction, improved health literacy and better health outcomes. The next phase of It's Safe to Ask is under way and involves MIPS, the Manitoba Society of Pharmacists and the Manitoba Pharmaceutical Association. They are working to develop, focus test and distribute a patient tool for medication safety, including a "how to and why" video for providers and patients. The tool is based on the best practice of medication reconciliation (Safer Healthcare Now!), the principles of It's Safe to Ask and the Emergency Response Information Kit initiative.

Conclusion

It's Safe to Ask is a step toward a healthcare culture that is open and welcoming of patient and family involvement. By providing patients with ongoing support and tools to help them request the information they need, and by continuing to offer supportive education to healthcare providers, It's Safe to Ask promises to have a significant impact on patient safety and satisfaction in Manitoba. HQ

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References

Allison-Ottey, S. 2006. *Implementing the Ask Me 3 Program in a Doctor's Office.* Proceedings of the Institute for Healthcare Advancement Health Literacy Conference, Irvine, CA.

Baker, D.W. 2005. *Framing the Issues.* Proceedings of the American Medical Association Mini-Conference on Health Literacy and Health Disparities, Chicago, IL.

Centre for Literacy of Quebec. 2001. *Health Literacy Project Phase 1: Needs Assessment for the Health Education and Information Needs of Hard-to-Reach Patients.* Montreal, QC: Author.

Davis, T.C. and M.S. Wolf. 2004. "Health Literacy: Implications for Family Medicine." *Family Medicine* 36(8): 571–4.

Delp, C. and J. Jones. 1996. "Communicating Information to Patients: The Use of Cartoon Illustrations to Improve Comprehension of Instructions." *Academy of Emergency Medicine* 3(3): 264–70.

Faguy, K. 2004. "Health Literacy." *Radiologic Technology* 76(2): 139–46.

Hixon, A.L. 2004. "Functional Health Literacy: Improving Health Outcomes." *American Family Physician* 69(9): 2077–8.

Institute of Medicine Committee on Health Literacy. 2004. *Health Literacy: A Prescription to End Confusion.* Washington, DC: National Academies of Science.

Kickbusch, I.S. 2001. "Health Literacy: Addressing the Health and Education Divide." *Health Promotion International* 16(3): 289–97.

Kleinbeck, C. 2005. "Reaching Positive Diabetes Outcomes for Patients with Low Literacy." *Home Healthcare Nurse* 23(1): 16–22.

"Literacy and Health in Canada: Perspectives from the Second Canadian Conference on Literacy and Health." 2006. *Canadian Journal of Public Health* 97(Suppl. 2).

Mayer, G.G. and M. Villaire. 2004. "Low Health Literacy and Its Effects on Patient Care." *Journal of Nursing Administration* 34(10): 440–2.

Perrin, B. 1998. *How Does Literacy Affect the Health of Canadians? A Profile Paper.* Ottawa: Health Canada, Health Promotion and Programs Branch, Policy Development and Coordination Division.

Rudd, R. 2005. *Improving Communications for Better Understanding.* Proceedings of the American Medical Association Mini-Conference on Health Literacy and Health Disparities, Chicago, IL.

Safer, R.S. and J. Keenan. 2005. "Health Literacy: The Gap between Physicians and Patients." *American Family Physician* 72(3): 463–8.

Schillinger, D., A. Bindman, F. Wang, A. Stewart and J. Piette. 2004. "Functional Health Literacy and the Quality of Physician-Patient Communication among Diabetes Patients." *Patient Education and Counseling* 52(3): 315–23.

Schwartzberg, J.G. 2005. *Framing the Issues.* Proceedings of the American Medical Association Mini-Conference on Health Literacy and Health Disparities, Chicago, IL.

Schwartzberg, J.G. 2006. American Medical Association Health Literacy Initiative. *Health Literacy: The Foundation for Patient Safety, Empowerment and Quality Health Care.* Conference proceedings. Winnipeg, MB.

Speros, C. 2005. "Health Literacy: Concept Analysis." *Journal of Advanced Nursing* 50(6): 633–40.

Statistics Canada. 2001. *Canadian Census Data.* Ottawa: Author.

Weiss, B.D., M.Z. Mays, W. Martz, K.M. Castro, D.A. DeWalt, M.P. Pignone, J. Mockbee and F.A. Hale. 2005. "Quick Assessment of Literacy in Primary Care: The Newest Vital Sign." *Annals of Family Medicine* 3(6): 514–22.

Wolf, M.S., T.C. Davis, A. Arozullah, R. Penn, C. Arnold, M. Sugar and C.L. Bennett. 2005. "Relation between Literacy and HIV Treatment Knowledge among Patients on HAART Regimens." *AIDS Care* 17(7): 863–73.

Canadian Patient Safety Champions: Collaborating on Improving Patient Safety

Katharina Kovacs Burns

Abstract

Patients for Patient Safety Canada champions have grown in numbers and purpose since their initiation into the World Health and Pan-American Health Organizations' Patients for Patient Safety initiative in May 2006. The 25 Canadian patients and family members not only share their adverse event experiences but are actively engaged in collaboration with health professionals, administrators and decision-makers to initiate proactive patient safety strategies. Their intention is to have their stories heard as tools for learning. They also wish to raise local, regional and national awareness of patient safety problems. The different patient and family stories and experiences share some common issues and suggested solutions that might make a difference in patient safety. One key solution is involving patients and families not only in discussions of treatment and follow-up when adverse events occur but also proactively on patient safety advisory committees. These actions would acknowledge a common interest in seeing that the right things are done. Patients and families share the common interest of all those advocating for patient safety, namely, *First do no harm* (attributed to Hippocrates, circa 470–360 B.C.). The patients and families of Patients for Patient Safety Canada are a group of committed, dedicated individuals who should be acknowledged for sharing their experiences and trying to make a difference in patient safety.

There are many different experiences of patients and families with patient safety in varying settings, with different health professionals and with a range of practices regarding the inclusion of patients and families in their care and treatment. Although each story is different, there is something familiar about them, regardless of whether the experiences are described by patients, parents, sons or daughters, spouses or other informal caregivers.

In addition to the data on adverse events in Canada (Baker et al. 2004; Canadian Institute for Health Information 2007), there are 25 Canadian patient safety champions who are sharing their detailed experiences of adverse events in hospitals and other healthcare settings across the country. Patients for Patient Safety (PFPS) Canada champions have grown in numbers and purpose since their initiation into the World Health and Pan-American Health Organizations' PFPS initiative in May 2006. The goals

for PFPS Canada include their collaboration with consumers, healthcare providers and health system decision-makers to ensure the implementation of patient-centred care and patient safety strategies at all levels of health professional education, healthcare delivery and healthcare policies. This article provides an overview of their experiences with patient safety practices in different healthcare settings and their activities in helping to improve patient safety.

"It was clear to us that the hospital did not regret our daughter's death as much as the fact that we discovered the truth of her care."

Experiences of Patients and Families

The 25 Canadian patient safety champions come from every province across Canada, with diverse work and personal experiences. They include 19 women and six men, of whom 12 are health professionals or employees working within the healthcare system.

Eighty-six percent of the PFPS champions experienced their adverse events in hospitals; the remaining events occurred in clinics or continuing care facilities. Some events were unexpected, while others were viewed as complications from diseases or medical conditions. All were rated as urgent requiring emergency treatment and care. Their stories include surgical errors or complications, drug treatment errors, routine day surgery or procedural problems, birth complications, missed diagnoses and misdiagnoses, patient neglect, wrong emergency department triage classification and hospital-based infections. The majority describe a lack of disclosures and apologies and little compassion and empathy from healthcare providers and institutions. Patients and families were expecting empathy. Most of the family members and three patients described their interactions during and following the event as "condescending," "disrespectful" and "non-empathetic."

Six of the 25 champions are patients, five of whom have related their stories and their resulting physical challenges and psychological trauma. Only one patient viewed his experience as "positive" and "satisfying" before, during and following his surgery. He felt this was because he had been included in pre-treatment discussions of what to expect including potential challenges with the procedure or treatment involved. The other patients were not so fortunate. One experience was described by Beth, a nurse who had surgery in 2001 to correct a cardiac dysrhythmia:

> "An error occurred during the procedure and my right ventricle was perforated. This led to bleeding into the pericardium … and a subsequent pericarditis occurred. It is referred to as Dressler's syndrome, and it usually responds to anti-inflammatory medications and clears up quickly. However, I did not respond to traditional therapy … It seems that prednisone is the only drug that will alleviate my symptoms, but I am now reaping the curse of long-term steroid use."

Beth continues to experience additional medical complications as a result of the medications on which she is now dependent.

Another patient survivor is Alice L., who was treated for a bladder infection for six months following a multitude of procedures including an unnecessary radical hysterectomy and peritoneal wash in 2003 and 2004. During subsequent surgery to remove a cancerous kidney in 2004, she experienced a near miss that would have removed the wrong kidney.

Other patient stories include misdiagnoses, medical and system errors and a lack of communication between health teams and the patients and family. The remaining 19 stories from family members describe what they observed and experienced; in more than half (63%), the patient involved died. Barb, a parent of a disabled child, describes the events they encountered at a children's hospital:

> "My three-month-old daughter died within 24 hours' arrival at the hospital. During that time, she was misdiagnosed for pneumonia, and policies regarding transfer to the ICU, 'Do Not Resuscitate' consent and multiple standards pertaining to nursing care including administration and documentation of medication were violated … We made suggestions of ways that physicians might be educated about the quality and value of the lives of disabled children by those who love them, but there was no interest. It was clear to us that the hospital did not regret our daughter's death as much as the fact that we discovered the truth of her care."

This parent is still in discussions with the hospital.

Sabina R. and Ryan S. have equally devastating experiences to relate about their two infant daughters. They describe two Canadian hospitals that failed to listen to and communicate with the families about what was happening prior to, during and following the adverse events. Sabina's daughter was diagnosed quite suddenly in April 2004 with idiopathic thrombocytopenia purpura and deteriorated in the hospital as Sabina tried to convey her concerns. Sabina stated:

> "The harsh reality is, [she] died. This April 5th [2007] marks three years … Let me tell you what it is like to be not heard … I have never felt so helpless in my entire life. I could feel my little girl slipping away, and I could not get anyone to listen to me. There is nothing worse than holding your child in your arms and watching her slowly and painfully

> die … It is heart-wrenching, it is unbearable and it sucks the life right out of you … Because no one would listen, they missed early signs of an intercerebral bleed … Because no one would listen, communication between attending resident and the nurses was non-existent."

"Throughout the experience, communication was paternalistic, at times condescending."

Ryan of Winnipeg, Manitoba, had a daughter, Paige, who died on October 30, 2003,

> "due to multi-organ failure brought about by a highly aggressive form of cancer, a type of cancer with less than a 30% survival rate at one year under 'ideal' conditions. These poor odds were further complicated by the fact that she was treated for a pathologically different type of cancer for over eight weeks due to misdiagnosis. Throughout the experience, communication was paternalistic, at times condescending, and always we were made to feel like a disease to be treated versus people to be cared for. There were no intentionally mean or bad people involved in my daughter's care. I saw enough tears in nurses' eyes to know that watching Paige slip away was very hard on them, both personally and professionally. However, the system in which these highly dedicated individuals work is so fundamentally flawed that it has become increasingly amazing to me how often they are able to actually get it right."

As a result of his experiences, Ryan has pursued a career with the Winnipeg Regional Health Authority and now works as leader in patient voice facilitation.

In January 2003, Theresa M. lost her 19-year-old son, Dan. He was misdiagnosed as having enteritis and dehydration when, in fact, he had viral myocarditis. Inappropriate treatment and care along with miscommunication led to a series of errors including laboratory work not done in a timely manner. In February 2007, after much persistence by Theresa and her family, they received

> "an open and honest disclosure conversation with hospital administrators, a verbal apology and a list of the changes that have been and are being made in the emergency department, the in-patient floor and the critical care unit. This came after a daunting and draining effort on our part to attain college reviews, appeals of the college reviews, a review by the Pediatric Death Review Committee of the Ontario Coroner's office, newspaper articles and a radio interview. All of the reviews found practice deficiencies, inappropriate care, failure in record keeping and breach of hospital guidelines."

Susan S. of Winnipeg, whose 19-year-old daughter has a congenital heart condition, had an experience transitioning from the pediatric to the adult system. On her first trip to the emergency department at an adult hospital, Susan was refused entry with her daughter to the treatment centre. The hospital had no records of her condition and refused her medical diary. Susan did try to enter to assist her daughter with the oxygen, which had been turned up too high, but she was threatened with security removing her. Things settled down when one of the residents recognized Susan from the Family Advisory Committee at the Winnipeg Children's Hospital, where she spoke on family-centred care to the residents. He spoke with the attending staff, and Susan was permitted to be with her daughter. Since then, Susan and her daughter have spoken to the managers of the Critical Care for Winnipeg Regional Health Authority and have assisted with the writing of a new protocol for families in the emergency room.

Ed M. of Orleans, Ontario, lost his wife, Madeleine, in March 2003 as a result of adverse events related to post-surgical care, including misdiagnosis, inappropriate clinical treatment and neglectful care. When Madeleine died, the surgeon offered his sympathies to Ed, who reminded the surgeon of the gastroenterologist report that pointed out that there were ulcers in Madeleine's colon next to the surgical site. The surgeon denied seeing these ulcers. The autopsy report confirmed that Madeleine had died from "gastrointestinal ulcer, perforated." Later when he talked with the surgeon by phone, Ed was told, "I know how you feel, Mr. M., but as you can see from the autopsy report, your wife had many serious bowel problems and probably wouldn't have lived very much longer."

Patients and families want to know that people are truly sorry for what happened and that the necessary steps are being implemented to prevent similar events from happening again.

Katarina S., a registered nurse living in Toronto, Ontario, saw her father receive devastating news about metastatic colon cancer. He experienced a series of system failures and died in 2004. There were problems in the tests to locate the primary site, surgery for a tumour in his colon and complications from the anesthetic related to his liver dysfunction. After an anesthetic-induced delirium and being physically restrained, a chemical restraint was given at double the maximum recommended dose, leading to coma and intubation. He could not receive any food or fluids because he was intubated. "He died three weeks later

– the same way he was born … unable to speak, with nothing to eat or drink."

There are many other stories of adverse events resulting from errors and a lack of communication at all levels of the healthcare system, including with patients and family members. Patients and families who have experienced adverse events have many questions for the hospital healthcare team and administrators: What happened? What went wrong? How did this happen? Why did this happen? Why were treatments and interventions done in error or not done, or not followed up? Why were we not listened to when we said, "Things are not right – something is very wrong!"? Why won't someone talk with me and tell me what is going on? Doesn't anyone in this place care? These patients and family members, in their commitment, have continued to ask questions in their current efforts to seek the truth for their own peace of mind and to ensure that appropriate education and changes to patient safety practices are implemented. All the PFPS Canada champions are active within their own regions and in the institutions where their adverse events occurred. Their stories and experiences have become valuable educational tools, and the lessons learned can be a tribute to patients and families who have experienced adverse events, and benefit patient safety education within and across healthcare institutions in Canada.

Most of the stories of Canadians who have experienced adverse events have not been told or made public. There are also many adverse events and patient care errors that are never reported by health professionals and remain silent experiences (Sinnema 2006, November 24).

Analysis and Discussion: Patient and Family Involvement in Improving Patient Safety in Canada

There are many common themes arising from patients and families who have experienced adverse events. These have become key elements in many institutional and regional guidelines that are currently being developed for "what should happen when an adverse event occurs" and for how-to guides for measuring and improving patient safety in organizations (Fleming 2005). Yet, each adverse event experience is unique, and some are frightening and fraught with intense emotions for all concerned. Most patients and families describe their experiences as painful, both in terms of their suffering and anxiety as well as the lack of support, compassion and answers from those providing care and treatment. For some, it is a deafening, uncomfortable silence with no answers or consolation, and for others, there is screaming, crying and yelling, with finger pointing. In the early post-event stage, any of these can happen.

What everyone involved in the event really wants are facts and explanations. Patients and families want answers – they need to know what actually happened soon after the event and be told that an investigation or root-cause analysis will be done. They want to know that people are truly sorry for what happened and that the necessary steps to assist patients and families will be taken and that measures are being implemented to prevent similar events from happening again (Duclos et al. 2005; Gallagher et al. 2003). No single patient, family member, health professional or administrator can tackle all aspects related to what needs to happen following an adverse event. Adverse events require collaborative efforts from all involved. These lessons learned need to be conveyed to others within and across healthcare settings.

Health professionals and administrators have important roles to play in all aspects of patient safety, including knowledge transfer and transformation of organizational culture. It is not quite as clear what role patients have or will be allowed to have in patient safety improvement efforts (Coulter and Magee 2003). "Plans for improving safety in medical care often ignore the patient's perspective" (Vincent and Coulter 2002: 76). So, how can patients and families be involved in working collaboratively with healthcare professionals, administrators, policy decision-makers and others to ensure patient safety knowledge transfer and transformation of practices occur?

Patients and families have had to first overcome challenges in being acknowledged and recognized as contributors to changing the current patient safety culture. There is a perception that patients and their families who have experienced adverse events are inclined to file legal claims against healthcare professionals and their institutions. But there are very few such cases. The more serious interests for the majority of patients and families concern two major areas that remain largely unaddressed – the impact of patient safety (or its absence) on patients and families, and the contributions that patients and families can make toward ensuring patient safety measures are in place (Vincent and Coulter 2002). Patients and families share the common interest of all those advocating for patient safety, namely, *First do no harm* (attributed to Hippocrates, circa 470–360 B.C.). Patients and families deserve nothing less than having access to safe healthcare services and environments.

With the recent emphasis on patient safety, patients and families are becoming more vocal, not only about open disclosure but also about improving awareness, education and safety practices. Patients and families are the best teachers for what happens when patient safety measures are not constantly monitored or checked (Anderson et al. 2006; Weingart et al. 2005). They also see a larger issue for the Canadian public: the number of adverse events is still very high. This has created a growing desire for patients and families to become more actively engaged in discussions, decisions and actions

- regarding their care and treatment to possibly identify and prevent unforeseen adverse events (Coulter and Magee 2003; Weingart et al. 2005);
- contributing to safe medication use and reporting side effects

or adverse events (Koutantji et al. 2005; Lowe et al. 1995);
- participating in infection control initiatives, such as ensuring that healthcare staff wash their hands (National Patient Safety Agency 2004);
- supporting and encouraging disclosure of treatment complications and adverse events (Duclos et al. 2005; Ford 2006); and
- advocating for changes in patient safety initiatives and policies in every institution and facility throughout the Canadian healthcare system (Mireles 2005).

More patients and families are being invited to participate as members of patient safety advisory committees at hospitals, such as the Toronto's Hospital for Sick Children's Families as Partners in Patient Safety. This group aims to raise awareness among health professionals about the role of parents in patient safety, empower family members to speak up and provide education to families about patient safety (Fleming-Carroll et al. 2006; Stevens et al. 2005). Regional health authorities also have patients and family members on patient safety advisory committees, including Calgary Health Region's Patient/Family Safety Council (Cuthbertson et al. 2007) and Winnipeg Regional Health Authority's Patient Advisory Council (Berry et al. 2005). Other similar committees or councils are in place across the country.

There are also public members, including patients and families, involved in various national organizations such as the Canadian Patient Safety Institute. Also, at a national level, patients and consumers are involved in Health Canada's consultations and advisory committees to discuss safety issues related to the Health Products and Food Branch, Office of Consumer and Public Involvement and National Pharmaceuticals Strategy.

Unless the current record of adverse events and the treatment of patients and families change, Canadians will not trust the healthcare system.

Conclusion

Important efforts are being made by Canadian patients and families through the PFPS initiative, but much work is still needed. Patients and families face challenges, the most critical being the need to convince more healthcare organizations and service providers to engage patients and families in every aspect of patient safety initiatives. These include health professional education, meetings, consultations, advisory committees, patient safety councils, research and knowledge transfer initiatives, disclosure guidelines and policies and patient safety policies. What is currently in place in these areas is not working, and transformation requires everyone's commitment. Unless the current record of adverse events and the treatment of patients and families change, Canadians will not trust the healthcare system and will choose to enter it only with a second medical opinion (Elder et al. 2005) and legal advice. This latter is not the best solution for anyone. Patients and families need and deserve to be part of the process, and not be perceived as liabilities!

In early 2005, the World Health Organization supported the role of patients, families and lay caregivers in identifying the gaps in the healthcare safety net that busy healthcare providers, administrators and decision-makers might unknowingly overlook. "Patients have much more to offer than visceral reminders to healthcare workers, administrators and policy makers that we are victims of tragic medical errors. Important as that perspective is, a victim orientation does not position us well as partners working with healthcare providers to prevent harm" (Sheridan et al. 2006: 6). As the rates of adverse events and patient harm continue to grow in Canadian healthcare settings, so will the patient safety movement. Patient safety is everyone's business! HQ

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References

Anderson, J., C. Aeah, C. Metge, M. Fricke, L. MacDonald, P. Davis and S. Ludwig. 2006. Interprofessional Education for Collaborative Patient-Centred Practice: The Manitoba Initiative. Poster presentation at the Canadian Interprofessional Health Collaborative. Winnipeg, MB.

Baker, G.R., P.G. Norton, V. Flintoft, R. Blais, A. Brown, J. Cox, E. Etchells, W. Ghali, P. Hebert, S. Majumdar, M. O'Beirne, L. Palacios-Derflingher, R. Reid, A. Shepts and R. Tamblyn. 2004. "The Canadian Adverse Events Study: The Incidence of Adverse Events among Hospital Patients in Canada." *Canadian Medical Association Journal* 170(11): 1678–86.

Berry, V., L. Smyrski and L.A. Thompson. 2005. "From Inquest to Insight." *Healthcare Quarterly* 8(Special issue): 115–8.

Canadian Institute for Health Information. (2007). "Patient Safety in Canada: An Update." Analysis in Brief August 14. Available at http://secure.cihi.ca/cihiweb/en/downloads/Patient_Safety_AIB_EN_070814.pdf . Last accessed December 3, 2007.

Coulter, A. and H. Magee. 2003. *The European Patient of the Future.* Maidenhead: Open University Press.

Cuthbertson, J., S. Nettleton and D. Prowse. 2007. Patient/Family Safety Council Disclosure Subcommittee Presentation. Edmonton, AB: CPSI National Disclosure Working Group.

Duclos, C.W., M. Eichler, L. Taylor, J. Quintela, D.S. Main, W. Pace and E.W. Station. 2005. "Patient Perspectives of Patient-Provider Communication after Adverse Events." *International Journal for Quality in Health Care* 17(6): 479–86.

Elder, N.C., C.J. Jacobson, T. Zink and L. Hasse. 2005. "How Experiencing Preventable Medical Problems Changed Patients' Interactions with Primary Health Care." *Annals of Family Medicine* 3(6): 537–44.

Fleming, M. 2005. "Patient Safety Culture Measurement and Improvement: A 'How To' Guide." *Healthcare Quarterly* 8(Special issue): 14–9.

Fleming-Carroll, B., A. Matlow, S. Dooley, V. McDonald, K. Meighan and K. Streitenberger. 2006. "Patient Safety in a Pediatric Centre: Partnering with Families." *Healthcare Quarterly* 9(Special issue): 96–101.

Ford, D. 2006. "Patient Safety: The Patient's Role." *World Hospitals and Health Services* 42(3): 45–8.

Gallagher, T.H., A.D. Waterman, A.G. Ebers, V.J.Fraser and W. Levinson. 2003. "Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors." *Journal of the American Medical Association* 289(8): 1001–7.

Koutantji, M., R. Davis, C. Vincent and A. Coulter. 2005. "The Patient's Role in Patient Safety: Engaging Patients, Their Representatives, and Health Professionals?" *Clinical Risk* 11(3): 99–104.

Lowe, C.J., D.K. Raynor, E.A. Courtney, J. Purvis and C. Teale C. 1995. "Effects of Self Medication Programme on Knowledge of Drugs and Compliance with Treatment in Elderly Patients." *British Medical Journal* 310: 1229–31.

Mireles, M.C. 2005. "The Patient in Patient Safety." *Patient Safety and Quality Healthcare* March/April. Retrieved February 4, 2008. <http://www.psqh.com/marapr05/patient.html>.

National Patient Safety Agency. 2004. *Achieving Our Aims: Evaluating the Results of the Pilot Cleanyourhands Campaign.* London: National Patient Safety Agency.

Sinnema, J. 2006, November 24. "Patient Care Errors Go Unreported." *Edmonton Journal* B5.

Stevens, P., A. Matlow and R. Laxer. 2005. "Building from the Blueprint for Patient Safety at the Hospital for Sick Children." *Healthcare Quarterly* 8(Special issue): 132–9.

Vincent, C.A. and A. Coulter. 2002. "Patient Safety: What about the Patient?" *Quality and Safety in Health Care* 11: 76–80. <http://www.qshc.bmj.com>.

Weingart, S.N., O. Pagovich, D.Z. Sands, J.M. Li, M.D. Aronson, R.B. Davis, D.W. Bates and R.S. Phillips. 2005. "What Can Hospitalized Patients Tell Us about Adverse Events? Learning from Patient-Reported Incidents." *Journal of General Internal Medicine* 20: 830–6.

World Health Organization. 2004. *Patients for Patient Safety: Statement of Case.* Geneva, Switzerland: Author. Retrieved August 16, 2007. <http://www.who.int/patientsafety/patients_for_patient/statement/en/index.html>.

Improving Patient Safety through a Multi-faceted Internal Surveillance Program

Anne Matlow, Polly Stevens, Lynn Urmson and Rick Wray

Abstract

Surveillance, a method used in epidemiology to study the incidence, distribution and control of disease, is an important means of gathering and analyzing information that can be used as needed to effect change. Surveillance has been an important component of the Blueprint for Patient Safety at the Hospital for Sick Children to identify potential and existing vulnerabilities and failures and put measures in place to avoid and mitigate any harm. Reviewing internal reports and actively seeking vulnerabilities has allowed us to make important changes to improve patient safety at the hospital. In this article, we review four internal surveillance strategies that have been particularly successful in driving change – safety reports, morbidity and mortality reviews, patient safety walkarounds and shoe leather infection control rounds – and discuss the successes and challenges we have experienced.

The Blueprint for Patient Safety at the Hospital for Sick Children (SickKids) is a 10-item road map that has guided the hospital in its active transition to a culture of safety (Stevens et al. 2005). An essential underpinning of the Blueprint is the ongoing need to identify failures, examine their contributing factors and apply the learnings to processes of care improvement and system redesign with the goal of preventing recurrences. This approach reflects two of the main characteristics of a safety culture: reporting (organizational encouragement for staff to report their errors and near misses) and learning (individuals' and groups' willingness and ability to understand and make changes based on the safety information that is provided through the system) (Reason 1997). Explicitly highlighted in the Blueprint are two key components, internal and external surveillance, that is, the search for potential and existing vulnerabilities and failures in order to put measures in place to avoid and mitigate any harm.

Surveillance, "the ongoing systematic collection, analysis and interpretation of healthcare data essential to the planning, implementation, and evaluation of public health practice,

closely integrated with the timely dissemination of these data to those contributing data or to other interested groups who need to know," is an important tool in the science of epidemiology (Horan and Gaynes 2004). The value of surveillance on process and outcome improvements makes it useful for studies beyond the standard epidemiological focus on disease.

No single method of surveillance is sensitive enough to detect all potential or true adverse events. For example, real-time record review has been more sensitive in the detection of adverse events than was incident reporting. Pharmacy surveillance found additional medication errors, and there was little overlap between the three systems (Olsen et al. 2007). Similarly, surgical site infections were identified more frequently by reviews of antibiotic records and diagnostic codes than by routine methods of surveillance of surgical site infections (Yokoe et al. 2004).

A multi-component strategy in each of the 10 blueprint elements was a key consideration in the blueprint's development. In this article, we review four strategies of internal surveillance that we have used to improve patient safety at SickKids – safety reports, morbidity and mortality (M&M) reviews, patient safety walkarounds and shoe leather infection control rounds – and discuss the successes and challenges experienced in the course of their implementation.

Safety Reporting System

Errors, near misses and adverse events are under-reported, particularly by physicians (Taylor et al. 2004). It has been proposed that clarification of the requirements of an incident report, simplification of the process and feedback to the reporters are strategies that could be used to increase reporting (Evans et al. 2006).

In May 2004, a secure web-based safety reporting system with an anonymous reporting feature was implemented at SickKids to support the reporting of potential and actual adverse events in support of our code of conduct, including issues involving patient care (e.g., medication, diagnostics, treatment), occupational health and safety issues, issues involving honesty and integrity, breaches of confidentiality and privacy, issues related to respect, issues related to parents and visitors, environmental hazards and equipment problems. This new system replaced multiple paper-based systems that were limited in their ability to generate reports and identify hospital issues and trends. The purpose of safety reporting is to generate knowledge to support system improvements and not to point fingers or find fault with the practice of individuals. This purpose is stated in a supporting safety reporting policy, which describes the process for reporting, managing and investigating adverse events including the following:

- Ensuring care of the patient, visitor or volunteer
- Ensuring care of staff members
- Creating a report
- Reviewing events – this outlines the responsibilities of the manager or director in following up the event, the responsible physician and other individuals and departments involved (e.g., pharmacy, medical engineering, occupational health)
- Providing oversight, managing the system, generating hospital-wide reports, assisting managers, highlighting reported events that require a critical occurrence review – these are responsibilities of the Quality and Risk Management Department

Features of the new safety reporting system include accessibility from all computers in the hospital, ease of reporting, immediate availability of reports to front-line managers for report resolution, identification of trends and opportunities for improvement and support of feedback to patients, families and staff in a timely manner.

Since the introduction of the safety reporting system, the rate of safety reporting has increased dramatically. Table 1 outlines the rates of reporting (adjusted to 1,000 patient-days) for all reports and for breakdowns into medication, patient and other reports. Reporting periods include the baseline year (the 12 months preceding the change) and each of the three years following system implementation. As can be seen, our rates exceed the median of 35 reports per 1,000 patient-days generated by 26 acute care centres (range nine to 95) across the United States using an electronic error reporting system, as

Table 1. Reporting Rates for total, medication, patient and other events reports

Year	Total Reports/1,000 Patient-Days	% Increase from Baseline	Medical Reports/1,000 Patient-Days	% Increase from Baseline	Patient Reports/1,000 Patient-Days	% Increase from Baseline	Other Reports/1,000 Patient-Days	% Increase from Baseline
Baseline	32.29		11.07		15.44		5.78	
Year 1	46.87	45	12.85	16	25.37	64	8.65	50
Year 2	49.17	52	13.82	25	28.39	84	6.96	20
Year 3	51.73	60	13.75	24	30.68	99	7.29	26

reported by Milch et al. (2006).

In the study by Milch et al. (2006), reports were classified as follows: 34% non-medication-related clinical, 33% medication/infusion related, 13% falls, 13% administrative and 6% other. Medication-related reports were the most common types of reports in two other studies – 47% in a study by Suresh et al. (2004) and 29% in a study by Nuckols et al. (2007). At SickKids, the most common type of report is the non-medication-related patient report at 59%, with medication-related reports making up 27%. Falls (a subset of patient reports) account for only a small percentage of reports (Table 2).

Severity codes are often applied to safety and incident reports as a measure of the potential or actual outcome of the event and are used to highlight the event's seriousness and assist in prioritization of system improvements. At SickKids, the introduction of the online system allowed for an eight-level event severity code, including two levels of near-miss events:

1. Event did not reach anyone; potential minor harm (i.e., if it had reached someone, there was potential for minor harm)
2. Event did not reach anyone; potential major harm (i.e., if it had reached someone, there was potential for major harm)
3. Event reached the person; minor or no harm resulted
4. Minor or no harm resulted; potential major harm (i.e., event reached the person – minor or no harm resulted but it could have been very serious)
5. Event resulted in extra observation or monitoring
6. Event resulted in treatment or intervention
7. Event resulted in increased length of stay
8. Event may have contributed to permanent disability or death

Events in levels five through eight are examined further through the M&M process described later.

Table 3 outlines the breakdown of events by severity code for the three years of system use and the overall average for all events and patient events. This breakdown compares with that in the Milch et al. (2006) study: 13% near miss, 67% no harm, 32% temporary harm, 0.8% life-threatening or permanent harm and 0.4% contributing to patient death. Another study reports a 25% near-miss rate (Taylor et al. 2004).

Table 2. Percentage of total reports by report type

Year	Medical Reports	Patient Reports	Patient Fall Reports	Other Reports
Baseline	34	48	–	18
Year 1	27	54	2.2	18
Year 2	28	58	1.9	14
Year 3	27	59	1.5	14

Absolute numbers are not the goal of a safety reporting system. The goal is, rather, the identification of areas for improvement.

Examples of Improvements Resulting from Safety Reporting

"As long as the system receives sufficient reports to identify the main safety issues, the absolute number of reports is not critical; however, to achieve this staff do have to be encouraged to report and to communicate their concerns" (Vincent 2006). As Vincent notes, absolute numbers are not the goal of a safety reporting system. The goal is, rather, the identification of areas for improvement. At SickKids, numerous improvements have resulted from the reporting of actual and potential events, including the following examples:

- Safety reports alerted us to inconsistent practices in intravenous (IV) fluid administration. In a few instances, patients were burned when IV fluid bags warmed in a microwave were used. Following reporting, a new product was purchased that was able to provide the optimal level of warmth without overheating.

Table 3. Severity for all reports and patient reports

	Near Miss, Potential Harm Codes 1 and 2		No or Minor Harm Codes 3 and 4		Moderate Harm Codes 5–7		Severe Harm Code 8	
Year	All Reports (%)	Patient Reports (%)	All Reports (%)	Patient Reports (%)	All Reports (%)	Patient Reports (%)	All Reports (%)	Patient Reports (%)
Year 1	1,135 (27)	612 (27)	2,710 (65)	1,494 (65)	297 (7.2)	187 (8.2)	1 (0.02)	1 (0.04)
Year 2	1,143 (26)	628 (25)	2,787 (64)	1,608 (64)	410 (9.4)	290 (11.5)	2 (0.05)	2 (0.08)
Year 3	1,014 (24)	617 (23)	2,760 (64)	1,749 (64)	535 (12.4)	370 (13.5)	1 (0.02)	1 (0.04)
Total	3,292 (26)	1,857 (25)	8,257 (65)	4,851 (64)	1,242 (11.2)	847 (11.2)	4 (0.03)	4 (0.04)

- A report of a patient who locked the door to his room to avoid medication administration led to an audit that identified other patient care areas with lockable doors, ultimately leading to the disengagement of inappropriate locking devices.
- A report on potential patient harm following the inadvertent flushing of an IV with concentrated potassium chloride instead of normal saline led to the widespread removal of this product from the nursing units and the purchase of premixed potassium solutions.
- Safety reports related to construction debris flying off our roof in high winds led to the implementation of a roof surveillance process and the notification of facility staff when third-party contractors require access to the roof.

M&M Reviews

M&M reviews are another important component of internal surveillance at SickKids. Historically, M&M reviews served as a form of physician peer review, but they have evolved over the years to focus on teaching and improvements in patient care.

At SickKids there is a defined process to ensure multidisciplinary and timely reviews of patient deaths and morbidity events to ensure that the care provided was appropriate and to identify opportunities for improvements in care processes and systems. Mortality events are deaths. Morbidity events are defined as "an untoward event or complication which, under optimal conditions, is not a natural consequence of the patient's disease or treatment" (Craddick and Bader 1983).

All clinical divisions within the hospital are responsible for conducting monthly M&M reviews of all deaths and significant morbidity events and submitting minutes to the Hospital M&M Review Committee. More recently, divisions were also charged with reviewing all code blue calls (cardiac or respiratory arrests) and safety reports specific to the division with severity codes of four (minor or no harm; potential major harm) through eight (may have contributed to permanent disability or death). The Hospital M&M Review Committee provides oversight for the M&M review process at SickKids by monitoring the adequacy of M&M review processes in each division. This hospital committee is responsible for identifying hospital-wide issues and trends, making recommendations regarding issues arising from M&M reviews and monitoring and reporting compliance with the M&M policy.

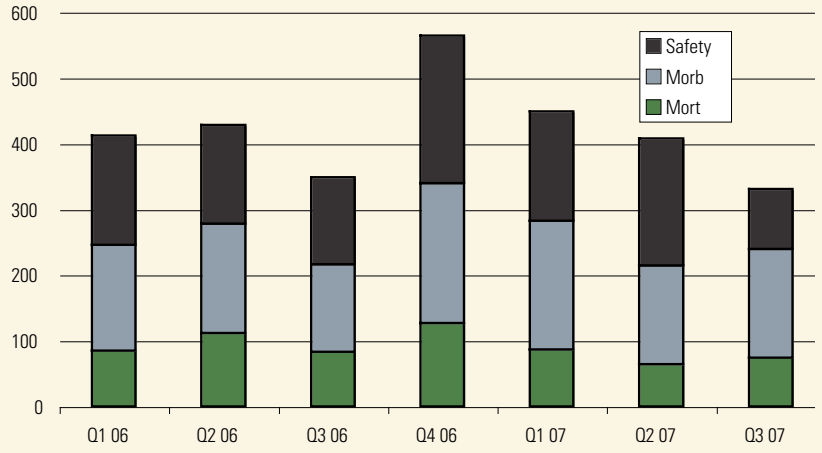
In January 2006 an electronic database was established to track all M&M reviews and targeted safety reports. Figure 1 shows the quarterly summary of these reviews. In the 21 months since this detailed record keeping was initiated, almost 3,000 reviews have been logged. It should be noted that for each death there are often multiple reviews, reflecting the involvement of a number of services and divisions.

No single method of surveillance is sensitive enough to detect all potential or true adverse events.

Examples of Improvements Resulting from M&M Reporting

Numerous local improvements in the quality and safety of care occur as a result of M&M reviews. In addition, a number of hospital-wide issues have been addressed or supported as a result of M&M reporting trends. Issues brought to our attention through this process included (1) problems with timely IV access for patients, following reorganization of resources within the hospital (the issue was reviewed and resources realigned to improve service) and (2) instances of wrong site procedures (which resulted in the timely implementation of a correct procedure/patient/site policy and practice).

Figure 1. Quarterly summary of the M&M reviews and targeted safety reports



Patient Safety Walkarounds

Patient Safety Leadership WalkRounds as first described by Frankel et al. (2003) engaged a core group of leaders, including senior executive and vice-presidents, who visited different areas of the hospital weekly involving local staff in discussions about recent safety events and the contributing factors involved. Data were recorded, entered into a database, analyzed and used to target improvement efforts. After two years of WalkRounds, 1,433 comments from 233 sessions had been reported: 30%

were related to equipment, 13% to communications, 7% to pharmacy and 6% to workforce (Frankel et al. 2005). Although WalkRounds were identified as "effective tool[s] for engaging leadership, identifying safety issues, and supporting a culture of safety," committed leadership and resources available for data management were identified as critical success factors (Frankel et al. 2005).

At Johns Hopkins, the ongoing collaboration between executives and clinical units was established differently. Individual executive members "adopted" an intensive care unit and worked with staff to identify and address patient safety issues (Pronovost et al. 2004). The approach has proven useful in enhancing executive awareness and improving staff trust, as well as in expediting action on issues of concern.

From November 2004 through December 2005, we conducted 15 leadership safety walkarounds (LSWs) in which one or two executive members, quality analysts and the medical director of patient safety visited areas throughout the hospital inquiring about patient and staff safety. Following these 15 LSWs, members of the executive were interviewed to see if they considered LSWs to be a value-added activity. The executive members agreed that LSWs represent an important opportunity for members of senior management to visibly demonstrate their commitment to safety at the hospital. A major deficiency identified was the ambiguous assignation of responsibility for issues raised and the lack of mechanism for prioritization and follow-up. Without adequate follow-up, there was concern that the entire process would lose credibility. In addition, focusing on both staff and patient safety was felt to detract from patient issues, making the recommendations too diffuse and extensive.

On reflection, we realized that no formal mechanism of educating clinical directors about the LSWs had occurred and that we lacked hospital-wide buy-in. As a result, a number of changes were made. A presentation was made to the directors, giving them a chance to voice their concerns. We amended the focus of the rounds to patient safety only and renamed them patient safety walkarounds (PSWs). Going forward, we decided that, although we would record all issues arising, two or three issues would be identified for action and have responsibility assigned. Since that time, after a PSW, a summary of the round has been forwarded to the attendees, with action items highlighted and the responsible person noted. A database has been developed and, recently, responsibility for data entry and analysis has been assigned.

Without adequate follow-up,
there was concern that the entire process would lose credibility.

Since January 2006, we have performed and analyzed 15 PSWs, 13 in clinical areas and two in non-clinical areas (pharmacy and medical engineering). Table 4 summarizes the categories of concerns raised and the types of concerns prioritized for improvement. As expected, the concerns in the clinical and non-clinical areas differed.

To date, improvements made as a result of PSWs include modifying light cords to minimize the risk of strangulation; highlighting the correct person, site and procedure policy outside the operating room; installing an emergency telephone in the occupational therapy gym; and acquiring a walkie-talkie system for communication in the large post-operative recovery suite. Most of the recommendations have now been entered into the database, which should facilitate ongoing follow-up.

Table 4. Categories of issues raised during patient safety walkarounds

Main Categories	Clinical Areas: No. of Issues Raised	Clinical Areas: No. of Action Items	Non-clinical Areas: No. of Issues raised	Non-clinical Areas: No. of Action Items
Equipment	18	6	5	2
Environment	16	4		
Access/beds	9	4		
Care/coordination	9	4		
Infection control	4			
Human resources			3	
Information technology			4	3
Documentation			1	1
Other	11	12	8	
Total	67	30	21	6

Shoe Leather Infection Control Rounds

Recent evidence suggests that, annually, approximately 8% of children and 10.5% of adults hospitalized in Canada acquire an infection (Gravel et al. 2007a, 2007b), amounting to 220,000 nosocomial infections and 8,000 excess deaths per year (Zoutman et al. 2003). Over two decades ago, Hozman used the term *shoe leather surveillance* to describe

monthly hospital tours conducted by members of the infection control committee (1983). Subsequently, Weems (1996) reported on a "shoe leather" approach he initiated in which the entire infection control team regularly visited selected clinical areas and reviewed patients in isolation or who had antibiotic-resistant organisms, as well as ad hoc practice-related issues. The perceived benefits of the rounds were the opportunities for education, real-time feedback and intervention and collaboration. Although electronic health records and computerized microbiology and pharmacy records have the potential to make walkaround surveillance obsolete, the opportunity to liaise face to face with front-line staff offers many of the advantages described above for PSWs.

The infection control audit is another shoe leather technique that complements routine surveillance practices. By searching for practices that breach infection prevention and control standards, measures can be taken pre-emptively to avoid the development of nosocomial infections. In Vancouver, Bryce and colleagues have developed an audit process incorporating a review of the physical layout and protocols and policies, an assessment of healthcare workers' knowledge of infection control principles and a review of workplace practices (Bryce et al. 2007). Others have used an audit process to assess the efficacy of environmental cleaning (Malik et al. 2003).

Harkening to Weems's (1996) "A Plea from the Sole: Let's Keep the 'Shoe Leather' in Healthcare Epidemiology," we initiated shoe leather infection control rounds, fondly known as *SLIC rounds* in June 2006; by October 2007, we had done 14 rounds. All members of the infection prevention and control team who are available at the scheduled time, including trainees, participate. It is thus an opportunity for observing and teaching, real-time feedback and facilitation of improvement activities. SLIC rounds are pre-scheduled. As a rule, a manager or other staff member in the area under review accompanies our group. However, the topic for the round is not necessarily geographically based; it may instead be thematic, for example, the status of the breast pump rooms, availability of hand hygiene dispensers or posted list of reportable communicable diseases. Soon after the completion of a round, a summary of recommendations is forwarded to the manager – on average, there are 10 recommendations (range two to 52). The following are the most commonly identified issue topics:

- Appropriate placement, installation and maintenance of waterless gel
- Hand hygiene and respiratory etiquette signage
- Storage of supplies and equipment
- Use of corrugated cardboard in high-risk patient care areas
- Presence of food in patient care areas
- Expiry of supplies

We estimate that approximately 75% of the recommendations have been effected to date, although an item-by-item follow-up by the infection control team is not carried out. SLIC rounds are collaborative exercises in which we share our expertise with the front-line people responsible for patient care. Done in the spirit of improvement, we feel these rounds are collegial and perceived as being less "top down" than other audits. They also afford each infection control practitioner an opportunity to apprise the other teammates of issues of concern in their area of coverage, thus creating a learning opportunity. A telling sign of the success of these rounds has been the voluntary participation of at least two infection control practitioners on each SLIC round.

Our multi-faceted internal surveillance program has demonstrated to us that the detection of hazards and vulnerabilities in hospitals is enhanced when multiple strategies are used.

Discussion

Our multi-faceted internal surveillance program has demonstrated to us that the detection of hazards and vulnerabilities in hospitals is enhanced when multiple strategies are used. We were able to identify issues with some processes (e.g., communication in the post-operative recovery suite) that would not have been picked up through the other reviews. In our hands, the combination of both active surveillance (trained personnel vigorously looking, i.e., the PSWs and SLIC rounds) and passive surveillance (the reviewing of reports submitted by others, i.e., safety reports and M&M reviews) maximized the detection of potential or real safety hazards or events and provided more opportunities to effect change. Furthermore, the types of active surveillance we used facilitated real-time input and remediation, which contrasts the response to events identified by retrospective review.

In considering what surveillance strategies best suit the needs of a given healthcare environment, it is important to recognize that analysis and feedback of the data are integral components of surveillance and necessary to improve patient safety. With the assumption that the collection of any relevant data can inform improvements and influence patient outcomes, we recommend asking the following questions when deciding what surveillance strategy(s) to undertake:

- What is the scope of vulnerabilities that we are interested in? For example, are we interested in all hazards or in select ones (e.g., medication related)? and do we want hospital-wide data or data from one area only (e.g., intensive care unit)?
- Have we sought stakeholder input? For example, are the executives prepared to do PSWs?

Table 5. Attributes of various surveillance methodologies

	Safety Reporting System	Morbidity and Mortality Review	Patient Safety Walkarounds	Shoe Leather Infection Control Rounds
Scope of vulnerabilities detected	Hospital wide, all hazards	Hospital wide, all hazards	Hospital wide, all hazards	Hospital wide, infection control hazards only
Real-time data collection and analysis	No	No	Yes	Yes
Retrospective data analysis	Yes	Yes	No	No
Personnel requirement	Input by personnel throughout hospital, data analyzer needed	Committee	Small team including executive member	Infection control practitioner(s) and unit director
Information technology requirement	Not necessary but facilitates input and analysis	Not necessary but facilitates tracking of actions arising	Not necessary but facilitates tracking of actions arising	Not necessary but facilitates tracking of actions arising

- Are certain data collections mandated (i.e., by hospital policy, accreditation or legislation)?
- Do we plan to collect the data in real time (which facilitates timely intervention but is time consuming) or retrospectively (which is good for trend analysis and can be collected when convenient)?
- What resources (personnel, content expertise, information technology, finances, etc.) are or can be made available to us for data collection, analysis, feedback and improvement? Can we leverage the resources of another department (e.g., get data regarding medical equipment from medical engineering)?
- What methods of surveillance will we be able to sustain over time?

Table 5 applies many of these considerations to the four methods of surveillance we use at SickKids.

Our experience is consistent with that of other investigators, who highlight the importance of follow-up and feedback to ensure practice and process improvement and sustain credibility in the institution's commitment to a culture of safety. In this context, follow-up includes prioritizing opportunities and actions, assigning responsibility and accountability and implementing the action plan; and feedback facilitates closing the loop, responding to those who reported the issue and communicating to the rest of the hospital staff and clinicians about the events and actions taken (Ghandi et al. 2005). A critical success factor is the ability to efficiently track issues and provide timely feedback. As noted by Ghandi et al., "Developing and maintaining a systematic method for feedback represents more of a challenge than the completion of any single recommended action item; however, it is the feedback to the reporter that perpetuates the influx of information and closes the loop" (2005).

The sustainability of any of these strategies is influenced by their real (e.g., fulfilling a legislative requirement) and perceived (e.g., executive becomes engaged in PSWs) values, which may subsequently affect the resources allocated. All strategies work best within a culture of safety, where a sense of justice and fairness prevails and where healthcare workers do not fear "shame and blame" if they report a hazard or mishap (Senge 2006). A culture of safety thrives best in a learning organization "where people continually expand their capacity to create the results they truly desire, where new and expansive patterns of thinking are nurtured, where collective aspiration is set free, and where people are continually learning how to learn together" (Connor et al. 2007). However, even in its absence, surveillance for hazards can actually foster a culture of safety if the data heighten awareness and lead to change. Data derived through surveillance activities will likely reveal problems with the system rather than with particular individuals. Indeed system improvements are the key to safer healthcare. HQ

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References

Bryce, E.A., S. Scharf, M. Walker and A. Walsh. 2007. "The Infection Control Audit: The Standardized Audit as a Tool for Change." *American Journal of Infection Control* 35(4): 271–83.

Connor, M., D. Duncombe, E. Barclay, S. Bartel, C. Borden, E. Gross, C. Miller and P.R. Ponte. 2007. "Creating a Fair and Just Culture: One Institution's Path toward Organizational Change." *Joint Commission Journal on Quality and Patient Safety* 33(10): 617–24.

Craddick, J.W. and B.S. Bader. 1983. *Medical Management Analysis, A Systematic Approach to Quality Assurance and Risk Management* (Vol. I). Auburn, CA: JW Craddick.

Evans, S.M., J.G. Berry, B.J. Smith, A. Esterman, P. Selim, J. O'Shaughnessy and M. DeWit. 2006. "Attitudes and Barriers to Incident Reporting: A Collaborative Hospital Study." *Quality and Safety in Health Care* 15(1): 39–43.

Frankel, A., E. Graydon-Baker, C. Neppl, T. Simmonds, M. Gustafson and T.K. Gandhi. 2003. "Patient Safety Leadership WalkRounds." *Joint Commission Journal on Quality and Safety* 29(1): 16–26.

Frankel, A., S.P. Grillo, E.G. Baker, C.N. Huber, S. Abookire, M. Grenham, P. Console, M. O'Quinn, G. Thibault and T.K. Gandhi. 2005. "Patient Safety Leadership WalkRounds at Partners Healthcare: Learning from Implementation." *Joint Commission Journal on Quality and Patient Safety* 31(8): 423–37.

Friedman, J.N., M.S. Pinard and R.M. Laxer. 2005. "The Morbidity and Mortality Conference in University-Affiliated Pediatric Departments in Canada." *Journal of Pediatrics* 146(1): 1–2.

Gandhi, T.K., E. Graydon-Baker, C.N. Huber, A.D. Whittemore and M. Gustafson. 2005. "Closing the Loop: Follow-Up and Feedback in a Patient Safety Program." *Joint Commission Journal on Quality and Patient Safety* 31(11): 614–21.

Gravel, D., A. Matlow, M. Ofner-Agostini, M. Loeb, L. Johnston, E. Bryce, M.L. Sample, V.R. Roth, C. Goldman, G. Taylor and the Canadian Nosocomial Infection Surveillance Program. 2007a. "A Point Prevalence Survey of Health Care-Associated Infections in Pediatric Populations in Major Canadian Acute Care Hospitals." *American Journal of Infection Control* 35(3): 157–62.

Gravel, D., G. Taylor, M. Ofner, L. Johnston, M. Loeb, V.R. Roth, J. Stegenga, E. Bryce and the Canadian Nosocomial Infection Surveillance Program. 2007b. "Point Prevalence Survey for Healthcare-Associated Infections within Canadian Adult Acute-Care Hospitals." *The Journal of Hospital Infection* 66(3): 243–8.

Horan, T.C. and R.P. Gaynes. "Surveillance of Nosocomial Infections." In C.G. Mayall, ed., *Hospital Epidemiology and Infection Control* (3rd ed). Philadelphia, PA: Lippincott Williams and Williams.

Hozman, S. 1983. "Shoe Leather Surveillance: Monthly Hospital Tours Conducted by Infection Control Committee Members." *American Journal of Infection Control* 11(3): 34A–5A.

Malik, R.E., R.A. Cooper and C.J. Griffith. 2003. "Use of Audit Tools to Evaluate the Efficacy of Cleaning Systems in Hospitals." *American Journal of Infection Control* 31(3): 181–7.

Milch, C.E., D.N. Salem, S.G. Pauker, T.G. Lundquist, S. Kumar and J. Chen. 2006. "Voluntary Electronic Reporting of Medical Errors and Adverse Events. An Analysis of 92,547 Reports from 26 Acute Care Hospitals." *Journal of General Internal Medicine* 21(2): 165–70.

Nuckols, T.K., D.S. Bell, H. Liu, S.M. Paddock and L.H. Hilborne. 2007. "Rates and Types of Events Reported to Established Incident Reporting Systems in Two US Hospitals." *Quality and Safety in Health Care* 16(3): 164–8.

Olsen, S., G. Neale, K. Schwab, B. Psaila, T. Patel, E.J. Chapman and C. Vincent. 2007. "Hospital Staff Should Use More than One Method to Detect Adverse Events and Potential Adverse Events: Incident Reporting, Pharmacist Surveillance and Local Real-Time Record Review May All Have a Place." *Quality and Safety in Health Care* 16(1): 40–4.

Pronovost, P.J., B. Weast, K. Bishop, L. Paine, R. Griffith, B.J. Rosenstein, R.P. Kidwell, K.B. Haller and R. Davis. 2004. "Senior Executive Adopt-a-Work Unit: A Model for Safety Improvement." *Joint Commission Journal on Quality and Safety* 30(2): 59–68.

Reason, J. 1997. *Managing the Risks of Organizational Accidents.* Brookfield, VT: Ashgate.

Senge, P.M. 2006. *The Fifth Discipline: The Art and Practice of the Learning Organization.* New York: Doubleday.

Stevens, P., A. Matlow and R. Laxer. 2005. "Building from the Blueprint for Patient Safety at the Hospital for Sick Children." *Healthcare Quarterly* 8: 132–9.

Suresh, G., J.D. Horbar, P. Plsek, J. Gray, W.H. Edwards, P.H. Shiono, R. Ursprung, J. Nickerson, J.F. Lucey and D. Goldmann. 2004. "Voluntary Anonymous Reporting of Medical Errors for Neonatal Intensive Care." *Pediatrics* 113(6): 1609–18.

Taylor, J.A., D. Brownstein, D.A. Christakis, S. Blackburn, T.P. Strandjord, E.J. Klein and J. Shafii. 2004. "Use of Incident Reports by Physicians and Nurses to Document Medical Errors in Pediatric Patients." *Pediatrics* 114(3): 729–35.

Vincent, C. 2006. *Patient Safety.* Edinburgh: Churchill Livingston, Elsevier Ltd.

Weems, J.J., Jr. 1996. "A Plea from the Sole: Let's Keep the 'Shoe Leather' in Healthcare Epidemiology." *Infection Control and Hospital Epidemiology* 17(1): 42–3.

Yokoe, D.S., G.A. Noskin, S.M. Cunningham, G. Zuccotti, T. Plaskett, V.J. Fraser, M.A. Olsen, J.I. Tokars, S. Solomon, T.M. Perl, S.E. Cosgrove, R.S. Tilson, M. Greenbaum, D.C. Hooper, K.E. Sands, J. Tully, L.A. Herwaldt, D.J. Diekema, E.S. Wong, M. Climo and R. Platt. 2004. "Enhanced Identification of Postoperative Infections among In-Patients." *Emerging Infectious Diseases* 10: 1924–30.

Zoutman, D.E., B.D. Ford, E. Bryce, M. Gourdeau, G. Hébert, E. Henderson and S. Paton; Canadian Hospital Epidemiology Committee, the Canadian Nosocomial Infection Surveillance Program and Health Canada. 2003. "The State of Infection Surveillance and Control in Canadian Acute Care Hospitals." *American Journal of Infection Control* 31(5): 266–72.

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Safe Medication Swallowing in Dysphagia: A Collaborative Improvement Project

Lawrence D. Jackson, Jane Little, Edward Kung, Evelyn M. Williams, Krystyna Siemiatkowska and Suzanne Plowman

Abstract

Episodes of choking during medication administration to patients with dysphagia prompted a chart audit and caregiver interview to identify system problems that allowed inappropriate drug administration to occur. Sixty elderly patients residing on two patient care areas in a 500-bed complex continuing care facility were studied. The audit explored the actual nursing medication administration methods and compared this to the information obtained from various communication tools including instructions that appeared on the medication administration record (MAR), the current diet order, the recommendations of the speech-language pathologist (SLP) and comments on the nursing care plan. The audit yielded a number of discrepancies between nursing actions and the instructions obtain from these sources.

We proposed that changes to the process of communicating medication swallowing recommendations among team members would lead to greater patient safety. Major practice changes included the use of standardized language by the SLP when making recommendations, the writing of SLP recommendations in the doctor's orders, the inclusion of SLP recommendations on the MAR and the creation of a "dysphagia alert" on the pharmacy computer system. An educational intervention was conducted to implement process changes. Its effectiveness was evaluated using a pre- and post-test and a participant satisfaction survey. A post-implementation audit showed compliance with the practice change.

In summary, process changes were implemented to improve compliance with SLP medication-related swallowing recommendations and to prevent the inadvertent prescribing, dispensing or crushing of sustained-release medications in patients with dysphagia.

Patients with dysphagia (swallowing difficulty) are at risk when a modification of the medication dosage form is not appropriately carried out and are at risk for adverse drug events caused by the inappropriate modification of the dosage form through the crushing of a tablet or capsule that should not be crushed. This article describes the extent of inappropriate medication administration identified in a population of elderly patients with dysphagia, contributing factors and the steps taken to ensure appropriate administration.

Dysphagia occurs commonly among residents living in long-term care facilities (LTCFs) (O'Brien and Barrow 1991; Trupe and Siebens 1984) and has been generally shown to be higher in LTCFs (ranging from 31.0 to 65.9%) than in the general community (16.6% of individuals aged 87 and older) or in hospitals (12 to 13%) (Bloem et al. 1990; Groher and Bukatman 1986; Layne et al. 1989; Smithard 1996; Trupe and Siebens 1984). Many LTCF residents have illnesses causing dysphagia, including neurological and neuromuscular diseases, structural changes in the oropharynx, salivary changes and psychological illness (Sonies 1992). Impaired swallowing can lead to a number of serious consequences, such as aspiration, upper airway obstruction, malnutrition, dehydration and increased mortality (Hudson et al. 2000; Palmer and Drennan 2000; Siebens et al. 1986). Therefore, the act of swallowing places the patient with dysphagia at risk. To ensure safety during oral medication administration, patients with dysphagia require an appropriate oral dosage form or modification of the dosage form. Nurses may also modify medications according to patient preference, even if there is no difficulty with swallowing food. However, certain modifications are undesirable, such as the crushing of enteric-coated or sustained-release tablets, and can lead to adverse events. Examples of such adverse events include opioid overdose occurring when sustained-release morphine products are crushed, abnormal movements occurring when sustained-release levodopa-carbidopa is crushed and the loss of efficacy of medications such as omeprazole, which are destroyed by stomach acid when crushed (Cornish 2005; Wright 2002a, 2002b).

Effective communication among healthcare professionals within the hospital is required to safeguard patients with dysphagia. Our aim was to promote appropriate drug administration in patients with dysphagia through improved communication among caregivers and to in turn reduce the likelihood of swallowing-related adverse events. Since it would be difficult to track actual swallowing-related adverse events, our primary outcome was adherence to process changes. This article describes the implementation and evaluation of process improvements designed to ensure appropriate and safe medication administration in patients with dysphagia.

Description of the Problem

Choking episodes and instances of inappropriate administration of medications to dysphagic patients have been reported in our hospital sporadically but have not been systematically quantified, nor have individual events been correlated with specific patient outcomes. However, based on the premise that inappropriate drug administration in patients with dysphagia (i.e., the crushing of sustained-release or enteric-coated tablets or the administration of oral medications with water) is undesirable and may be associated with adverse events (e.g., choking episodes, adverse drug reactions resulting from the immediate release of drug from a sustained-release product, refusal to take medications), implementation of procedures that limit the chance of this occurring should improve patient safety. Root-cause analysis revealed that a lack of awareness of dysphagia, due to poor communication practices among the healthcare team members, contributed to inappropriate medication administration in these patients. A systems improvement was implemented to remedy the problem.

Background and Rationale

In our facility, the speech-language pathologist (SLP) assesses patients with dysphagia and recommends the most appropriate diet texture (food and liquid components) as well as any modifications to oral medications that are required to promote safe swallowing. Communication of this information occurs through a consult note in the chart. However, existing procedures provided no assurance that the pharmacist reads this note or that the nurse relays SLP recommendations regarding medication swallowing to the pharmacy. Because nurses use a pharmacy-generated medication administration record (MAR), they routinely requested that the pharmacy add messages to the "comments" section of the MAR related to swallowing or other concerns; however, this occurred inconsistently. Another potentially unsafe practice involved the switching of solid medications to a liquid form, prior to receiving specific SLP recommendations, for patients who developed acute dysphagia. This was deemed unsafe since the patient may have difficulty with both solids and liquids.

Due to the occurrence of medication swallowing–related problems and the inconsistency with which information was being relayed to the pharmacy, existing communication procedures between the nurse, pharmacist, physician and SLP were examined and new processes were designed and implemented to address the problem (Coles et al. 2005; Wreathall and Nemeth 2004).

Methods

Using a quality improvement framework (Institute for Healthcare Improvement 2007), we studied existing communication procedures used to convey medication swallowing–related concerns among the healthcare team and the method used by nurses to administer oral medication in patients with

dysphagia. The study sample included patients residing on two complex continuing care units of a 500-bed LTCF affiliated with a tertiary acute care hospital. We conducted a chart and MAR audit, interviewed the primary nurse for each patient and compared SLP recommendations with actual nursing practice, and examined the extent to which SLP recommendations appeared on various documents (Table 1).

For the purposes of this study, dysphagia was defined by the presence of a modified texture diet order on the patient's chart. Modified diet orders included various food textures (pureed, minced and chopped), three graduated levels of thickened liquids (nectar-thick, honey-thick and pudding-thick) and "no mixed consistencies" (foods containing both solid and liquid components combined, such as vegetable soup). It was anticipated that patients with these diet orders would require the nurse to modify the medication (e.g., crushing or halving tablets, mixing crushed or whole tablets in food or opening capsules and mixing the powder in food) prior to administration to facilitate safe swallowing. Patients receiving gastric tube feeding and designated nothing by mouth, or NPO, are considered to have dysphagia but are not routinely seen by the SLP and were not included in the analysis. Key components of the audit included the current diet order, the presence of SLP medication swallowing recommendations on the MAR and nursing Kardex and the presence of SLP medication swallowing recommendations on the chart (i.e., consult note). These documents represent the primary means of communicating medication administration instructions among nurses and between the various stakeholders (i.e., nurse, pharmacist, physician and SLP).

The results of the audit were used to design a new communication process and stakeholder responsibilities. The implementation of process changes was supported by education sessions, which were evaluated using pre- and post-education test of knowledge. General dissemination to nursing staff throughout the hospital was conducted through an education campaign using teams composed of a nurse educator, pharmacist and SLP. Two years after the implementation, we conducted a follow-up audit on the original study units to evaluate the sustainability of the process change (see Table 1). Patient consent to participate was not obtained due to the quality improvement nature of this initiative and because the improved communication process was applied to all patients with dysphagia in the study group.

The initial audit revealed an inefficient and ineffective communication process that resulted in inappropriate medication administration in a significant number of patients with dysphagia.

Results and Interpretation of the Initial Audit

Results of the initial audit conducted in August 2003 are presented in Table 1. Although we anticipated that all patients with dysphagia would receive medications in a modified form, this occurred in only 15 of 22 (68%) of the cases. The other patients with dysphasia received medications with water – a potentially unsafe practice. When the various communication documents were examined, SLP medication swallowing recommendations were present on the MAR for 68% and on the Kardex for 5% of the patients with dysphagia. An SLP consult note was present on only 55% of the charts. Consult notes had been relocated to an archival chart in the remaining cases.

When information from the nursing interview regarding the actual medication administration method (nursing action) was compared with the various communication documents, the nurses' actions agreed with the MAR, Kardex and SLP consult note in 100%, 100% and 66% of the cases, respectively. When we examined the extent to which the nurses modified medication based upon whether the patient was receiving a modified texture diet, a 45% correlation was found. A review of

Table 1. Initial and post-intervention audit

Parameter	Initial Audit, August 2003	Post-intervention Audit, June 2005
No. of patients	60	63
Patients with dysphagia	22 (37%)	25 (40%)
MAR comments exist	15/22 (68%)	23/25 (92%)
SLP recommendations on chart	12/22 (55%)	21/23 (91%)
SLP recommendations on Kardex*	1/22 (5%)	N/A
MAR comment agrees with SLP recommendations	8/12 (66%)	23/25 (92%)
Nursing intervention† agrees with MAR comments	15/15 (100%)	21/23 (91%)
Nursing intervention† agrees with SLP recommendations	8/12 (66%)	23/25 (92%)
Nursing intervention† agrees with the diet order	10/22 (45%)	24/25 (96%)
Pharmacy computer has "dysphagia alert"	None	100%

MAR comments = speech-language pathologist (SLP) recommendations entered into the "comments" section of the medication administration record (MAR); N/A = not applicable.

*Kardex = customary care document.

†Nursing intervention = any action to modify a medication to facilitate swallowing.

SLP consult notes revealed that recommendations for swallowing solid oral medications were present, but recommendations regarding the administration of liquid medications were absent.

In summary, the initial audit revealed an inefficient and ineffective communication process that resulted in inappropriate medication administration in a significant number of patients with dysphagia. The documents that nurses relied on for guidance at the time of medication administration did not reliably contain SLP recommendations, and, in many instances, the recommendations had been removed from the current chart. The existence of a modified diet texture order alone did not ensure that medications would be modified prior to administration. However, we did observe that nursing actions consistently agreed with the MAR, a correlation that became central in our process redesign.

Table 2. Key process changes

- SLP to use standard phrases to make medication-related swallowing recommendations
- SLP recommendations to be written on the doctor's order sheet (pharmacy automatically receives copies of the doctor's order sheet)
- SLP to include recommendations for both solid and liquid oral medications
- Pharmacist to enter SLP recommendations in "comments" section of MAR
- Pharmacist to enter a "dysphagia alert" in the pharmacy computer system

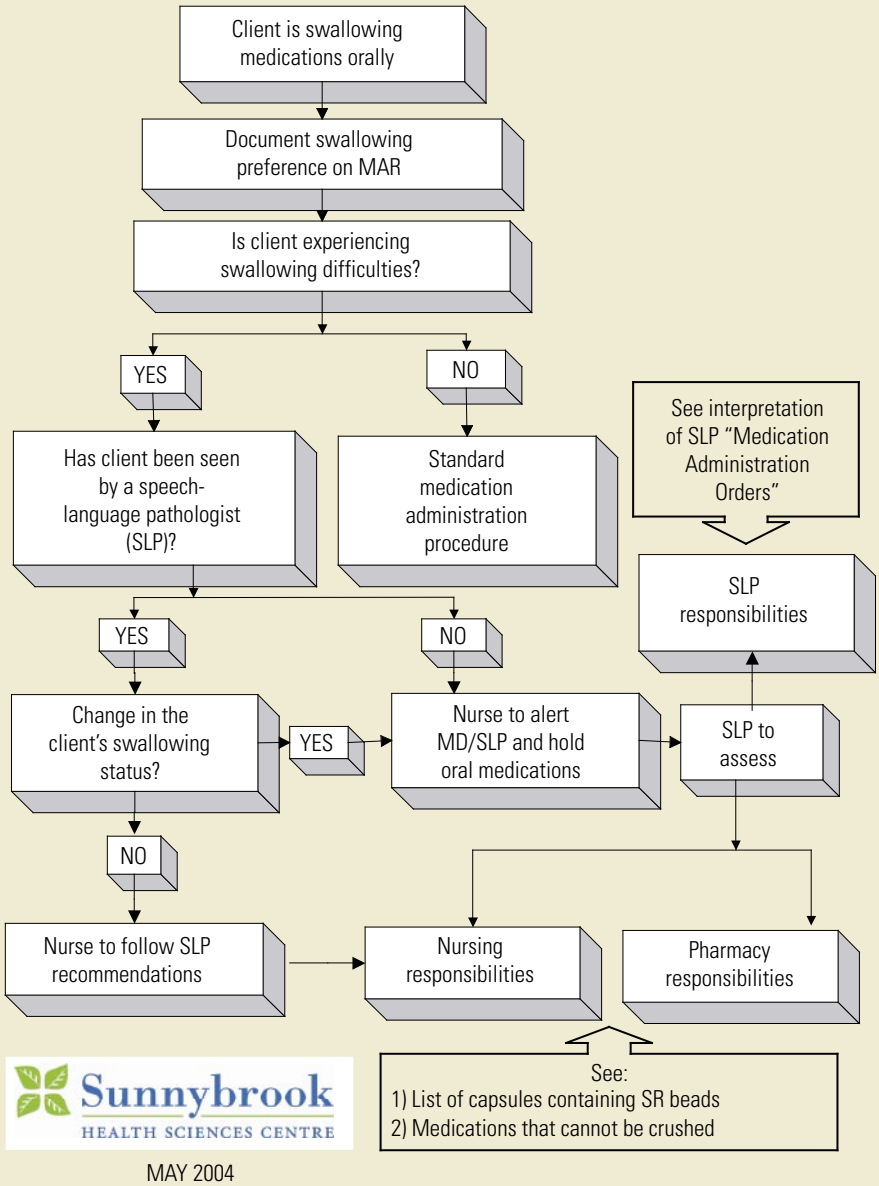
MAR = medication administration record; SLP = speech-language pathologist.

Interventions

Process Redesign and Stakeholder Responsibilities

The new process design is summarized in the Safe Medication Swallowing in Dysphagia algorithm (Figure 1 and Table 2). Changes included the placement of SLP swallowing recommendations in the comments section of the MAR (Figure 2). This ensures that SLP recommendations are available to the nurse at the time of medication administration. The SLPs agreed to write their medication swallowing recommendations for both solid and liquid medications using standard phrases. These are to be written on the doctor's order sheet in addition to the consult note. The pharmacy automatically receives all copies of the doctor's order sheet, making this a shared communication document that fulfills a key aspect of our process redesign. The pharmacists enter

Figure 1. Safe Medication Swallowing in Dysphagia



MAR = medication administration record; SR = sustained release.

Source: Reproduced with permission from Sunnybrook Health Sciences Centre.

the SLP recommendations in the comments section of the MAR and flag the computer profile with a "dysphagia alert" (Figure 3). With this change, pharmacists entering medication orders must acknowledge the pop-up alert before proceeding. This feature enables the pharmacist to contact the physician promptly to discuss the most appropriate dosage form that the patient can safely swallow. The alert feature has been used previously for allergies, but this was its first application for dysphagia.

The nurse is responsible for monitoring patients closely during medication administration and notifying the physician and SLP if a change in swallowing status occurred.

SLP Standard Phrases and Other Resources

To avoid misinterpretation of SLP instructions, a common language, in the form of standard phrases, was created for use by the SLP when describing specific modifications to solid or liquid medications (Tables 3 and 4). Other resource materials included lists of medications that should not be crushed and medications available as sustained-release beads within a capsule, which can be opened but not crushed. All these documents were placed in the MAR binder for easy access.

Figure 2. "Comments" section of the medication administration record

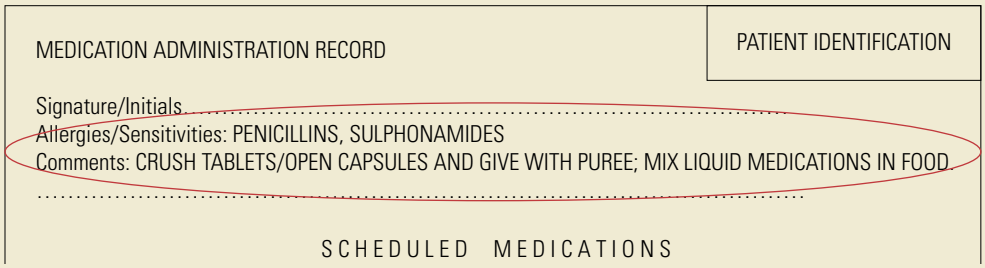
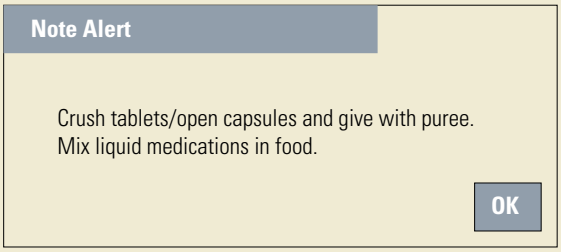


Figure 3. Pharmacy computer system alert pop-up screen showing the dysphagia alert message



Education and Process Spread

The process changes and stakeholder responsibilities were disseminated through a formal education campaign delivered during staff meetings of the respective stakeholders (Table 5). Dissemination to nursing staff was conducted via unit in-services and the posting of supporting documents on units and on the hospital intranet. The effectiveness of the initial nursing education sessions was evaluated using a written pre- and post-education knowledge test. (The test is available from the authors.) The test examined knowledge of diet textures, types of dosage forms that should not be crushed and stakeholder responsibilities. Participants were asked to complete a feedback form to determine satisfaction with these education sessions. The average knowledge score of 60% improved to 80% after the in-service. Average satisfaction score for the educational sessions was 4.5 out of 5.

Table 3. Medication administration orders for tablets and capsules in dysphagia

Standard Phrases*	Typical Diet Order	Interpretation of Standard Phrases
Crush tablets finely/open capsules and mix into a small amount of pureed food	Pureed†	Requires a uniform smooth texture (no lumps, no hard bits)
Crush tablets/open capsules and mix into a small amount of pureed food	Minced, pureed†	Can tolerate some variation in pureed texture
Give tablets/capsules whole in a small amount of pureed food	No mixed consistencies, minced, chopped	Cannot swallow tablets/capsules with water (i.e., medication with water represents a mixed consistency)
Dispense smallest tablet/capsule possible	Chopped, dental soft, regular	Preference for a small tablet/capsule size
Halve large tablets	Chopped, dental soft, regular	Difficulty swallowing large tablets or capsules
Give tablets/capsules one at a time	Chopped, dental soft, regular	Difficulty swallowing several tablets or capsules at once

*Exact wording of standard phrases appears in the "comments" section on the MAR. †Pureed food = applesauce, yogurt, pudding or other pureed food. When mixing in pureed food, put medication in a small portion of food (in case patient does not consume all of the mixture.)

Table 4. Medication administration orders for liquid medications in dysphagia

Standard Phrases*	Typical Diet Order	Interpretation of Standard Phrases
No liquid medication	Pudding-thick liquids	Requires very thick liquids
Mix liquid medication in food	Nectar-thick liquids, honey-thick liquids	Does not require very thick liquids
Liquid medication allowed	All diets except nectar-thick liquids, honey-thick liquids and pudding-thick liquids	Can tolerate any volume of liquid
Medication must be in liquid form	Clear fluids, wired jaw diet	Can swallow liquids but not solid food

*Exact wording of standard phrases appears in the "comments" section on the MAR.

Table 5. Education program for nurses

Speech-language pathologist presentation:
- Swallowing physiology and pathophysiology
- Risks due to dysphagia
- Diet texture, consistency of solids and liquids
- Standard order phrases and their interpretation

Stakeholder responsibilities:
- Nurse, SLP, pharmacist, physician

Documents:
- Medications which cannot be crushed and rationale
- Medications available as sustained-release beads

Evaluation:
- Pre- and post-education knowledge test
- Participant evaluation and feedback on the education session

The new process was implemented on the two study units first and then spread to all units of the LCTF. Spread to the acute care hospital occurred through a series of information meetings with stakeholders, specifically acute care SLPs, pharmacists and nursing leaders.

The average knowledge score of 60% improved to 80% after the in-service.

Analysis and Interpretation of the Post-intervention Audit

In June 2005, a post-intervention audit on the two original study units revealed over 90% adherence with the process changes that were implemented in 2003 (see Table 1), which is our primary outcome. We anticipate that the process changes will result in a reduction in swallowing-related adverse events. In the two cases where nursing action did not adhere to the SLP recommendations, patients had a "no mixed consistencies" restriction. This restriction implies mild dysphagia, and the nurse or patient may have felt that receiving medications whole with water was safe. SLP recommendations had been moved to the archival chart in two cases. In the two cases where nursing action disagreed with the MAR, it was due to patient preference. It is clear that nurses generally continued to follow the MAR instructions closely. Entering the SLP recommendations on the MAR was a key factor in improving nursing adherence with SLP recommendations from 66% in the initial audit to 93% in the second audit. There was complete adherence with the pharmacy computer alert.

Entering the SLP recommendations on the MAR was a key factor in improving nursing adherence.

Summary

Patient safety is now prominent on the agenda of healthcare institutions (Baker et al. 2004). Understanding the contributing factors leading to adverse events is seen as important for hospitals to correct deficiencies that might act as barriers to providing safe patient care (El-Jardali and Lagacé 2005). Inadequate communication of important information for the safe administration of medication to patients with swallowing difficulty was identified as the key contributing factor to adverse patient outcomes related to medication administration, such as choking and adverse events resulting from the inappropriate crushing of sustained-release tablets. Communication of SLP medication swallowing recommendations to nurses and pharmacists via the doctor's order sheet using standard order phrases was implemented as a simple change to existing procedures that remedied this communication gap.

Improved compliance with interdisciplinary communication procedures and medication administration practices was demonstrated in this study. The ease with which the process changes were implemented was gratifying and due, in part, to the fact that buy-in was required from a small number of staff in two of the stakeholder groups (i.e., pharmacists and SLPs). The larger nursing group had already demonstrated adherence with the MAR. The formal education campaign was considered important in raising the level of knowledge among the nursing staff regarding swallowing problems and associ-

ated risks. Incorporating the pharmacy computer system and pharmacy-generated MAR in this process change was important in terms of sustaining the process, ensuring the communication loop between the SLP, pharmacist and nurse was closed and preventing the crushing of sustained-release medications. The "dysphagia alert" concept will be included in the physician computer order entry system that is being developed for our hospital. HQ

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References

Baker, G.R., P.G. Norton, V. Flintoft, R. Blais, A. Brown, J. Cox, E. Etchells, W.A. Ghali, P. Hébert, S.R. Majumdar, M. O'Beirne, L. Palacios-Derflingher, R.J. Reid, S. Sheps and R. Tamblyn. 2004. "The Canadian Adverse Events Study: The Incidence of Adverse Events among Hospital Patients in Canada." *Canadian Medical Association Journal* 170: 1678–86.

Bloem, B.R., A.M. Lagaay, W. Van Beek, J. Haan, R.A. Roos and A.R. Wintzen. 1990. "Prevalence of Subjective Dysphagia in Community Residents Aged over 87." *BMJ* 300: 721–2.

Coles, G., B. Fuller, K. Nordquist and A. Kongslie. 2005. "Using Failure Mode Effects and Criticality Analysis for High-Risk Processes at Three Community Hospitals." *Joint Commission Journal on Quality and Patient Safety* 31(3): 132–40.

Cornish, P. 2005. "Avoid the Crush: Hazards of Medication Administration in Patients with Dysphagia or a Feeding Tube." *Canadian Medical Association Journal* 172(7): 871–87.

El-Jardali, F. and M. Lagacé. 2005. "Making Hospital Care Safer and Better: The Structure-Process Connection Leading to Adverse Events." *Healthcare Quarterly* 8(2): 40–8.

Groher, M.E. and R. Bukatman. 1986. "The Prevalence of Swallowing Disorders in Two Teaching Hospitals." *Dysphagia* 1: 3–6.

Hudson, H.M., C.R. Daubert and R.J. Mills. 2000. "The Interdependency of Protein-Energy Malnutrition, Aging, and Dysphagia." *Dysphagia* 15: 31–8.

Institute for Healthcare Improvement. 2007. *Quality Improvement Model*. Cambridge, MA: Author. <http://www.ihi.org/IHI/Topics/Improvement/>. Retrieved December 9, 2007.

Laffel, G. and M. Blumenthal. 1989. "The Case for Using Industrial Quality Management Science in Health Care Organizations." *Journal of the American Medical Association* 262: 2869–73.

Layne, K.A., D.S. Losinski, P.M. Zenner and J.A. Ament. 1989. "Using the Fleming Index of Dysphagia to Establish Prevalence." *Dysphagia* 4: 39–42.

O'Brien, P.J. and D. Barrow. 1991. "Prevalence of Eating Problems of Nursing Home Residents." *Australian Journal of Human Communication Disorders* 19(1): 35–43.

Palmer, J.B. and J.C. Drennan. 2000. "Evaluation and Treatment for Swallowing Impairments." *American Family Physician* 61: 2453–62.

Siebens, H., E. Trupe, A. Siebens, F. Cook, S. Anshen, R. Hanauer and G. Oster. 1986. "Correlates and Consequences of Eating Dependency in Institutionalized Elderly." *Journal of the American Geriatrics Society* 34: 192–8.

Smithard, D.G. 1996. "Feeding and Swallowing Problems in the Institutionalized Elderly." *Clinical Rehabilitation* 10: 153–4.

Sonies, B. 1992. "Oropharyngeal Dysphagia in the Elderly." *Clinics in Geriatric Medicine* 8(3): 569–77.

Trupe, E.H. and A.A. Siebens. 1984. "Prevalence of Feeding and Swallowing Disorders in a Nursing Home." *Archives of Physical Rehabilitation* 65: 651–2.

Wreathall, J. and C. Nemeth. 2004. "Assessing Risk: The Role of Probabilistic Risk Assessment (PRA) in Patient Safety Improvement." *Quality and Safety in Health Care* 13: 206–12.

Wright, D. 2002a. "Medication Administration in Nursing Homes." *Nursing Standard* 16(42): 33–8.

Wright, D. 2002b. "Swallowing Difficulties Protocol: Medication Administration." *Nursing Standard* 17(14–15): 43–5.

An Intervention Program to Reduce Falls for Adult In-Patients Following Major Lower Limb Amputation

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Abstract

A qualitative and quantitative assessment was conducted regarding falls sustained by in-patients receiving rehabilitation therapy following major lower limb amputation at the Glenrose Rehabilitation Hospital. During the nine-month assessment period, 18 of 58 patients in the amputee unit experienced a fall, of which 17% resulted in a moderate injury. The majority of falls occurred during patients' use of a wheelchair (14 of 18) and involved poor balance (nine of 14). Patient wheelchair self-transfers accounted for 71% (10 of 14) of the falls, while sitting in the wheelchair and reaching represented 29% (four of 14). The hospital's rehabilitation program teaches patient safety including using assistive devices such as wheelchairs but did not include a comprehensive graded learning path to monitor patients' ongoing risk for falls.

Based upon the data collected, an intervention program was initiated to improve patient safety and reduce the number of falls. The multidisciplinary program encompassed aspects ranging from an environmental assessment of the patients' room to medication management, continuous patient wheelchair skills training and alteration of the care plan. The effectiveness of the intervention program was assessed through a series of interviews and questionnaires administered to medical personnel.

This article presents the preliminary data collected during the first three months of the six-month study. Overall, satisfaction has significantly improved as a direct result of the intervention program. The article provides evidence-based interventions that improve safety for a subset of in-patients known to be susceptible to falls when using wheelchairs. Other in-patient groups will also benefit from these findings as many are universally applicable.

Background

Glenrose Rehabilitation Hospital (GRH), Capital Health Edmonton Region, is a 220-bed facility whose mandate is to provide high-level rehabilitation care for both adults (including the elderly) and children. As the largest integrated health region in Canada, Capital Health implemented a web-based tracking and management system (NetSAFE) in 2005 to record the occurrence and avoidance of adverse events involving patient safety. All staff members are encouraged to use the NetSAFE program as management and quality committees routinely access the information to identify trends or areas of concern.

GRH has an eight-bed ward dedicated to the rehabilitation of patients recovering from the amputation of a lower limb. During a consecutive nine-month period from 2006 to 2007, the NetSAFE data indicated that 18 of 58 (31%) patients experienced falls, of which three sustained moderate injuries. The fall incidence was concerning for several reasons: (1) fallen amputee patients can experience serious physical and psychological events such as stump trauma or fractures and fear of falling again or loss of confidence, respectively (Behar et al. 1991; Gonzalez and Matthews 1980; Lewallen and Johnson 1981; Miller et al. 2001a, 2001b); (2) the amputee ward had the highest fall rate compared with that in the other adult wards (excluding geriatrics), suggesting the presence of mitigating factors; and (3) although the amputee ward's fall rate was similar to that of other hospitals (range 20–32%), GRH regarded this as unsatisfactory (Gooday and Hunter 2004; Pauley et al. 2006). Thus, the GRH adult amputee program needed to minimize the number and severity of patient falls.

The aim of this study was to identify the associated and causative factors that led to falls in the adult amputee patient population. In turn, this information was used to develop two products: (1) an effective falls prevention program and (2) a falls risk assessment specific for adult amputee patients.

Methods

A literature review was conducted to identify the root causes of falls experienced by rehabilitation in-patients recovering from extensive lower limb amputation. This information was then compared with that collected through NetSAFE for GRH. Concurrently, the existing GRH Falls Prevention Program was critically assessed for its value and applicability to amputee patients. Several observational sessions were conducted in which team members noted factors that might contribute to falls in the amputee ward. The nursing staff provided voluntary feedback regarding the existing Falls Prevention Program via an anonymous questionnaire.

Interventions selected by the project team were implemented and assessed in terms of effectiveness on improving patient safety. Each patient admitted to the amputee ward qualified as a study participant during the initial three-month study period. At its conclusion, the questionnaire was re-circulated to the nursing staff and data regarding amputee patient falls were retrieved from NetSAFE.

Results

Causes of Amputee In-Patient Falls

Two recent articles were retrieved that presented data from retrospective cohort studies of adult amputee in-patients (Gooday and Hunter 2004; Pauley et al. 2006). The UK study (Gooday and Hunter 2004) was conducted over 2.5 years and reported a fall incidence of 32.0%, while the Canadian study (Pauley et al. 2006) found a fall incidence of 20.5%. In the majority of instances, the patient was sitting in a wheelchair and attempted to perform an unassisted transfer to a bed, chair or toilet and fell due to a loss of balance, restricted movement, ignored instructions or other undefined issue related to the proper use of a wheelchair. The fall incidence at GRH was 31.0% according to the first nine months of data collected through NetSAFE. Of these, 14 of 18 amputee patients fell while using a wheelchair; poor balance was associated with nine of 14 falls. Patient self-transfers involving a wheelchair accounted for 71% (10 of 14) of the falls, while sitting and reaching in the wheelchair was the cause of 29% (four of 14). Patients who fell once had a one-in-three chance of falling again. The GRH amputee patient fall data are similar to that of previous studies (Gooday and Hunter 2004; Pauley et al. 2006).

Studies and best practices regarding falls incidences for amputee patients are sparse in contrast to the volume of literature highlighting the need for this information.

Interventions

Based upon NetSAFE data, observational sessions and the literature, the multidisciplinary team developed several interventions to reduce patient falls:

- The Falls Assessment Tool was revised to accurately identify patients who may be at risk for falls.
- The Falls Assessment Tool was revised to delineate a clear process by which a customized intervention plan would be developed shortly for patients assessed to be at risk for falls.
- If a fall occurred, the multidisciplinary team identified the root cause and developed a customized plan to prevent the patient from subsequent falls.
- The NetSAFE falls data for the amputee ward were reviewed monthly by the multidisciplinary team to monitor the effectiveness of the interventions.

Figure 1. Results of the pre- and post-intervention questionnaires for nursing staff

Results for the five survey statements listed below are presented in graphs A to E and compare pre- and post-intervention responses:

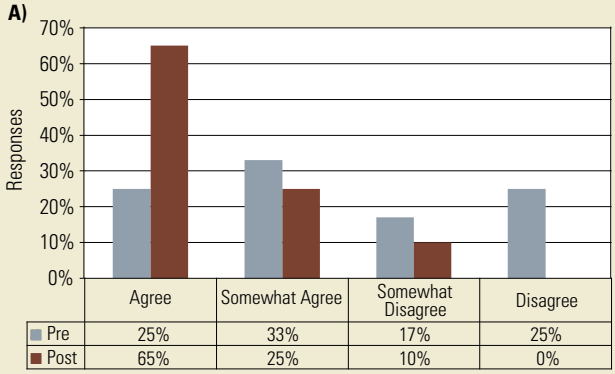
A. The current Falls Prevention Program uses a Falls Assessment Tool that accurately differentiates amputee patients who are at high risk for falling from those who are not.

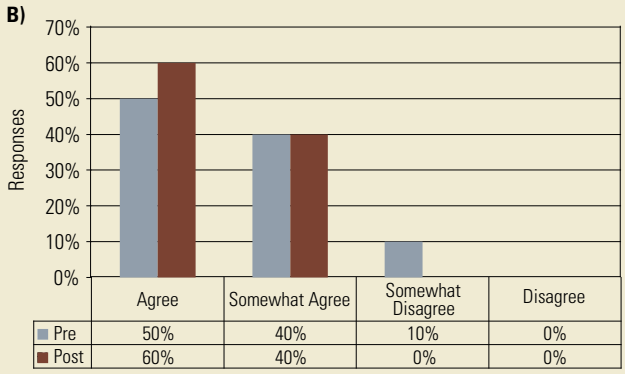
B. The current Nursing Assessment Tool is valuable in identifying and differentiating amputee patients who are at high risk for falling from those who are not.

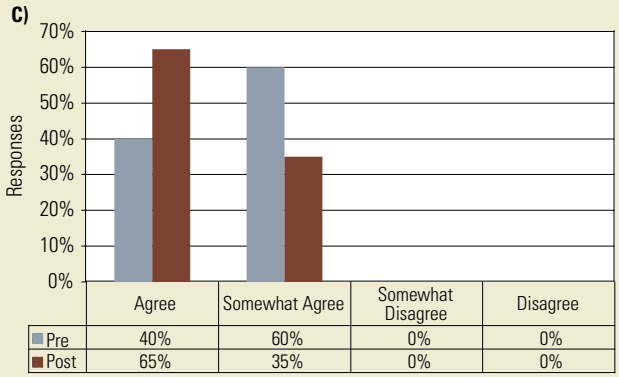
C. Identifying an amputee patient on the unit as being at risk for a fall helps prevent the patient from falling.

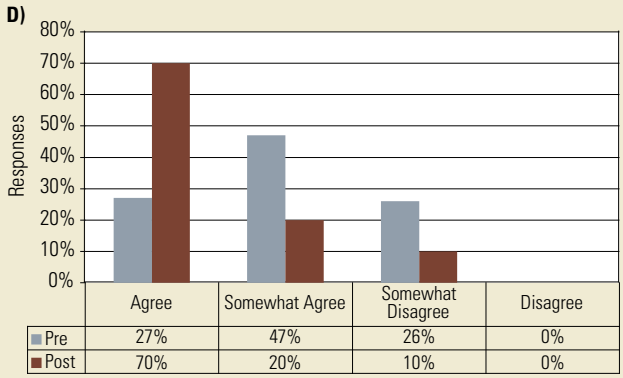
D. After an amputee patient has fallen on the unit, a multidisciplinary team investigation routinely takes place, and the information is shared among the staff and shifts.

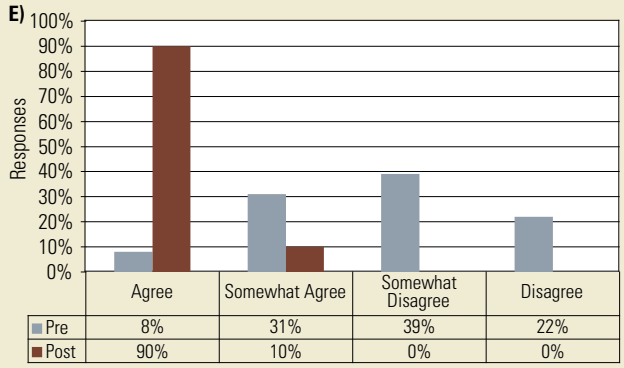
E. A summary and interpretation of the NetSAFE data regarding the root cause(s) for falls by amputee patients on Unit 4A is routinely presented and discussed with the staff.











- Nursing staff were educated about the main causes and locations of falls specific to the GRH amputee patient population.

Effectiveness of the Interventions: Preliminary Data

The preliminary three-month study included a total of 24 patients, of whom two fell. This represented a 5% decrease in the falls incidence. Most importantly, neither fall resulted in any physical injuries, nor did either patient fall again. In one incident, the patient had disregarded wheelchair training instructions; the second incidence involved a balance issue.

The response to the pre- and post-intervention implementation questionnaire for the nursing staff was 60% (18 of 30). Prior to the implementation of the interventions, the nursing staff had had a negative view of the existing GRH Falls Prevention Program. This sharply contrasted with the positive views expressed post-implementation (Figure 1). Initially, 25% had agreed that the Falls Assessment Tool was being used effectively; this increased to 65% after implementation. Only 50% of the nurses had agreed that the Nursing Assessment Tool was useful for differentiating patients at risk for falling; following implementation, this increased to 60%. The efficacy of identifying patients as being at risk for a fall had been agreed to be effective by 40%. Post-implementation, this increased to 65%. Post-intervention, nursing staff indicated a 43% increase in investigations into falls and information dissemination regarding falls. Finally, the majority of staff agreed that there was a substantial improvement regarding the effective reporting and discussion of NetSAFE data (pre-implementation 8%, post-implementation 90%).

The marked reduction in the severity of falls and the fact that no one fell more than once both represent a substantial improvement to amputee patient safety.

Discussion

Following lower limb amputations, patients undergo an adjustment period to adapt to their altered biomechanical characteristics, increased postural sway and changes in sensory perception in their amputated and healthy legs. They must also mentally cope with effectively manipulating devices such as wheelchairs, walkers and prostheses (Pauley et al. 2006). In conjunction with traditional risk factors for falling (e.g., advanced age, impaired cognitive function, muscular weakness), wards for adult amputee patients typically report the greatest incidence of falls relative to other adult wards. However, studies and best practices regarding falls incidences for amputee patients are sparse in contrast to the volume of literature highlighting the need for this information (Gavin-Dreschnack et al. 2005; Gooday and Hunter 2004; Lord et al. 2003; Miller et al. 2001b; Pauley et al. 2006; Vlahov et al. 1990; Zucker Levin 2004).

The multidisciplinary team devised and executed a well-designed research plan in accordance with the plan-do-study-act (PDSA) quality management research cycle. The interventions recommended and implemented were subject to a preliminary three-month study that collected quantitative and qualitative data. The incidence of falls was reduced marginally (5%). However, the marked reduction in the severity of falls and the fact that no one fell more than once both represent a substantial improvement to amputee patient safety. Previous studies have indicated that reducing the fall incidence is difficult; but fall severity can be successfully reduced, as is evidenced in this study (Gooday and Hunter 2004). The qualitative data revealed a large improvement on the nursing staff's acceptance and use of the revised Falls Assessment Tool and Falls Prevention Program. The coordinated efforts of the multidisciplinary team to create customized fall interventions for each patient deemed to be at risk for a fall were considered effective and worthwhile.

The three-month preliminary study provided sufficient data to assess the value of the interventions to reduce falls in the amputee patient population at GRH in Edmonton, Alberta. A longer study is under way to fully assess the impact of the interventions. Concurrently, the revisions to the Falls Assessment Tool and Falls Prevention Program are being communicated and integrated into the pediatric and geriatric wards since they also admit patients with major lower limb amputations. The multidisciplinary team's involvement in fall prevention is also being implemented throughout the hospital.

The coordinated efforts of the multidisciplinary team were considered effective and worthwhile.

Although the interventions were implemented with minimal financial or staffing resources, the efforts of the project team were considerable. These successes reflect the effort to ensure that all associated healthcare professionals are involved and in agreement regarding the strategies and interventions to improve patient safety. HQ

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References

Behar, T.A., S.J. Burnham and G. Johnson. 1991. "Major Stump Trauma following Below-Knee Amputation. Outcome and Recommendation for Therapy." *Journal of Cardiovascular Surgery* 32: 753–6.

Gavin-Dreschnack, D., A. Nelson, S. Fitzgerald, J. Harrow, A. Sanchez-Anguiano, S. Ahmed and G. Powell-Cope. 2005. "Wheelchair-Related Falls: Current Evidence and Directions for Improved Quality Care." *Journal of Nursing Care Quality* 20(2): 119–27.

Gonzalez, E.G. and M.M. Matthews. 1980. "Femoral Fractures in Patients with Lower Extremity Amputations." *Archives of Physical Medicine and Rehabilitation* 61: 276–80.

Gooday, H.M.K. and J. Hunter. 2004. "Preventing Falls and Stump Injuries in Lower Limb Amputees during Inpatient Rehabilitation: Completion of the Audit Cycle." *Clinical Rehabilitation* 18(4): 379–90.

Lewallen, R.P. and E.W. Johnson. 1981. "Fractures in Amputation Stumps: Review of Treatment of 16 Fractures." *Mayo Clinic Proceedings* 56: 22–6.

Lord, S.R., H.B. Menz and A. Tiedemann. 2003. "A Physiological Profile Approach to Falls Risk Assessment and Prevention." *Physical Therapy* 83(3): 237–52.

Miller, W.C., B. Deathe, M. Speechley and J. Koval. 2001a. "The Influence of Falling, Fear of Falling, and Balance Confidence on Prosthetic Mobility and Social Activity among Individuals with a Lower Extremity Amputation." *Archives of Physical Medicine and Rehabilitation* 82: 1238–44.

Miller, W.C., M. Speechley and B. Deathe. 2001b. "The Prevalence and Risk Factors of Falling and Fear of Falling among Lower Extremity Amputees." *Archives of Physical Medicine and Rehabilitation* 82(8): 1031–7.

Pauley, T., M. Devlin and K. Heslin. 2006. "Falls Sustained during Inpatient Rehabilitation after Lower Limb Amputation: Prevalence and Predictors." *American Journal of Physical Medicine and Rehabilitation* 85: 521–32.

Vlahov, D., A.H. Myers and M.S. Al-Ibrahim. 1990. "Epidemiology of Falls among Patients in a Rehabilitation Hospital." *Archives of Physical Medicine and Rehabilitation* 71(1): 8–12.

Zucker Levin, A. 2004. "Functional Outcome following Amputation." *Topics in Geriatric Rehabilitation* 20(4): 253–61.

Using Human Factors Methods to Evaluate the Labelling of Injectable Drugs

Kathryn Momtahan, Catherine M. Burns, Jennifer Jeon, Sylvia Hyland and Sandra Gabriele

Abstract

Adverse drug events, including in-hospital medication errors, are a well-documented world-wide problem. This interdisciplinary team set out to examine the issues related to the labelling of injectable drugs. We sought answers to the following two questions: (1) To what extent do injectable drug labels adhere to existing Canadian design practice recommendations and regulations for labelling and (2) is there a need to make changes to the recommendations or regulations for labelling of injectable drugs in Canada? The project contained three phases. The first phase involved taking a sample of vials and ampoules from a hospital pharmacy and identifying adherence to the 1999 Canadian Standards Association standard for the labelling of drug ampoules, vials and prefilled syringes, as well as with the Canadian (Health Canada) Food and Drug Regulations for labelling. The second phase involved a failure mode and effects analysis of the label-reading process in order to identify information on the label considered critical for safe medication use. The third phase involved a preliminary human factors experiment addressing one problem identified with existing labels. Our finding is that existing injectable drug labels do not adhere sufficiently to available best design standards for labels and also do not adhere to all Canadian Food and Drug Regulations. Recommendations are made to inform future enhancements to labelling standards, guidelines and regulations.

Poor labelling of injectable medications can be a contributing factor to medication errors leading to adverse drug events. In 2001, Orser et al. reported the results of a survey they conducted regarding medication errors in anesthesia practice. The researchers received survey responses from 687 anesthesiologists who reported knowledge of a total of 1,038 medication errors. The anesthesiologists were asked to identify factors that they felt contributed to the errors. Table 1 provides a list of these factors. In this same survey, 84% of the anesthesiologists agreed that improved standards for drug labels would reduce the incidence of error.

Table 1. Factors contributing to errors

Contributing Factors	Percentage of Total Errors
Syringe swap	60
Did not read label	53
Misidentification of ampoule or vial	39
Drug incorrectly stocked	18
Wrong dose injected	10

Source: Data from Orser et al. (2001: 142).

In an analysis of medication errors reported to the United States Pharmacopoeia (USP) voluntary Medication Errors Reporting Program for a one-year period between 1996 and 1997, the USP found that 33% of the reports cited labelling or packaging as having contributed to the medication error (USP 1998). In nearly 30% of the fatalities reported, labelling or packaging was cited as a contributing factor to the medication error that led to the fatality. The types of problems listed were the following:

- Lack of prominent placement of drug name and strength
- Small size and poor readability of printed information
- Insufficient prominence given to route of administration (e.g., nasal versus injection, intravenous versus intramuscular)
- Poorly designed or cluttered labels
- Lack of differentiation between drug products that have similar names
- Similar-appearing labels or packages of different products
- Poor use or absence of colour to differentiate products
- Prominence of company logos versus information that identifies the product
- Inadequate warnings about proper drug use

There are several extensive reviews of the causes of medication errors and possible solutions to medication system designs (e.g., Berman 2004; Cohen 2007; Institute of Medicine of the National Academies 2007). Medication label design is an area where the consideration of human factors principles is critical (Greenall et al. 2004). Confusing drug labels have been identified as a contributing factor to medication errors across different disciplines in medicine (Ashcroft et al. 2005; Cohen 1999, 2007; Kenagy and Stein 2001; Orser and Oxorn 1994). Injectable drugs, in particular, were found to be the most common dosage form associated with medication errors that resulted in patient death reported to the US Food and Drug Administration from 1993 to 1998 (Phillips et al. 2001). Furthermore, injectable drugs were involved in more than half the medication error reports submitted by hospital pharmacists to the USP Drug Product Problem Reporting program between 1995 and 1999 (USP 2000).

Phase One: Existing Manufacturer Labels and Adherence to Current Standards and Regulations

The Canadian Standards Association (CSA) published a standard in 1999, CAN/CSA-Z264.2-99, for the labelling of drug ampoules, vials and pre-filled syringes (CSA 1999). The Canadian Anesthesiologists' Society, the Canadian Society of Hospital Pharmacists, the Centre for Health Promotion and the Institute for Safe Medication Practices were key groups involved in the development of the standard. The standard defines minimum design requirements for the presentation of information on the inner label for injectables and complements the requirements in the Canadian Food and Drug Regulations (Government of Canada 2006). The inner label is the label on, or affixed to, the immediate container of a drug product.

The CSA standard focuses on ensuring the organization and the legibility of label content, especially for what it calls "critical information": the drug product's common name(s) in English and French and the total amount of drug ingredient(s) as milligrams per total millilitres, followed by the concentration of drug ingredient(s) as milligrams per one millilitre. The standard's legibility section, which was adopted from the Man-Systems Integration Standard of the National Aeronautics and Space Administration (NASA 1995), defines typographical specifications for ensuring legibility of critical information. There is no legal requirement for pharmaceutical manufacturers to follow the CSA standard, but there is a legal requirement for them to follow the Canadian Food and Drug Regulations. In addition, although some of the requirements set out in both the CSA standard and the NASA standard are based on previous research, there are many aspects of the CSA standard that are based on expert opinion. The objectives of phase one of this study were to answer the following two questions: (1) to what extent do the inner labels on ampoules and vials of injectable drugs currently used in Canadian hospitals adhere to the CSA standard? and (2) to what extent do they adhere to the Canadian Food and

Table 2. Summary of Canadian Standards Association standard adherence scores for the samples

Clause Category*	Total No. of Clauses	Average No. of Clauses Samples Adhered to (n = 78)	Average Adherence Score
Shall	23	14	59%
Should	6	5	80%

*Shall clauses are proposed as mandatory requirements; should clauses are considered recommendations (CSA 1999).

Drug Regulations?

Method

A total of 78 samples (21 ampoules and 57 vials) were randomly collected from a pharmacy inventory in a large urban teaching hospital. This represented 18% of the 116 different ampoules and 22% of the 265 different vials carried by the hospital. The evaluation was conducted from May 2006 to July 2006. The first two thirds of the samples were collected from used, or expired, ampoules and vials returned to the pharmacy. The remaining third were randomly collected from all areas of inventory to ensure refrigerated items and narcotic products were included in the sample. The final sample is thought to be representative of the currently available ampoules and vials in a hospital formulary in Canada.

Typographical dimensions (i.e., the stroke width, character height, character width, etc.) were measured on the inner labels of the containers. A transparent plastic ruler marked in millimetres and a magnifying glass were used to make the measurements. The measurements are considered accurate to 0.5 mm.

Results

Table 3. Requirements from Items of the Canadian Standards Association standard that had a non-adherence rate of 50% or greater

Clause*	% Non-adherence	Brief Description†	Findings and Possible Reasons for Non-adherence
Shall			
4.2.2	100	Common name printed immediately below the brand name and legible according to requirements of 4.4.	Not all legibility requirements are clearly defined.
4.2.3	55	After common name, include: (i) the amount of drug ingredient(s) as milligrams per total millilitres followed by (ii) the concentration of drug ingredient(s) as milligrams per 1 mL. In some instances, the convention may be to express the amount of drug(s) in milliequivalents, millimoles or international units.	Findings: 1. The amount of drug ingredient(s) per total millilitres was displayed after the concentration per 1 mL. 2. The amount of drug ingredient(s) per total millilitres was missing. 3. The amount of drug ingredient(s) was not expressed in the recommended units. The reasons for the above are likely to be varied.
4.2.8	99	Expiration date on the label in format EXP CCYYMM, e.g., EXP. 1999DE.	A variety of different formats were used.
4.4.11	63	A mixed character set shall be used.	Capital letters were often solely used. This may be due to a lack of awareness that mixed characters can increase legibility.
4.4.2	60	For critical information, character height on ampoules/vials: >2 mL: 1.76 mm or more ≤2 mL: 1.5 mm or more	A combination of a large amount of text and a limited amount of space for labelling on small containers may have dictated the use of smaller type.
4.4.3	50	For critical information, specified width of letters (0.6 of the height with some exceptions).	
4.4.6	96	The critical information field shall be represented in black characters on a white background.	Awareness of this recommendation may be limited.
4.4.7	97	For critical information, height-to-stroke ratio of 6:1 to 7:1	1. The absence of a description for what the height-to-stroke ratio expresses. 2. Difficult to measure small type accurately. 3. Designers may not think of type in this way.
Should			
4.2.9	54	Storage conditions should be clearly identified on the label.	The joint USP-FDA Advisory Panel on Simplification and Improvement of Injection Labeling recommended eliminating storage requirements from injection labels when the product is to be stored at room temperature in normal light (USP 1994).

USP-FDA = United States Pharmacopoeia/US Food and Drug Administration. *Shall clauses are proposed as mandatory requirements; should clauses are considered recommendations. †Paraphrased from the Canadian Standards Association standard (CSA 1999).

The clauses of the CSA standard are divided into three categories: clauses worded with shall are proposed as mandatory requirements, clauses worded with should are considered recommendations and clauses worded with may are taken as suggestions. There are 25 shall clauses, eight should clauses and two may clauses relevant to the labelling of ampoules and vials. For the purposes of this study, 23 shall clauses and six should clauses were considered.

None of the samples adhered to all of the shall and should clauses of the CSA standard. Table 2 summarizes the average adherence score for shall and should clauses. The adherence score for a sample was calculated by determining the ratio of the number of adhered-to clauses to the total number of clauses. Table 3 lists the shall and should clauses and suggests findings and possible reasons for non-adherence for the CSA standard clauses that had a non-adherence rate of 50% or more.

Three samples were determined to be special access drugs that are not available for sale in Canada and were excluded from the analysis for evaluating adherence to Canadian Food and Drug Regulations. All three drugs failed one or more requirements of the regulations. Table 4 lists the non-adherence rate for the remaining 75 samples.

A more detailed examination of non-adherence can be found in Appendix A ("Rates of Non-adherence to CSA Standards") and Appendix B ("Rates of Non-adherence to Government of Canada Food and Drug Regulations"), both of which are available at http://www.longwoods.com/product.php?productid=19598.

Phase Two: Failure Mode and Effects Analysis of the Label-Reading Process

To investigate potential failures, causes and effects of the label-reading process, a failure mode and effects analysis (FMEA) was conducted with a group of seven healthcare professionals with previous FMEA training. The results of this FMEA revealed the components of the label on injectable drugs considered important by the end-users for safe medication use. Failure modes (or errors) that are related to reading the brand name, common name, concentration, total amount of drug ingredient(s) and route of administration were rated as potentially severe modes of failure; therefore, these elements need to be carefully considered

Table 4. Non-adherence to Canadian Food and Drug Regulations*

	Total No. of Samples (N = 75)	No. of Samples That Do Not Adhere to One or More Regulation Requirements	% Non-adherence
Ampoules	19	4	21
Vials	56	22	39
Total	75	26	35

*As per Government of Canada (2006).

Table 5. Injectable products with label information printed directly on glass or clear substrate

Drug No.	Generic Name	Brand Name	Concentration	Route of Administration	Volume
D1	Desmopressin	DDAVP	4 µg/mL	IV, IM, SC	1 mL
D2	Epinephrine	N/A	1 mg/mL	IM, IV, SC	1 mL
D3	Paraldehyde	N/A	1 mg/mL	IM, IV	5 mL

IM = intramuscular; IV = intravenous; SC = subcutaneous.

Figure 1. Existing and newly-generated labels

The three on the left are existing labels for desmopressin (D1), epinephrine (D2) and paraldehyde (D3); the three on the right are the newly-generated labels for D1, D2 and D3 in the same order.

when designing labels. A full account of this FMEA has been reported elsewhere (Jeon et al. 2007).

Phase Three: Human Factors Experiment with One Type of Existing Label

Although Cohen (2007) argues against printing directly on ampoules because the lack of contrast between the print and the background renders the text illegible, this concern related to printing is not fully addressed in the CSA standard and is not addressed in the Canadian Food and Drug Regulations. We therefore designed an experiment to test the speed and accuracy of identifying information on ampoules with type printed directly on the glass container, or on a clear substrate that is adhered to the glass, and compared the results to those with the same label design printed with black ink on an opaque, white substrate adhered to a container.

Method

Participants

Twenty-four registered nurses (two males and 22 females) from an acute care hospital were recruited for the experiment. They ranged in age from 33 to 60 years (mean age 44) and had eight to 37 years of practice experience (mean 21.4 years). Participants were allowed to wear their glasses or contact lenses. All participants were tested for visual acuity and colour vision.

Stimuli

Three ampoules with type printed directly on the glass or a clear substrate (existing labels) that are currently available in Canada and identical ampoules with label information printed with black ink on an opaque, white substrate were presented to the participants (i.e., a total of six different labels). The details of the existing drugs used are summarized in Table 5. The labels designed for this experiment were identical to the existing labels except for the use of black lettering on a white paper substrate (Figure 1).

Procedure

For each of the six ampoules, participants were asked three different questions: (1) What is the concentration? (2) What is the generic name? and (3) What are the routes of administration? The rate of response for each was timed. The experiment was conducted in two rooms with similar lighting conditions. The sessions were video recorded with a camera positioned behind and diagonally from the participants such that their faces were not shown in the recordings. A set of six ampoules were placed upright in a single row on top of a flat table surface covered by a white foam cup until the participant was ready. The participant read a question displayed on a computer monitor and then picked up the ampoule to answer the question. Time to respond to the information being asked and accuracy of the response were recorded. Each 40-minute session consisted of six practice trials preceding 18 actual trials divided into three blocks of six trials.

Results

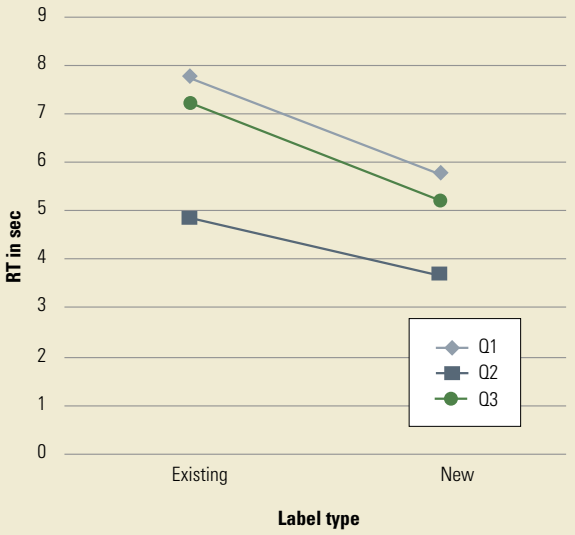
Since the participants were allotted as much time as they needed to identify the concentration, generic name and routes of administration of the drug, the accuracy rate for reading the existing labels and the new labels was similar. These results are presented in Table 6. The only statistically significant difference ($p < .05$) between the accuracy of responses for the existing and new labels was for the route of administration for D3.

The amount of time that it took to identify the information

Table 6. Accuracy of responses with existing and new labels

Drug Type	Concentration		Generic Name		Route of Administration	
	Existing	New	Existing	New	Existing	New
D1	91.7%	91.7%	56.5%	47.8%	100.0%	100.0%
D2	100.0%	95.8%	100.0%	95.8%	100.0%	100.0%
D3	95.8%	83.3%	95.8%	100.0%	50.0%	79.2%

Figure 2. Mean reaction time to correctly identify essential information for the original epinephrine label and the new black and white label



Q1 = question regarding drug concentration; Q2 = question regarding generic name; Q3 = question regarding routes of administration; RT = reaction time.

on the existing labels that were printed directly on glass or a clear substrate versus the new labels printed with black ink on an opaque, white substrate was statistically significantly longer ($p < .0001$). For instance, the mean correct reaction time for each of the three questions asked for epinephrine (D2) is presented in Figure 2.

Discussion and Recommendations

Two approaches to examining the labelling of injectable drugs that have not been extensively employed and that have been reported in this paper are (1) routine examination of the adherence of drug labels to standards and regulations and (2) experimentation to support existing and future recommendations (although some experiments have been conducted by others, i.e., Filik et al. [2006], Gabriele [2006] and Wogalter and Vigilante [2003]).

In phase one of our study, 78 sample vials and ampoules collected from a hospital pharmacy inventory were evaluated against the current CSA (1999) recommendations that define minimum design requirements for labels on ampoules and vials. The vials and ampoules were also evaluated for adherence to the Canadian Food and Drug Regulation for labelling (Government of Canada 2006). Some of the statements in the CSA standard and in the Food and Drug Regulations are worded in a way that requires interpretation. For example, the Government of Canada (2006) Food and Drug Regulation C.01.004. (3) states, "Where the container of a drug is too small to accommodate an inner label that conforms to the requirements of these Regulations," but it is not clear what is considered too small to accommodate an inner label as required in the regulations. For the purposes of this study, a container capacity of five millilitres or less was considered to be "too small" as is the case in the CSA standard. An unclear statement in the CSA standard specifies the minimum space between characters for displaying critical information (clause 4.4.8). However, the word "space" is not clearly defined in the standard. For the purposes of this study, the space was interpreted as the space between two straight-sided characters such as H and L as defined in the NASA's Man-Systems Integration Standard (NASA 1995), from which the legibility section of the standard was derived. Other examples of wording that could be interpreted incorrectly can be found in Appendix C ("Ambiguities in the Canadian Food and Drug Regulations and in the CSA standard"), which is available at http://www.longwoods.com/product.php?productid=19598.

The adherence rate to the 23 mandatory requirements in the CSA standard was 59%. The average proportion of the inner labels for ampoules and vials that did not adhere to one or more of the requirements in the Canadian Food and Drug Regulations was 35%. It is important to note that although the percentage of drugs that did not meet one or more of the Canadian Food and Drug Regulation requirements was 35%, a large portion of the non-adherence resulted from not including both the English and French versions of the word sterile and stérile (24% of the total samples) and for not including the manufacturer address on the label (9.3% of the total samples). It is also noted that Health Canada does allow exceptions to the labelling information requirements through a policy for labelling of "special containers." The policy applies to containers that are too small to accommodate a full label and containers whose design causes their label to be destroyed during use. Also, at the time of this publication, there was no labelling guideline by Health Canada available to verify our interpretations of the regulations since Health Canada is in the process of developing a new labelling guideline. Therefore, the non-adherence rate found in this study might change if the new labelling guideline or the special container policy were to be taken into consideration. Of interest, Health Canada has recently initiated a Progressive Licensing Project which aims to improve the drug regulatory system and will include a review of current drug regulations and labelling requirements.

Of concern is that one of the samples did not display the common name properly and two of the samples did not display the route(s) of administration. In the case of an improperly displayed common name, it appears that there was preferential emphasis placed on the manufacturer's branding. There may be instances where explaining the rationale for specific recommendations in a document might improve adherence. For example, an explanation of why a mixed set of characters is preferable to all capital characters (lowercase characters have more variation in character design and thus the visual cues provided by a combination of capitals and lowercase characters renders type more legible than if it is set in all capital characters) conveys the importance of the choice of a mixed character set.

Phase two of the project was an FMEA conducted with seven healthcare professionals with previous experience with FMEA in order to identify the critical information needed on an ampoule or vial for safe medication use. Failure modes related to reading brand name, common name, concentration, total amount of drug ingredient(s) per total volume and route(s) of administration were rated with higher-than-average criticality in the FMEA.

Phase three involved a human factors experiment with a group of 24 nurses. This experiment demonstrated the superiority of black lettering on a white background over printing directly on ampoules (or on a clear substrate that is adhered to ampoules).

This research has focused on some of the concerns with the current labelling of ampoules and vials from a human factors perspective. Although the three-phased study reported here is limited in scope, there are several recommendations, based on the results, that can be made regarding the improvement of guidelines, standards and regulations related to drug labelling:

1. When the CSA standard and the government regulations are under review, consider
   - performing user testing regarding the interpretation of the guideline or regulations;
   - including an explanation (evidence) of the rationale for particular recommendations or requirements;
   - examining the failure modes (or errors) related to the brand name, common name, concentration, total amount of drug ingredient(s) and route of administration;
   - evaluating the necessity of the information required in regulations, such as "address of manufacturer," which takes valuable space on the label.
2. Study the feasibility of using larger-sized ampoules and vials for small volumes to increase surface area for label information.
3. Prohibit the use of printing directly on glass or a clear substrate in the labelling of ampoules or vials containing medications. HQ

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References

Ashcroft, D.M., P. Quinlan and A. Blenkinsopp. 2005. "Prospective Study of the Incidence, Nature and Causes of Dispensing Errors in Community Pharmacies." *Pharmacoepidemiology and Drug Safety* 14(5): 327–32.

Berman, A. 2004. "Reducing Medication Errors through Naming, Labeling, and Packaging." *Journal of Medical Systems* 28(1): 9–29.

Canadian Standards Association. 1999. *Labelling of Drug Ampoules, Vials, and Prefilled Syringes* (Vol. CAN/CSA-Z264.2-99). Etobicoke, ON: CSA.

Cohen, M.R. 1999. "The Role of Drug Packaging and Labeling in Medication Errors." In M.R. Cohen, ed., *Medication Errors.* Washington, DC: American Pharmaceutical Association.

Cohen, M.R. 2007. "The Role of Drug Packaging and Labeling in Medication Errors." In M.R. Cohen, ed., *Medication Errors* (2nd ed.). Washington, DC: American Pharmacists Association.

Filik, R. K. Purdy, A. Gale and D. Gerrett. 2006. "Labeling of Medicines and Patient Safety: Evaluating Methods of Reducing Drug Name Confusion." *Human Factors: The Journal of the Human Factors and Ergonomics Society* 48: 39–47.

Gabriele, S. 2006. "The Role of Typography in Differentiating Look-Alike/Sound-Alike Drug Names." *Healthcare Quarterly* 9: 88–95.

Government of Canada. 2006. *Food and Drug Regulations*, C.R.C., c. 870. Ottawa: Author.

Greenall, J. S. Hyland, M. Colquhoun and V. Jelincic. 2004. "Applying Engineering Principles to Medication Safety." *Canadian Journal of Hospital Pharmacy* 57(2): 110-13.

Health Canada. 2008. Progressive Licensing Project. Accessed March 3, 2008. http://www.hc-sc.gc.ca/dhp-mps/homologation-licensing/index_e.html.

Institute of Medicine of the National Academies. 2007. *Preventing Medication Errors.* Washington, DC: The National Academies Press.

Jeon, J., S. Hyland, K. Momtahan and C.M. Burns. 2007. *Challenges with Applying FMEA to the Process for Reading the Labels on the Containers for Injectable Drugs.* Proceedings of the 51st Annual Meeting of the Human Factors and Ergonomics Society, Baltimore, MD.

Kenagy, J.W. and G.C. Stein. 2001. "Naming, Labeling, and Packaging of Pharmaceuticals." *American Journal of Health Promotion* 58(21): 2033–41.

National Aeronautics and Space Administration. 1995. *Man-Systems Integration Standards* (B ed., Vol. 1). Washington, DC: Author.

Orser, B.A., R.J. Chen and D.A. Yee. 2001. "Medication Errors in Anesthetic Practice: A Survey of 687 Practitioners." *Canadian Journal of Anaesthesia* 48(2): 139–46.

Orser, B.A. and D.C. Oxorn. 1994. "An Anaesthetic Drug Error: Minimizing the Risk." *Canadian Journal of Anaesthesia* 41(2): 120–4.

Phillips, J., S. Beam, A. Brinker, C. Holquist, P. Honig, L.Y. Lee and C. Pamer. 2001. "Retrospective Analysis of Mortalities Associated with Medication Errors." *American Journal of Health-System Pharmacy* 58(19): 1835–41.

United States Pharmacopoeia. 1994, November. "Simplifying Overcrowded Injection Labels." *USP Quality Review* 45.

United States Pharmacopoeia. 1998, May. "National Recommendations: Practice Safe Labeling." *USP Quality Review.* 62

United States Pharmacopoeia. 2000, September. "DPPR – A Final Glance." *USP Quality Review* 75.

Wogalter, M.S. and W.J. Vigilante Jr. 2003. "Effects of Label Format on Knowledge Acquisition and Perceived Readability by Younger and Older Adults." *Ergonomics* 46(4): 327–44.

Using Human Factors Methods to Evaluate the Labelling of Injectable Drugs

Kathryn Momtahan, Catherine M. Burns, Jennifer Jeon, Sylvia Hyland and Sandra Gabriele

Appendix A. Rates of non-adherence to Canadian Standards Association standard

	Non-adherence Rate				
Clause	**Ampoules**	**Vials**	**Total**	**Percentage of Total No. of Samples (*N* = 78)**	**Standard Description***
Shall					
4.1	1	4	5	6.4	The objective of the inner label design shall be drug product identification rather than manufacturer recognition. The legibility of the inner label shall be the primary consideration in its design.
4.2.1	8	24	32	41.0	Drug product information shall be placed in standard locations on the label to enhance proper identification and safe administration. Critical information – common name(s), concentrations, and total amounts – shall be the most prominent features on the main panel of the label. Critical information shall appear in English and French in a single field on the main panel. This field shall not be disrupted by colour or graphics (see Clauses 4.4.6 and 4.5).
4.2.2†	21	57	78	100.0	The common name(s) of the drug(s) shall be printed immediately below the brand name (if included), shall be legible, and shall be printed in a typeface having a stroke width, weight, character height, and x-height according to the requirements of Clause 4.4. If the size of the label does not permit this, the brand name shall be reduced in size or eliminated.
4.2.3	7	36	43	55.1	The following statements shall be included after the common name on the label: (a) in the case of liquid, (i) the total amount of drug ingredient(s) as mg per total mL, followed by (ii) the concentration of drug ingredient(s) as mg per 1 mL. In the instance where the total volume of the drug product is 1 mL, and thus the expression of both the total amount and the concentration of the drug ingredient(s) is identical, a single statement of drug ingredient(s) as mg per 1 mL is acceptable. (b) in the case of powder, the total amount of drug ingredient(s) per total amount of powder. *Note: In some instances, the convention may be to express the amount of drug(s) in milliequivalents (mEq), millimoles (mmol), or international units (IU).*

Appendix A. Continued

4.2.6	4	5	9	11.5	Where a drug is available in different formulations, the particular formulation shall be specified on the main panel with the brand and common name(s) of the drug, e.g., diazepam (emulsion) versus diazepam (solution).
4.2.8	21	56	77	98.7	All drug products shall have an expiration date indicated on the label. The expiration date should be represented as an alphanumeric expression comprising six characters as shown in the example below, where *CCYY* represents a calendar year in four digits, and MM the calendar month within the calendar year in two letters (JA, FE, MR, AL, MA, JN, JL, AU, SE, OC, NO, DE). Format: EXP CCYYMM Example: EXP 1999DE
4.3.1	2	3	5	6.4	Values and amounts appearing on labels shall be expressed in SI (metric) units.
4.4.1	5	20	25	32.1	The character height of the typeface of the common name shall be equal to or greater than that used for the brand name.
4.4.2	10	37	47	60.3	For containers larger than 2 mL, the character height of letters and numerals shall be at least 1.76 mm. For containers of 2 mL or less, the character height of letters and numerals shall be at least 1.5 mm.
4.4.3†	15	24	39	50.0	The width of letters shall be 0.6 of the height, except for the following: (a) the letter "I," which shall be one stroke in width; (b) the letters "J" and "L," which shall be 0.5 of the height; (c) the letter "M," which shall be 0.7 of the height; and (d) the letter "W," which shall be 0.8 of the height.
4.4.4†	4	25	29	37.2	The width of numerals shall be 0.6 of the height, except for the following: (a) the numeral "4," which shall be one stroke width wider; and (b) the numeral "1," which shall be one stroke in width.
4.4.6	19	56	75	96.2	The critical information field shall be represented in black characters on a white background.
4.4.7†	21	55	76	97.4	Characters representing critical information shall have a height-to-stroke ratio of 6:l to 7:l.
4.4.8	3	11	14	17.9	The minimum space between characters shall be 1 stroke width.
4.4.9	9	24	33	42.3	The minimum space between two words shall be 1 character, except "L" or "I."
4.4.10	2	6	8	10.3	The minimum space between lines of text shall be 0.5 of character height.
4.4.11	12	37	49	62.8	A mixed character set shall be used.
4.4.12	4	13	17	21.8	Common, unornamented typefaces shall be used, e.g., Futura Heavy, Futura Medium, Alternate Gothic No. 3.

Appendix A. Continued

4.4.14	8	15	23	29.5	Lines of text shall be flush with the left margin, with a ragged right margin.
4.5.1	6	27	33	42.3	The use of colours or trade dress is acceptable on labels, providing they do not intrude upon the critical information field or distract from the legibility of critical information (see Clauses 4.2.1 and 4.4.6). *Note: While colour and graphics can be used to facilitate differentiation among the formulations of the same drug product, the best use of colour and graphics is to supplement legible label information. Black lettering on a white field is the most legible form of communication under daylight conditions.*
5.2	1	7	8	10.3	Inner labels for parenteral drug products of volume greater than 5 mL requiring reconstitution shall provide reconstitution information, including (a) type and volume of diluent; (b) strength per unit volume resulting from reconstitution; (c) final volume; and (d) stability of reconstituted solution. This information should be positioned in the same field of vision.
6.1	2	9	11	14.1	For small-volume (5 mL or less) parenterals, the inner label shall read from left to right when the top of the container is held in the right hand.
6.2	2	1	3	3.8	For small-volume (5 mL or less) parenterals, the orientation of the label shall be such that the brand and common names, the concentration, and the total content are legible with minimum rotation of the container.
Should					
4.2.4	10	21	31	39.7	The route of administration of the drug(s) should immediately follow the strength of the drug(s). *Note: In some instances, the route of administration may be expressed within the common name.*
4.2.5	5	10	15	19.2	The DIN should be located at the top right corner of the main panel of the label.
4.2.9	18	24	42	53.8	Storage conditions should be clearly identified on the label.
4.3.2	1	3	4	5.1	Abbreviations for common drug names should not be used on a label.
4.4.13	0	1	1	1.3	Intagliated information should be avoided. *Note: Intagliated information, e.g., when used for a lot number or expiration date, is often difficult to read.*

Appendix A. Continued

5.1	0	2	2	2.6	Inner labels for parenteral drug products of volume of 5 mL or less requiring reconstitution should provide reconstitution information, including (a) type and volume of diluent; (b) strength per unit volume resulting from reconstitution; (c) final volume; and (d) stability of reconstituted solution. This information should be positioned in the same field of vision.

*Data from Canadian Standards Association International. 1999. *Labelling of Drug Ampoules, Vials, and Prefilled Syringes* (Vol. CAN/CSAZ-264.2). Etobicoke, ON: CSA International.

† Affected by limited accuracy in typographical measurements.

Appendix B. Rates of non-adherence to Government of Canada Food and Drug Regulations

Regulation	**Non-adherence Rate**				**Regulation Description***
	Ampoules	**Vials**	**Total**	**Percentage of Total No. of Samples (*N* = 75)**	
C.01.004.(1).(a).(ii)	0	1	1	1.3	The inner and outer labels of a drug shall show on the main principal display panel the common name of the drug which, if there is a brand name for the drug, shall immediately precede or follow the brand name in type not less than one-half the size of that of the brand name.
C.01.004.(1).(a).(v)	1	17	18	24	The inner and outer labels of a drug shall show on the main principal display panel in both official languages the notation "sterile" "stérile" if the drug is required to be sterile.
C.01.004.(1).(c).(i)	1	6	7	9.3	The inner and outer labels of a drug shall show on any panel the name and address of the manufacturer of the drug.
C.01.004.(3).(b).(iv)	0	2	2	2.7	The inner label of a drug shall show the route of administration of the drug if other than oral.
C.01.005.(1)	2	1	3	4	The principal display panel of both the inner and outer labels of a drug sold in dosage form shall show in a clear and legible manner the drug identification number assigned by the Director for that drug pursuant to subsection C.01.014.2.(1), preceded by the words "Drug Identification Number" or "Drogue : identification numérique" or both, or the letters "DIN."

*Data from Government of Canada. 2006. *Food and Drug Regulations, C.R.C., c. 870.* Ottawa: Author.

Appendix C. Ambiguities in the Canadian food and drug regulations and in the Canadian Standards Association standard

Regulation	Ambiguity	Description and Recommendation
Food and Drug Regulations*		
C.0.1.004.(1).(c).(iii)	"Adequate" directions	Needs clarification. How much information and of what type would be considered "adequate"?
C.01.004.(3)	"Too small" to accommodate an inner label that conforms to the requirements	It is not clear under which conditions a container could be considered "too small." The maximum volume of a container that can be considered too small could be specified while considering the amount of information that needs to be included in the labels.
C.01.004.(3).(b).(ii)	"Potency" of the drug	Potency can be interpreted as the amount of drug ingredient(s) per unit volume (e.g., 5 mg per mL) or as total amount in total volume (e.g., 50 mg in 10 mL).
Canadian Standards Association Standard†		
Clause 4.4.8	"Space between characters"	Depending on the types of characters, spacing between characters varies. The definition for character spacing should be clarified as in the NASA standard: "approximate visual equivalent of one stroke width between two straight-sided letters such as H and I."‡
Clause 4.4.9	"Space between two words"	Depending on the last letter of a preceding word and the first letter of the following word, the spacing between two words varies. The definition of space between two words should be clarified as in the NASA standard: "the approximate visual equivalent of the letter W between two straight-sided letters such as N and F."‡
Clause 4.4.10	"Space between lines of text shall be 0.5 of character height"	When the font size varies between two lines of text, it is not clear which character height should be used to set the spacing between lines of text.
Clause 4.4.12	"Common, unornamented typefaces"	It is ambiguous what typefaces are considered common and what can be considered as ornamentation on typefaces. Rather than listing examples of such typefaces, including graphical examples of the typefaces would be easier to understand and verify. Also, the definition of ornamentation should be added to the standard.
Clause 6.2	"Minimum rotation of the container"	It is not clear how much rotation is considered minimal. The clause would better specify the degree of field of view within which the label content should be contained.

* Data from Government of Canada. 2006. *Food and Drug Regulations, C.R.C., c. 870.* Ottawa: Author.

† Data from Canadian Standards Association International. 1999. *Labelling of Drug Ampoules, Vials, and Prefilled Syringes* (Vol. CAN/CSAZ-264.2). Etobicoke, ON: CSA International.

‡ Data from National Aeronautics and Space Administration. 1995. *Man-Systems Integration Standards* (B ed., Vol. 1). Washington, DC: Author.

Prevention of Ventilator-Associated Pneumonia in the Calgary Health Region: A Canadian Success Story!

Rosmin Esmail, Greg Duchscherer, Jennifer Giesbrecht, Jennifer King, Pamela Ritchie and Dan Zuege – for the Ventilator Associated Pneumonia Team*

Abstract

This article describes the experiences of a Canadian multidisciplinary critical care team striving to reduce the incidence of ventilator-associated pneumonia (VAP). Several interventions, including a VAP bundle, were used and applied across a health region. Our regional VAP rate has seen a steady decline over the past 12 months and has been largely under our goal of 9.8 cases per 1,000 ventilator-days. The team's success in lowering VAP has provided the momentum for sustained improvement, which has spread to other areas.

Ventilator-associated pneumonia (VAP) is a leading cause of morbidity and mortality among hospitalized patients. VAP develops in 10–20% of mechanically ventilated patients, with those acquiring VAP experiencing greater attributable mortality and longer lengths of stay in intensive care units (ICUs) (Keith et al. 2004; Safdar et al. 2005; US Centers for Disease Control and Prevention 2005).

The Calgary Health Region (CHR) provides healthcare services to 1.2 million residents in Southern Alberta and tertiary services for 1.3 million residents of Alberta and British Columbia. The Department of Critical Care Medicine has three adult multi-system ICUs, admitting over 3,000 patients per year to 38 ICU beds. In recent years, our infection control–based VAP surveillance system discovered a significant incidence of VAP in our regional ICUs. From 1998 to 2002, CHR's rate of VAP was 19 cases per 1,000 ventilator-days. Paralleling published observations from other centres, patients acquiring VAP in the CHR had significantly longer ICU stays, contributing to suboptimal resource use. Accordingly, the department elected to focus on the prevention of VAP.

This focus began in 2002 in conjunction with our participation in the Institute for Healthcare Improvement's Project Impact, with a focus on the ventilator bundle. Joining the Canadian Collaborative on Improving Patient Care and Safety in the ICU (www.improvementassociates.com) in 2004 allowed us to further benefit from the sharing of practice and experience by introducing additional change concepts including the VAP bundle.

This "ideas at work" case study is unique in that it provides a Canadian context, makes use of a modified bundle focused exclusively on measures linked to the prevention of VAP and exemplifies strategies for VAP prevention as applied across a health region rather than an individual hospital.

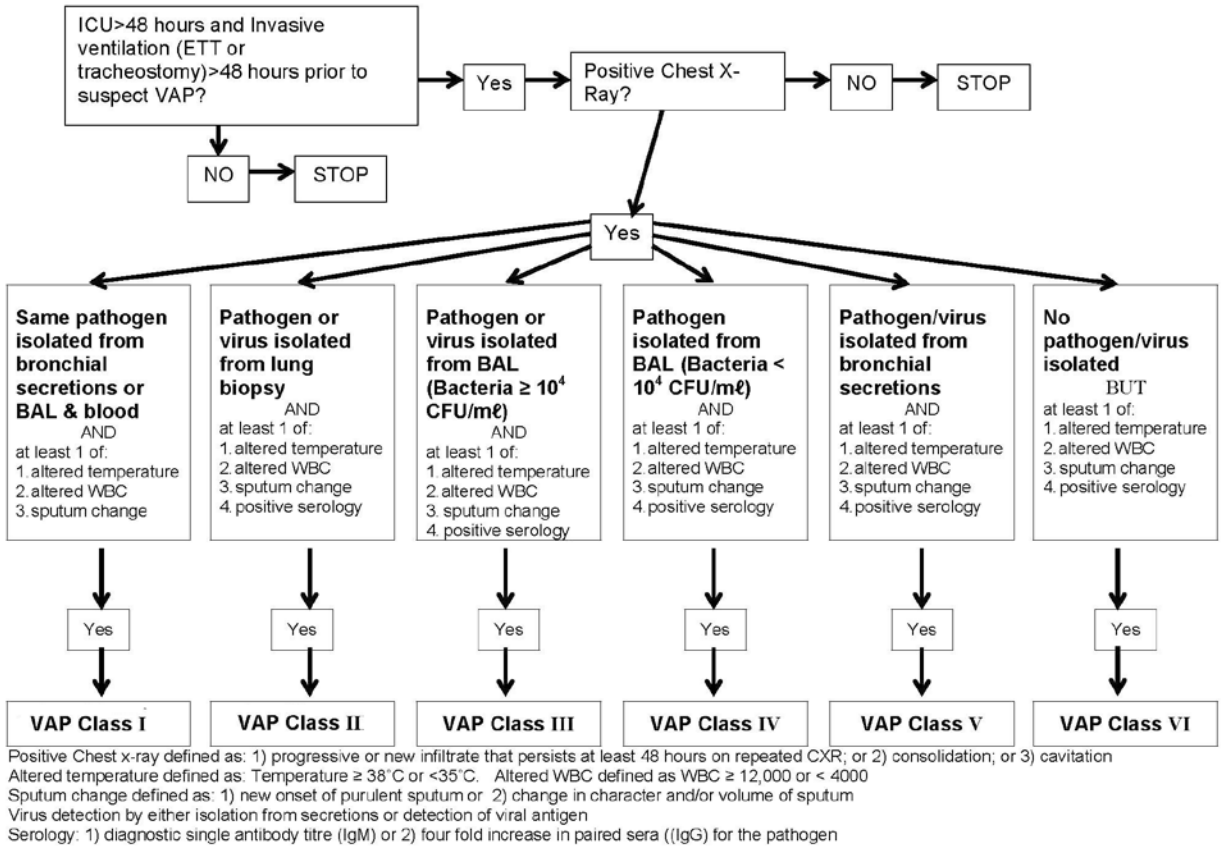
Definition and VAP Surveillance

The definition of VAP varies among healthcare institutions, surveillance bodies and published guidelines. The Canadian ICU Collaborative and the Canadian Safer Healthcare Now! Campaign (http://www.saferhealthcarenow.ca) define VAP as "a pneumonia occurring in patients requiring a device intermittently or continuously to assist respiration through a tracheostomy or endotracheal tube. Further, the device must have been in place within the 48-hour period before onset of infection and for at least two consecutive days" (Safer Healthcare Now! Campaign 2007). The surveillance definition of pneumonia itself is based on the combination of new radiographic densities and supportive clinical signs (Safer Healthcare Now! Campaign 2007). The number of cases of VAP is usually referenced to the number of ventilator-days to yield a rate. The best approach for obtaining supportive microbiological data for VAP remains controversial, with recent randomized trials demonstrating equivalency in important clinical outcomes with invasive and non-invasive approaches (Canadian Critical Care Trials Group 2006). Although a diagnosis of VAP is commonly associated with the growth of a pathogen, this is not always the case (Lambotte et al. 2002). Accordingly, most contemporary definitions of VAP do not depend on adjuvant microbiological data.

CHR uses a similar definition of VAP that further classifies cases of VAP based on the strength of any additional microbiological data (Figure 1) to better understand patterns of diagnosis over time. Though surveillance definitions for VAP clearly contribute to a more objective diagnosis, ultimately there remain significant subjective components to the diagnosis, including the interpretation of chest radiographic and clinical data in patients who frequently have multiple nidi of inflammation. Critical to surveillance as it applies to quality improvement is internal consistency in definition and classification so that performance can be reliably compared over time without the bias of changing definitions.

Surveillance for VAP is accomplished by infection control practitioners (ICPs) conducting standardized surveillance in the three multidisciplinary ICUs. The surveillance system is illustrated in Figure 2. Case finding is accomplished using microbiology-based triggers via daily automated downloads from

Figure 1. Classification of ventilator-associated pneumonia



Positive Chest x-ray defined as: 1) progressive or new infiltrate that persists at least 48 hours on repeated CXR; or 2) consolidation; or 3) cavitation
Altered temperature defined as: Temperature ≥ 38°C or <35°C. Altered WBC defined as WBC ≥ 12,000 or < 4000
Sputum change defined as: 1) new onset of purulent sputum or 2) change in character and/or volume of sputum
Virus detection by either isolation from secretions or detection of viral antigen
Serology: 1) diagnostic single antibody titre (IgM) or 2) four fold increase in paired sera ((IgG) for the pathogen

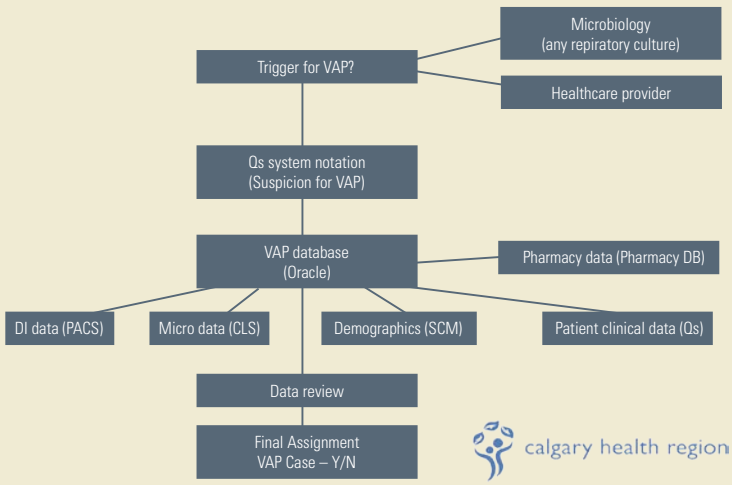
Calgary Laboratory Services that indicate whenever a respiratory specimen of any kind has been received on a patient from one of the ICUs. Given that our routine practice does not include the performance of any surveillance respiratory cultures, the assumption with this kind of case finding is that the performance of a respiratory culture indicates some clinical suspicion for respiratory infection. Secondary triggers for case finding include verbal or written reports of a suspected VAP from the ICU medical staff.

Using an electronic bedside charting system, Quantitative Sentinel, the ICPs determine if the patient initially meets the case definition for VAP, that is, the patient has been in the ICU and mechanically ventilated continuously for at least 48 hours and has at least one clinical sign of an infection, such as altered temperature, white blood cell count or sputum (see Figure 1). The ICP then marks in the Quantitative Sentinel system that a VAP is suspected; this triggers the creation of a chart in a web-based VAP surveillance system, which forms part of our critical care data warehouse and reporting system.

The VAP surveillance system, through interfaces with various other databases, collates in a single record chest radiographic, microbiology (sputum, bronchoscopy and blood specimens), demographical, clinical and antibiotic data. Automatically populated fields facilitate the review from any network computer and decrease data-entry errors. ICPs review in a single record the above data and decide if the case definition is met. Ambiguous cases undergo review by a multidisciplinary group.

The key advantages of this system are (1) efficiency – given that all relevant data are collated into a single record; (2) accuracy – given that the system helps to ensure that data are complete and builds in some error checking; and (3) the ability to easily create and share real-time reports and graphs. The web-based application has reduced the amount of time ICPs dedicate to VAP surveillance by minimizing the time spent on chart review, contributing to a more sustainable system over the long term.

Figure 2. VAP surveillance system



CLS = Calgary lab services; DB = Database; DI = Diagnostic imaging; PACS = Picture archiving and communications system; Qs = Quantitative Sentinel system; SCM = Sunrise clinical manager; VAP = ventilator-associated pneumonia.

Quality Improvement Initiatives and VAP Background

There have been numerous articles published describing quality improvement methodologies associated with decreasing the rate of VAP (American Health Consultants 2003; Berriel-Cass et al. 2006; Cocanour et al. 2006; Fox 2006; Goeschel et al. 2006; Keith et al. 2004; Misset et al. 2004; Murray and Goodyear-Bruch 2007; Resar et al. 2005; Simmons-Trau et al. 2004; Youngquist et al. 2007). All of these studies have been conducted in the United States and illustrate that by implementing a quality improvement program, including use of a ventilator bundle and education strategies, VAP rates decrease substantially.

The traditional ventilator bundle, as popularized by the Institute for Healthcare Improvement, consists of (1) elevation of the head of the bed to 30–45 degrees, (2) daily "sedation vacation" and daily assessment of readiness to extubate, (3) peptic ulcer disease prophylaxis and (4) deep venous thrombosis prophylaxis (unless contraindicated) (Institute for Healthcare Improvement 2006). The Canadian Safer Healthcare Now! Campaign in 2005 advocated for a modified prevention bundle via the inclusion of two additional practices that were alluded to in the clinical practice guidelines for the prevention of VAP published by the Canadian Critical Care Society and the Canadian Critical Care Trials Group (Dodek et al. 2004): (1) elevation of the head of the bed to 30–45 degrees, (2) daily sedation vacation and daily assessment of readiness to extubate, (3) preferential use of oral versus nasal tubes for access to the trachea or stomach and (4) use of EVAC tubes for the drainage of subglottic secretions. Though prophylaxis against peptic ulcer disease and deep venous thrombosis are desirable practices in mechanically ventilated patients, they are not directly related to VAP prevention (Safer Healthcare Now! Campaign 2007).

Team Formation and Objectives

A regional multidisciplinary team was created to work on VAP prevention in conjunction with the Canadian ICU Collaborative in May 2004. Its membership included intensivists, registered nurses, respiratory therapists, infection prevention and control practitioners, physiotherapists, a respiratory therapy

manager, an intensivist with infectious disease training, an information technology manager and a quality improvement and patient safety leader. An intensivist and a respiratory therapy clinical development leader co-chaired the team. Membership was distributed across the three ICUs.

The overall aim was to reduce the impact of VAP in all multi-system ICUs within the CHR; specifically, within one year, to reduce the incidence of VAP across all units by 25% and to ensure that >90% of ventilated patients have all four components of the VAP bundle applied (where appropriate).

Interventions and Change Concepts

The Department of Critical Care Medicine first focused on the prevention of VAP in early 1998 with a systematic review of the literature and the establishment of new and modification of existing policies, procedures and guidelines related to various aspects for care of the ventilated patient in ICU. In November 2002, the ventilator bundle was initiated based on an involvement with the Institute for Healthcare Improvement's Project Impact.

In September 2004, the VAP committee instituted a new VAP bundle to replace the ventilator bundle. The new bundle included head-of-the-bed elevation >30

Table 1. Change concepts and ideas tested and implemented by regional and site-based teams

Change Concept*	Ideas Tested, Implemented, Spread
Develop operational definitions	• Standard and consistent Calgary Health Region definition for VAP developed, adapted from those of CDC
Use proper measurements	• Tracking of VAP through sustainable surveillance database • VAP bundle compliance tracked through monthly audits done on 10% of ventilated patients at each site
Apply best science	• VAP bundle components tested and implemented • Audit additional components: PUD, DVT, hand hygiene, oral care • EVAC tube use and function and readiness for extubation assessed on daily rounds • Hallway huddles focusing on HOB and patient positioning • Online quizzes, VAP discussions at site quality committee meetings, "safety snippets" posted on departmental website
Use checklists	• Use of VAP bundle audit sheets
Create a culture of collaboration and teamwork	• Establish multidisciplinary teams • Engaged RRT to share responsibility of VAP bundle audits
Standardize care	• Implementation of sedation scoring system and practice guideline for sedation • Implementation of a weaning protocol including daily spontaneous breathing trials
Establish reliable processes	• Charting of HOB position in the clinical record q1h by nursing • RRTs documenting HOB q2h and reporting HOB on daily rounds • Charting frequency of oral care • When audits are conducted, families are told what is being done to prevent VAP
Design systems to avoid mistakes	• Signs for HOB >30 degrees • HOB alarm on all new total care and sport beds
Give people access to information	• VAP rates and bundle compliance posted on website, in department newsletter and on bulletin boards • VAP project reviewed at Quality and Safety Council and site quality committees • Communication of the cost of a VAP • Review a VAP case at meeting • Reported on VAP project and outcomes to the regional board • Regional newspaper articles • Posters on HOB and hand hygiene in family room
Develop alliances, co-operative relations	• Regional implementation of EVAC tubes (critical care, emergency, code carts, ambulance and air rescue organizations) • Co-operation with OR for postoperative ICU patients to have EVAC tubes inserted selectively • Change to minimum pressure rather than volume technique for EVAC tube cuffs • Linkage with Cardiac Sciences to spread VAP bundle to CVICU
Reassess current paradigms – change target or set points	• Poster on VAP-free days at one site • Downward adjustment of goal once it has been reached by another 25%

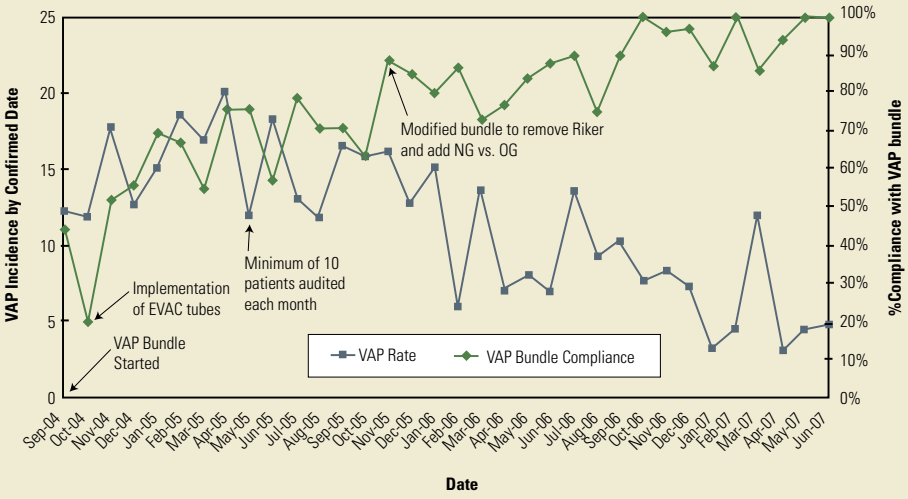
CDC = US Centers for Disease Control and Prevention; CVICU = Cardiovascular Intensive Care Unit; DVT = deep venous thrombosis; HOB = head of the bed (elevation); ICU = Intensive Care Unit; OR = operating room; PUD = peptic ulcer disease; RRT = rapid response team; RT = respiratory therapist; VAP = ventilator-associated pneumonia.

*Data from Couves and Harris (2007).

degrees, daily assessment for spontaneous breathing trial, preferential use of an oral gastric tube, preferential use of an endotracheal tube (ETT) – which allows for continuous aspiration of subglottic secretions (CASS) – and use of the Riker sedation scale. The revised bundle was introduced because it was felt that the new care practices were more directly related to the prevention of VAP; also, our department was influenced by its involvement in the Canadian ICU Collaborative.

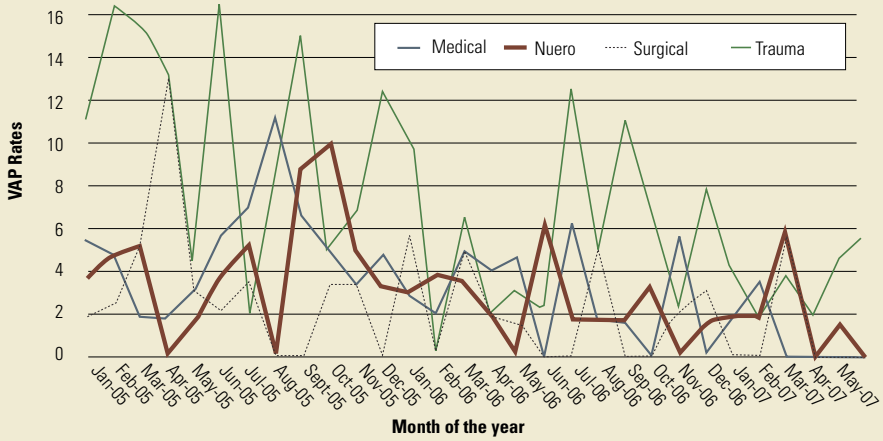
One of the most significant and widespread changes that the team spearheaded was the region-wide introduction of EVAC tubes … if the region were to prevent just one case of VAP, this cost savings would cover the entire cost for the change to EVAC tubes.

Figure 3. Incidence of VAP* and compliance with VAP bundle† over time



NG = nasogastric; OG = orogastric; VAP = ventilator-associated pneumonia.
*VAP cases/1,000 ventilator-days.
†Percentage of audits compliant with all four bundle components.

Figure 4. Incidence of VAP* over time by admitting medical category†



VAP = ventilator-associated pneumonia.
*VAP cases/1,000 ventilator-days.
†Medical category is assigned on admission to the Intensive Care Unit based on the diagnosis most responsible for the admission.

One of the most significant and widespread changes that the team spearheaded was the region-wide introduction of ETTs that allow for CASS (or EVAC ETTs). In October 2004, all areas in all three adult sites in Calgary, except for the operating room, converted to exclusive use of EVAC ETTs. The business case for this change was based on the premise that if the region were to prevent just one case of VAP, this cost savings would cover the entire cost for the change to EVAC tubes. (In CHR, the acquisition of VAP increases ICU length of stay by about 10 days. At approximately $3,000 per ICU-day, this added "cost" to the system is roughly $30,000 for a single case of VAP. The yearly additive cost to change over to EVAC ETTs was approximately $16,000 per year [based on yearly utilization data provided by our purchasing and supply department given that the EVAC ETT costs about three times that of a standard ETT].) To gain support from the various stakeholders (ICU, emergency department, anesthesia, purchasing and supply management etc.), committee members met with key clinical, medical and administrative leaders in each area. Within the following year, this initia-

tive was also spread to our ground ambulance system in Calgary and to the air rescue system in Southern Alberta.

In November 2005, the assessment of the use of the Riker sedation scale was removed from the bundle audit form as it was felt that compliance with this assessment alone did not directly relate to the potential for developing VAP. Rather, the department developed and instituted a sedation protocol and a sedation vacation procedure to be used in conjunction with the assessment for readiness to extubate.

Other initiatives implemented but not directly related to the VAP bundle included those on hand hygiene and the implementation of appropriate equipment cleaning guidelines. Though hand hygiene may be less formally evidence based, it is considered a core quality improvement initiative within our region and department for which ongoing measurement, feedback and action are undertaken.

The team tested, implemented and is continuing to work on numerous interventions, change concepts and ideas using the improvement model and plan-do-study-act cycles (Langley et al. 1996). Table 1 describes the change concepts and ideas that we have tested to support changes to clinical processes.

Our regional VAP rate has seen a steady decline over the past 12 months and has been largely under our goal of 9.8 cases per 1,000 ventilator-days since August 2006.

Measures and Results

The team used several measures to determine if changes were leading to improvement. The key outcome measure was the incidence of VAP as expressed by the number of VAPs per 1,000 ventilator-days. The key process measures were the overall compliance with the VAP bundle and compliance with the individual bundle components. The auditing process for measurement of the compliance with the VAP bundle consisted of bedside reviews of a minimum of 10 selected ventilated patients per month; this number needed to account for at least 10% of the total ventilation-days at each unit.

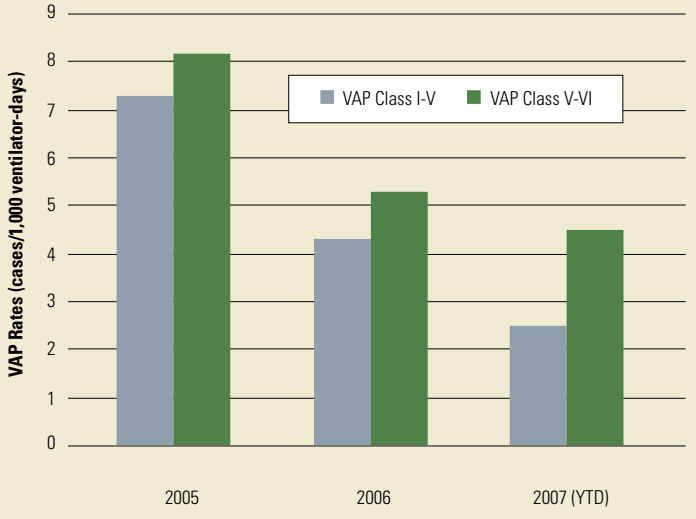
Our regional VAP rate (Figure 3) has seen a steady decline over the past 12 months and has been largely under our goal of 9.8 cases per 1,000 ventilator-days since August 2006. Figure 4 demonstrates the variation in VAP incidence across patient admission categories and a general decline in VAP incidence across all groups. Concurrently, a gradual improvement in regional compliance with the VAP bundle, largely meeting or exceeding our goal of 90% compliance for all components for the past 10 months (see Figure 3), has occurred. This is inversely related to due reduction in our VAP rate.

Figure 5 demonstrates that VAP rates fell in both higher- and lower-class categories of VAP per the classification scheme of Figure 1. This data, though reassuring, must be interpreted with caution given the likely shift in utilization toward less invasive diagnostic techniques to gain supportive microbiological data over time reflecting evolving trial data (Canadian Critical Care Trials Group 2006).

The variability of VAP when measured monthly is well demonstrated in Figures 3 and 4. Recognizing this variability, our quality improvement teams do not typically react to what is perceived as normal random variation. However, whenever there is a signal suggestive of a special cause for a change in rates, the site quality committees initiate a process-based analysis in an attempt to isolate causes for unusual or uncontrolled variation. (*Special cause variation* is defined as a single data point beyond the upper or lower control limits or 99.7% probability limits [three standard deviations from the mean], or a run of five or more consecutive data points on one side of the mean.) The learnings from these analyses are used as teaching points for staff and ask the question, is there anything that can be done to address this special cause?

For many of our staff, it is more intuitive to show our VAP data in terms of the number of cases each month or the days between VAP cases rather than an overall rate, primarily because

Figure 5. Incidence of VAP* over time by VAP diagnostic classification†



VAP = ventilator-associated pneumonia.
*VAP cases/1,000 ventilator-days.
†See Figure 1. VAP diagnostic classes I–IV and V and VI are grouped separately.

of the variability of the data and the difficulty interpreting a number expressed as cases per 1,000 ventilator-days. More importantly, Figures 3 and 4 indicate that, regardless of the way the data are expressed, overall our VAP rates have decreased over time, which is our ultimate goal.

Given the achievement of our initial goal of reducing the incidence of VAP across all units by 25%, the team in September 2007 reviewed its charter and reset the goal to reduce the incidence of VAP by another 25% by March 2008. Therefore, our regional goal has been reduced from 9.8 to 7.4 cases per 1,000 ventilator-days.

The support and lessons gained from each of the national collaborative ventures we have been a part of have been invaluable.

Key Learnings and Challenges

Support and Leadership

The VAP team is fortunate to be led and sponsored by those with expertise and who genuinely value the importance of VAP prevention. Through this commitment, these values are subsequently passed on to each multidisciplinary team and staff member. Similarly, the moral, financial and human resource supports from departmental and regional levels to pursue this initiative have been critical. The support and lessons gained from each of the national collaborative ventures we have been a part of have been invaluable.

Multidisciplinary Participation

When appropriate, families have been involved in the audit process. In most cases, family members have valued the opportunity to be integrated into the care process. For example, families often commented that they enjoyed checking the elevation of the head of the bed each time they entered the room and felt as though they were helping the staff by doing so.

Education

Throughout the implementation of the VAP bundle, the department has been challenged to revise and update clinical care to establish new care values and norms. Transmission of the importance of the VAP bundle to staff was accomplished through hallway huddles and brief group education sessions held within proximity to patient beds. The strongest correlate of staff acceptance of the VAP bundle seemed to be educational strategies that incorporated rationale in addition to process.

Sustainable Reliable Measurement

The ability to measure our VAP rates in a sustainable fashion is crucial. To help accomplish this, our VAP surveillance system builds in efficiencies. Maintenance of internal consistency for the definition and classification of VAP is crucial to allow for reliable comparisons of performance over time without the bias of changing definitions.

Local Oversight and Responsibility

It was difficult to oversee and put into action VAP-prevention strategies across a health region via a high-level regional team alone. The creation of unit-based teams charged with local VAP oversight and implementation was an important evolution, allowing quality-of-care processes to have oversight as close to the bedside as possible.

Persistence

The observed decreases in VAP incidence occurred only after many months of sustained application of VAP-prevention strategies, as reflected in our VAP bundle compliance.

Challenges

There were two key areas of challenge during the implementation of the VAP bundle. Concerns related to the EVAC ETTs include that a percentage of patients have secretions too thick to effectively be evacuated and that the EVAC suction lines produce sounds that can mimic a cuff leak. As well, the radiopaque line within the EVAC tube is interrupted by the Murphy eye on the end of the ETT, thereby making the radiographic assessment of exact ETT depth more challenging. Staffing levels in the ICU continue to pose major challenges and have been linked to increases in VAP (Hugonnet et al. 2007). This issue will continue to require specific attention by the department in the coming years.

Conclusion

The implementation of the VAP bundle, with the goal to apply it on every patient every time, has contributed to a decrease in VAP rates for CHR. Participation in both the Canadian ICU Collaborative and Safer Healthcare Now! Campaign has clearly been of benefit in the development and implementation of our change concepts, in particular the bundle concept. In our experience, keys to achieving sustained improvement include persistence, oversight and responsibility placed as close to the bedside as possible; a sustainable and reliable VAP surveillance system; implementation of several change concepts as bundled interventions; and regular performance measurement, feedback and action to drive improvement. Next steps are to hold and extend our gains in our ICUs and to spread VAP prevention to other areas, including the Cardiovascular ICU. We also look forward to continued participation with national collaboratives. HQ

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References

American Health Consultants. 2003. "Ventilator Education Program Reduces VAP." *Healthcare Benchmarks and Quality Improvement* 10(2): 17–9.

Berriel-Cass, D., F.W. Adkins, P. Jones and M.G. Fakih. 2006. "Eliminating Nosocomial Infections at Ascension Health." *Journal on Quality and Patient Safety* 32(11): 612–20.

Canadian Critical Care Trials Group. 2006. "A Randomized Trial of Diagnostic Techniques for Ventilator-Associated Pneumonia." *New England Journal of Medicine* 355: 2619–30.

Cocanour, C.S., M. Peninger, B.D. Domonoske, T. Li, B. Wright, A. Valdivia and K.M. Luther. 2006. "Decreasing Ventilator-Associated Pneumonia in a Trauma ICU." *Journal of Trauma Injury, Infection and Critical Care* 61(1): 122–30.

Couves, L. and B. Harris. 2007. *Improving Patient Care and Safety in the ICU: Improvement Guide.* Edmonton, AB: Improvement Associates Ltd.

Dodek, P., S. Keenan, D. Cook, D. Heyland, M. Jacka, L. Hand, J. Muscedere, D. Foster, N. Mehta, R. Hall and C. Brun-Buisson, for the Canadian Critical Care Trials Group and the Canadian Critical Care Society. 2004. "Evidence-Based Clinical Practice Guideline for the Prevention of Ventilator Associated Pneumonia." *Annals of Internal Medicine* 141: 305–13.

Fox, M.Y. 2006. "Toward a Zero VAP Rate. Personal and Team Approaches in the ICU." *Critical Care Nursing Quarterly* 29(2): 108–14.

Goeschel, C.A., A. Bourgault, M. Palleschi, P. Posa, D. Harrison, L.L. Tacia, M.A. Adamczyk, D. Falkenberg, L. Barbret, P. Clark, K. Heck, M. O'Neil, V. Pitts, K. Schumacher, D. Sidor, M. Thompson, E. Wahl and D.M. Bosen. 2006. "Nursing Lessons from the MHA Keystone ICU Project: Developing and Implementing an Innovative Approach to Patient Safety." *Critical Care Nursing Clinics of North America* 18(4): 481–92.

Hugonnet, S., I. Uckay and D. Pittet. 2007. "Staffing Level: A Determinant of Late-Onset Ventilator-Associated Pneumonia." *Critical Care* 11: R80. Retrieved August 16, 2007. <http://ccforum.com/content/11/4/R80>.

Institute for Healthcare Improvement. 2006. "Getting Started Kit: Prevent Ventilator-Associated Pneumonia How-to Guide." *Critical Care Nursing Quarterly* 29(2): 157–73.

Keith, D.D., K.M. Garrett, G. Hickox, B. Echols and E. Comeau. 2004. "Ventilator-Associated Pneumonia: Improved Clinical Outcomes." *Journal of Nursing Care Quality* 19(4): 328–33.

Lambotte, O., J.F. Timsit, M. Garrouste-Orgeas, B. Misset, A. Benali and J. Carlet. 2002. "The Significance of Distal Bronchial Samples with Commensals in Ventilator-Associated Pneumonia." *Chest* 122(4): 1389–99.

Langley, J.G., K.M. Nolan, T.W. Nolan, C.L. Norman and L.P. Pronovost. 1996. *The Improvement Guideline: A Practical Approach to Enhancing Organizational Performance.* New York: Jossey-Bass.

Misset, B., J.F. Timsit, M.F. Dumay, M. Garrouste, A. Chalfine, I. Flouriot, F. Goldstein and J. Carlet. 2004. "A Continuous Quality-Improvement Program Reduces Nosocomial Infection Rates in the ICU." *Intensive Care Medicine* 30(3): 395–400.

Murray, T. and C. Goodyear-Bruch. 2007. "Ventilator-Associated Pneumonia Improvement Program." *AACN Advanced Critical Care* 18(2): 190–9.

Resar, R., P. Pronovost, C. Haraden, T. Simmonds, T. Rainey and T. Nolan. 2005. "Using a Bundle Approach to Improve Ventilator Care Processes and Reduce Ventilator-Associated Pneumonia." *Journal on Quality and Patient Safety* 31(5): 243–8.

Safdar, N., C. Dezfulian, H. Collard, and S. Saint 2005. "Clinical and Economic Consequences of Ventilator-Associated Pneumonia: A Systematic Review." *Critical Care Medicine* 33(10): 2184–93.

Safer Healthcare Now! Campaign. 2007. *Getting Started Kit: Prevention of Ventilator-Associated Pneumonia in Adults How-to Guide.* Institute for Healthcare Improvement and Safer Healthcare Now! Campaign. Retrieved August 2, 2007. <http://www.saferhealthcarenow.ca/Default.aspx?folderId=82&contentId=180>.

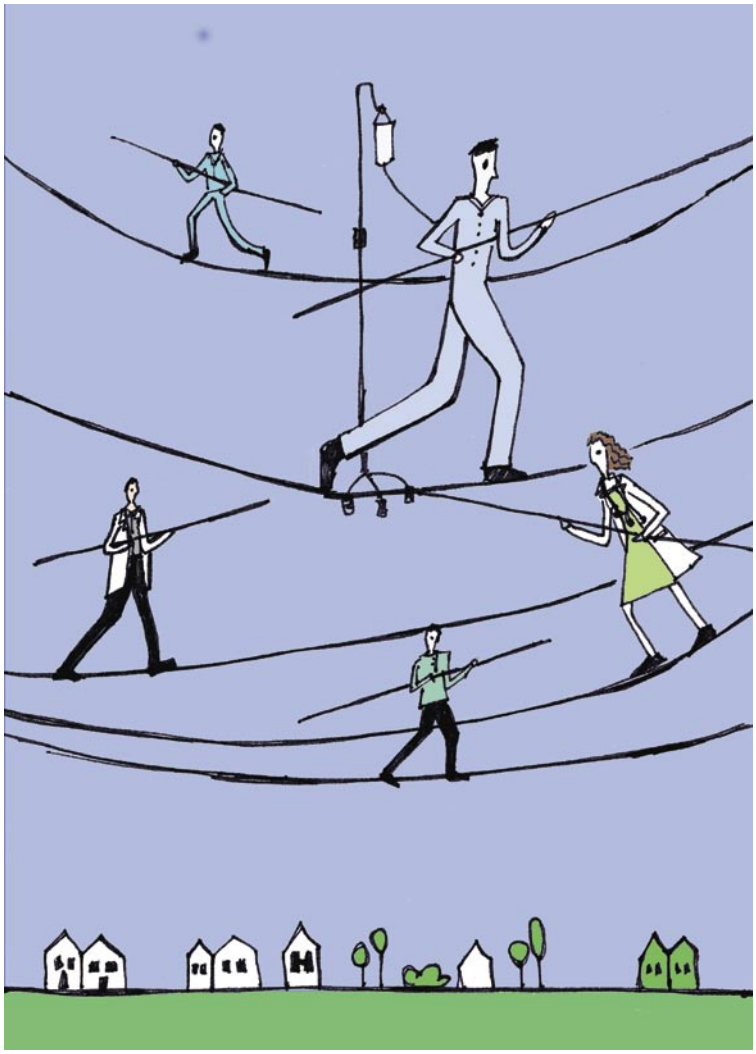
Simmons-Trau, D., P. Cenek, J. Counterman, D. Hockenbury and L. Litwiller. 2004. "Reducing VAP with 6 Sigma." *Nursing Management* 35(6): 41–5.

US Centers for Disease Control and Prevention. 2005. *An Overview of Ventilator Associated Pneumonia.* Atlanta, GA: Department of Health and Human Services, Division of Healthcare Quality Promotion. Retrieved August 2007. <http://www.cdc.gov/ncidod/dhqp/dpac_ventilate_data.html>.

Youngquist, P., M. Carroll, M. Farber, D. Macy, P. Madrid, J. Ronning and A. Susag. 2007. "Implementing a Ventilator Bundle in a Community Hospital." *Joint Commission Journal on Quality and Patient Safety* 33(4): 219–25.

An Evaluation of a Fall Management Program in a Personal Care Home Population

Elaine M.J. Burland



Abstract

Falls are a common problem among institutionalized adults, often resulting in serious negative consequences (Tideiksaar 2002). Fortunately, many of these falls are preventable (Tideiksaar 2002). However, there has been a recent shift from a fall "prevention" approach to one of fall "management," which aims at preventing injuries rather than falls. Falling is regarded as indicative of activity, which strengthens muscles, improves balance, and ultimately reduces the risk of falling (North Eastman Health Association Inc. 2005). For this research, the effectiveness of a fall "management" program that has been implemented in five provincial personal care homes (PCHs) in a Manitoba rural regional health authority will be evaluated. Fall-related administrative data will be analyzed to determine if there are differences (i) within the study sites over time (from pre- to post-intervention) and (ii) between the study and comparison sites. Qualitative information from staff interviews and chart audits will supplement the quantitative information.

Background

Falls are a common problem among institutionalized adults, resulting in serious negative physical (e.g., injuries), psychological (e.g., loss of confidence) and financial (e.g., increased healthcare costs) consequences (Tideiksaar 2002). Approximately 60% of personal care home (PCH) residents fall each year (Hofman et al. 2003; Kannus et al. 2005).

Rather than trying to prevent falls, the goal is to prevent or at least minimize injuries while simultaneously encouraging mobility and functionality.

Fortunately, many falls are preventable (JEL Health Education, Ltd. 2002; Tideiksaar 2002), including those occurring in PCHs (Ray et al. 1997). But some efforts to prevent falls can actually increase the risk of falling (Kane 2001). Specifically, physical and chemical restraints have been found to be more detrimental than helpful (Rubenstein et al. 1994). Not only do they hamper quality of life by restricting residents' interaction and involvement in life, but they result in decreased activity, which contributes to muscle atrophy that, in turn, decreases residents' strength, balance and ultimately confidence – all of which increase the risk of falling (Komara 2005; North Eastman Health Association Inc. 2005a). Since the 1990s, there has been a national effort in the United States to reduce and eventually eliminate the use of restraints (Tideiksaar 2002).

Recently, there has been a philosophical shift from fall prevention to fall management as a response to the problem of seniors' falls. Rather than trying to prevent falls, the goal is to prevent or at least minimize injuries while simultaneously encouraging mobility and functionality (North Eastman Health Association Inc. 2005a), which contribute to improved quality of life (North Eastman Health Association Inc. 2006).

Fall management builds on the already established fall prevention theoretical base, keeping components found to be effective (e.g., exercise, nutrition and the minimization of fall risk factors) and revising those found to be ineffective (i.e., restraint use). As well, fall management is consistent with injury prevention and public health efforts to "think upstream," which is to prevent situations that can cause injury and disease, identify high-risk groups and develop and implement interventions that will reduce the incidence and prevalence of those injuries and diseases (Ashton and Lee 1998). Fall management is also consistent with current proactive seniors' health-related policies and initiatives worldwide, including those in Canada (Public Health Agency of Canada 2005), the United States (Smith and Gamroth 1995), the United Kingdom (Higgs et al. 1998) and Australia (Queensland Health Australia 2003).

Moreover, fall management is an important part of a larger effort to move toward a more social model of care (i.e., person-centred care) that acknowledges that quality of life is as important as (if not more important than) simply extending life (North Eastman Health Association Inc. 2006). Research on institutional efforts to operate under a more social model shows overwhelmingly positive results. Resident (and staff) quality of life improved (Ogden 1998; Reese 2001; Sherbrooke Community Centre 2004), as did resident functionality and health (Ogden 1998). There were also fewer negative outcomes, such as pressure sores, weight loss, falls and restraint use (Reese 2001).

However, fall management and injury prevention efforts are not without their limitations. First, not all research results have been positive. Some studies have found no change in fall rates, and others have even found increases (Vu et al. 2004). However, since falling is indicative of activity and mobility, an increase in falls is not necessarily a negative outcome, especially if injuries do not increase. Moreover, much of this research has acknowledged study shortcomings such as small samples (Vu et al. 2004) and differences in the intervention, outcome measures, geography and/or samples sizes (Becker et al. 2003).

Fall management is part of a social model of care that acknowledges that quality of life is as important as simply extending life.

A second limitation of fall management efforts is that implementation and assessment of fall management and person-centred care efforts can be difficult. It is challenging to promote safety and independence simultaneously (Theodos 2003) and, in practice, the former continues to take precedence over the latter (Kane 2003). Fall management and person-centred care efforts are difficult to sustain (Dempsey 2004; Rantz et al. 2001). Issues such as inadequate staff numbers and training (Resnick et al. 2004), high staff turnover (Amann Talerico et al. 2003), resistance from residents and families (Boise and White 2004) and finance systems that continue to favour technical and standardized care over prevention and person-centred care efforts (Amann Talerico et al. 2003) all hinder program sustainability.

Assessment also proves to be challenging. Few tools exist for adequately assessing quality of life (Kane et al. 2004). There is an abundance of measures for assessing health-related quality of life, but health is only one aspect of a person's overall quality of life (Kane 2003). The Minimum Data Set (MDS) is one example of a widely used tool for assessing nursing home residents (Kane 2003; Wodchis et al. 2003) that does not adequately assess quality of life: only two of the 24 items are related to quality of life, and these focus on restraint use and

level of daily activity (Kane et al. 2004). Moreover, the MDS is based on staff observation rather than resident perceptions, and residents themselves are the best source of information about their quality of life (Kane et al. 2003).

A third limitation facing fall management and person-centred care efforts is the time, resources and expertise needed to implement and interpret the research to assess these complex endeavours. Still a fourth limitation is that there is no guarantee a program is actually being implemented. Continuous monitoring and evaluation of programs can help ensure proper program implementation. While few programs can afford a continuous formal evaluation, computerizing as much information as possible (e.g., patient information, occurrence reports and charts) can facilitate informal monitoring by providing quickly accessible, real-time data (Chies 2004; Wagner et al. 2005).

Fortunately, many of these limitations are not insurmountable, and the benefits of the implementation of fall management and person-centred care greatly outweigh the challenges.

Outcomes of the Fall Management Intervention

The first objective of this research is to evaluate the effectiveness of a fall management program recently implemented in the five PCHs in one of Manitoba's regional health authorities in order to assess how well it contributes to minimizing residents' injuries while simultaneously promoting their mobility, functionality and quality of life. The second objective is to disseminate the research findings, positive or negative, to a wide range of audiences.

The design used to measure changes in fall-related risk factors (e.g., polypharmacy) and outcomes (e.g., hip fractures) is multi-faceted: quasi-experimental (non-randomized), time series (pre- and post-intervention), comparison group (control PCHs without a program) and mixed methods (combination of quantitative and qualitative data and methods). These comparisons will be made between (1) study PCHs over time and (2) study PCHs that have a program versus control PCHs that do not have a program.

The research is currently in progress. To date, a program evaluability assessment has indicated that the program is ready to be evaluated as it meets the criteria set out in the professional literature (e.g., goals and objectives are realistic and measurable, and there are no apparent program-related issues that could interfere with program delivery or the evaluation) (Rutman 1980).

The expected outcome of the program is the minimization of preventable negative consequences associated with residents falling through the implementation of a sustainable fall management program (North Eastman Health Association Inc. 2005b). Specifically, it is expected that the rates of fall-related risks and negative outcomes will be lower in the study PCHs following program implementation. As well, lower rates are expected in the study PCHs compared with the control PCHs that do not have a program in place. Finally, improvement is also expected in resident quality of life as measured by a resident and family survey that is to be re-administered in 2007–2008.

Implications of Research

Fall management may be a better practice than fall prevention. However, because it is a relatively new theory, there is not much research on fall management itself, especially in PCH populations. Most research focuses on fall prevention in community-dwelling seniors (Vu et al. 2004), and many studies involve sample-based randomized control trials (Moreland et al. 2003). This research project provides an opportunity to test the new fall management theory in a PCH population, a group for whom fall interventions have proven less effective than in their community-counterparts (Vu et al. 2004); it is thus an area in need of more research.

Future research could expand this scope and test fall management at the provincial level, looking at each region within Manitoba rather than just two. Moreover, because of a single-payer, universal system across Canada, similar data exist in other provinces (Martens 2004) that could be used as additional sources for comparative analysis. HQ

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Bibliography

Amann Talerico, K., J.A. O'Brien and K.L. Swafford. 2003. "Person-Centered Care: An Important Approach for 21st Century Health Care." *Aging Matters* 41(11): 12–6.

Ashton, J. and B. Lee. 1998. "Being Prepared to Protect the Public Health. Information for Thinking the Unthinkable and Doing the Essential." *Journal of Epidemiology and Community Health* 52: 702–3.

Becker, C., M. Kron, U. Lindemann, E. Sturm, B. Eichner, B. Walter-Jung and T. Nickolaus. 2003. "Effectiveness of a Multifaceted Intervention on Falls in Nursing Home Residents." *Journal of the American Geriatric Society* 51: 306–13.

Boise, L. and D. White. 2004. "The Family's Role in Person-Centered Care: Practice Considerations." *Aging Matters* 42(5): 12–20.

Chies, S. 2004. "Building on Patient-Based Software." *Provider* 30: 34–7.

Dempsey, J. 2004. "Falls Prevention Revisited: A Call for a New Approach." *Journal of Clinical Nursing* 13: 479–85.

Higgs, P.F.D., L.D. MacDonald, J.S. MacDonald and M.C. Ward. 1998. "Home from Home: Residents' Opinions of Nursing Homes and Long-Stay Wards." *Age and Ageing* 27(2): 199–207.

Hofman, M.T., P.F. Bankes, A. Javed and M. Selhat. 2003. "Decreasing the Incidence of Falls in the Nursing Home in a Cost-Conscious Environment: A Pilot Study." *Journal of the American Medical Directors Association* March/April 4(2): 95–7.

JEL Health Education, Ltd. 2002. *Preventing Falls among Older Clients: Essential Guide for the Facilitator.* St. John's, NL: Author.

Kane, R.A. 2001. "Long-Term Care and a Good Quality of Life: Bringing them Closer Together." *The Gerontologist* 41(3): 293–304.

Kane, R.A. 2003. "Definition, Measurement, and Correlates of Quality of Life in Nursing Homes: Toward a reasonable Practice, Research, and Policy Agenda." *The Gerontologist* 43(Special issue 2): 28–36.

Kane, R.A., K. Kling, B. Bershadsky, R.L. Kane, K. Giles, H.B. Degenholtz, J. Liu and L.J. Cutler. 2003. "Quality of Life Measures for Nursing Home Residents." *Journals of Gerontology: Series A: Biological Sciences and Medical Sciences* 58(3): 240–8.

Kane, R.L., B. Bershadsky, R.A. Kane, H. Degenholtz, J. Liu, K. Giles and K.C. Kling. 2004. "Using Resident Reports of Quality of Life to Distinguish among Nursing Homes." *The Gerontologist* 44: 624–32.

Kannus, P., H. Sievanen, T. Jarvinen and J. Parkkari. 2005. "Prevention of Falls and Consequent Injuries in Elderly People." *Lancet* 366: 1885–93.

Komara, F.A. 2005. "The Slippery Slope: Reducing Fall Risk in Older Adults." *Primary Care* 32: 683–97.

Martens, P.J. 2004. *What Works? Evaluating Manitoba's Rural and Northern Regional Health Programs and Policies at the Population Level.* Winnipeg: University of Manitoba Faculty of Medicine, Manitoba Centre for Health Policy.

Moreland, J., J. Richardson, D.H. Chan, J. O'Neill, A. Bellissimo, R.M. Grum and L. Shanks. 2003. "Evidence-Based Guidelines for the Secondary Prevention of Falls in Older Adults." *Gerontology* 49: 93–116.

North Eastman Health Association Inc. 2005a. *Fall Management Program Education Strategy* (Phases 1–3). Pinawa, MB: Author.

North Eastman Health Association Inc. 2005b. *Long Term Care: Fall Management Program* (Guide). Pinawa, MB: Author.

North Eastman Health Association Inc. 2006. *Warming the Soil: Long Term Care Mandatory Training Day.* Pinawa, MB: Author.

Ogden, R.G. 1998. "Improving Nursing Home Residents' Function and Quality of Life." *Balance* 2(6): 10–3.

Public Health Agency of Canada: Division of Aging and Seniors. 2005. *Report on Seniors' Falls in Canada.* Ottawa: Minister of Public Works and Government Services Canada.

Queensland Health Australia. 2003. *Falls Prevention Best Practice Guidelines: For Public Hospitals and State Government Residential Aged Care Facilities.* Brisbane, Australia: Author.

Rantz, M.J., L. Popejoy, G.F. Petroski, R.W. Madsen, D.R. Mehr, M. Zwygart-Stauffacher, L.L. Hicks, V. Grando, D.D. Wipke-Tevis, J. Bostick, R. Porter, V.S. Conn and M. Maas. 2001. "Randomized Clinical Trial of a Quality Improvement Intervention in Nursing Homes." *The Gerontologist* 41(4): 525–38.

Ray, W.A., J.A. Taylor, K.G. Meador, B.T. Purushottam, A.K. Brown, H.K. Kajihara, C. Davis, P. Gideon and M.R. Griffin. 1997. "A Randomized Trial of a Consultation Service to Reduce Falls in Nursing Homes." *Journal of the American Medical Association* 278(7): 557–62.

Reese, D. 2001. "Putting the Resident First." *Contemporary Long Term Care* 24(5): 24.

Resnick, B., C. Quinn and S. Baxter. 2004. "Testing the Feasibility of Implementation of Clinical Practice Guidelines in Long-Term Care Facilities." *Journal of the American Medical Directors Association* Jan/Feb 5(1): 1–8.

Rubenstein, L.Z., K.R. Josephson and A.S. Robbins. 1994. "Falls in the Nursing Home." *Annals of Internal Medicine* 121: 442–51.

Rutman, L. 1980. *Planning Useful Evaluations: Evaluability Assessment.* Beverly Hills, CA: Sage Publications.

Sherbrooke Community Centre. 2004. *Exploring the Sherbrooke Community.* Saskatoon, SK: Author. Retrieved August 2, 2007. <http://www.sherbrookecommunitycentre.ca/exploring.php?id=321>.

Smith, J. and L.M. Gamroth. 1995. "The Resident: The Heart of It: A Home Caregiving Experience Leads to a Fresh Look at Caring for Residents in Nursing Homes." *Geriatric Nursing* 16(3): 113–6.

Takasaki, D.A. 1997. "Tying the Knot Between Resident Care and Quality of Life." *Balance* 1(3): 16–18.

Theodos, P. 2003. "Fall Prevention in Frail Elderly Nursing Home Residents: A Challenge to Case Management: Part 1." *Lippincott's Case Management* 8: 246–50.

Theodos, P. 2004. "Fall Prevention in Frail Elderly Nursing Home Residents: A Challenge to Case Management: Part 2." *Lippincott's Case Management* 9: 32–44.

Tideiksaar, R. 2002. *Falls in Older People: Prevention and Management* (3rd ed.). Baltimore, MD: Health Professions Press.

Vu, M.Q., N. Weintraub and L. Rubenstein. 2004. "Falls in the Nursing Home: Are They Preventable? Controversies in Long-Term Care." *Journal of the American Medical Directors Association* 5: 401–6.

Wagner, L.M., E. Capezuti, J.A. Taylor, R.W. Sattin and J.G. Ouslander. 2005. "Impact of a Falls Menu-Driven Incident-Reporting System on Documentation and Quality Improvement in Nursing Homes." *The Gerontologist* 45: 835–42.

Wodchis, W.P., J.P. Hirdes and D.H. Feeny. 2003. "Health-Related Quality of Life Measure Based on the Minimum Data Set." *International Journal of Technology in Health Care* 3: 490.

Practice Changes to Improve Delivery of Surgical Antibiotic Prophylaxis

Rosemary Zvonar, Pam Bush and Virginia Roth

Abstract

Timely administration of appropriate antibiotics preoperatively can decrease the incidence of surgical site infection. We evaluated compliance with quality indicators in the delivery of antimicrobial surgical prophylaxis at The Ottawa Hospital and assessed the impact of a change to the hospital's Surgical Prophylaxis Policy.

An audit in 2002 revealed improvement was necessary in the timing of preoperative doses, dosing for patients with a high body mass index, and intra-operative redosing. As a result, a multidisciplinary group was formed and a new surgical prophylaxis policy was approved. The policy included administration of preoperative doses by the anesthesiologist, and an automatic substitution for higher doses of antibiotics for select patients. This practice change resulted in significant improvements to the preoperative timing and dosing in subsequent audits. A mechanism to address intra-operative redosing will be implemented.

Background and Objectives

Surgical site infections (SSIs) are associated with increased patient morbidity, mortality and healthcare costs (Kirkland et al. 1999). It has been well established that properly timed preoperative antibiotics at the correct dose reduce the incidence of SSIs for a variety of surgical procedures (Classen et al. 1992; Forse et al. 1989; van Kasteren et al. 2007). Additional aspects of surgical prophylaxis – such as selection of the appropriate agent(s), administration of intra-operative doses and duration of post-operative prophylaxis – are also important components of antimicrobial stewardship and infection prevention. Patient safety agencies in both the United States and Canada have identified the prevention of SSIs and appropriate antimicrobial prophylaxis as a primary quality target.

The objectives of this study were to evaluate compliance with quality indicators in the delivery of antimicrobial surgical prophylaxis at The Ottawa Hospital and to assess the impact of a change to the hospital's Surgical Prophylaxis Policy.

Methods

Quality indicators for antibiotic surgical prophylaxis were derived from the current literature (American Society of Health-System Pharmacists 1999; "Antimicrobial Prophylaxis in Surgery" 2001; Auerbach 2001; Dellinger et al. 1994; Forse et al. 1989; Mangram et al. 1999; Scottish Intercollegiate Guidelines Network 2000; Swoboda et al. 1996; Zanetti et al. 2001). A baseline audit was performed between January and March 2002 to assess compliance with the quality indicators in five surgical divisions (Orthopedic, Neurosurgery, Vascular, Thoracic and General Surgery). As part of the continuous quality improvement process, the antibiotic prophylaxis quality

Table 1. Compliance with surgical prophylaxis quality indicators

Date of Audit	Total Charts Reviewed*	Appropriate Agent	OR (95% CI); p Value†	Appropriate Dose	OR (95% CI); p Value†
Jan–Mar 2002	290	241/258, 93.4%	–	173/239, 72.4%	–
May–July 2004	261	217/235, 92.3%	0.8 (0.4–1.8); .64	180/217, 83%	1.9 (1.2–3.0); .007
June–Sept 2006	273	234/253, 92.5%	1.0 (0.5–2.1); .9	208/232, 89.7%	1.8 (0.9–3.2); .04

Date of Audit	Appropriate Administration	OR (95% CI); p Value†	Intra-operative Dose Given if Required	OR (95% CI); p Value†	Post-operative Duration ≤24 Hours	OR (95% CI); p Value†
Jan–Mar 2002	94/261, 36%	–	13/33, 39.4%	–	233/260, 89.6%	–
May–July 2004	170/251, 67.7%	3.7 (2.5–5.5); < .001	27/50, 54%	1.8 (0.7–0.9); .19	N/A‡	–
June–Sept 2006	205/261, 78.5%	1.7 (1.2–2.6); .006	22/58, 37.9%	0.5 (0.2–1.2); .09	236/264, 89.4%	1.0 (0.5 – 1.8); .9

CI = confidence interval; N/A = not assessed; OR = odds ratio.
*Note: Denominators to do not equal total charts reviewed due to missing data.
†Compared with the previous audit period.
‡As the duration of post-operative prophylaxis did not exceed 24 hours in 90% of the cases in the 2002 audit, it was not re-examined in 2004.

indicators were prospectively re-evaluated between May and July 2004 and between June and September 2006. For each audit, a convenience sample of approximately 50 patient charts per division were reviewed.

Findings and Solutions

A summary of the audit results is shown in Table 1. The baseline audit revealed that the selection of antimicrobial agents and duration of post-operative prophylaxis were appropriate in 90% of cases. However, only 40% of patients received an intra-operative dose of antibiotic when indicated. In addition, only one third of patients received a preoperative dose of antibiotic within the recommended time period. Finally, only 15% (seven of 47) of patients with a large body mass index (BMI) received an antibiotic dose that was greater than the standard recommended dose.

Following the baseline audit, a multidisciplinary team was formed to review the institution's process for antimicrobial prophylaxis and to make recommendations for improvement. Members included the antimicrobial pharmacist, the clinical director, clinical managers and nurse educators for peri-operative services, the pharmacy operations manager and physician representatives from surgery, anesthesiology and infection prevention and control. The working group recommended that the preoperative antibiotics be administered by the anesthesiologist at the induction of anesthesia (with the exceptions of vancomycin and clindamycin due to their longer administration times). Orders written as "preop" or "on call to OR" were to be understood as indicating that the antibiotic was to be administered in the operating room (OR) as per this new protocol. To facilitate delivery, premixed preoperative doses of antibiotics were to be sent to the OR attached to a patient's chart and were also made readily available in the OR suites. These interventions, along with additional practice changes to facilitate the process (Table 2), were implemented in June 2003.

The subsequent audit, conducted in 2004, demonstrated that preoperative antibiotics were four times more likely to be administered in a timely manner and that the dosing was two times more likely to be appropriate following these interventions (see Table 1). These increases were statistically significant. In addition, an intra-operative dose was given when required to a higher percentage of patients, although this increase was not significant. In this audit, a higher antibiotic dose was administered in 63% (44 of 70) of patients with a BMI ≥30 or weight ≥90 kilograms. Selection of the appropriate agent occurred in 92.3% of instances, consistent with the 2002 audit.

Despite these improvements, our desired target of 90% for all quality indicators was not yet attained. Therefore, a *preoperative pause* was implemented in March 2005 during which verification is made of the patient, the procedure, the surgical site and whether the preoperative antibiotic has been administered prior to the initial incision. The subsequent audit in 2006 demonstrated a further statistically significant improvement in the percentage of patients who received a preoperative dose of antibiotic within the recommended time period (78.5%, versus 67.7% in 2004). There was also a non-statistically significant

Table 2. Strategies implemented to improve delivery of surgical antibiotic prophylaxis at The Ottawa Hospital

1. Implementation of a new Surgical Prophylaxis Policy (June 2003):
   - Anesthesiologist to administer preoperative antibiotic(s) at induction of anesthesia
   - Patients with a body mass index (BMI) ≥30 (or weight ≥90 kg if BMI not available) to receive a 2 g dose of cefazolin, or a 1,500 mg dose of vancomycin
   - Surgeon to confirm that any required prophylactic antibiotic(s) have been administered
   - Antibiotics to be redosed intra-operatively for surgeries >3–4 hours (6 hours for vancomycin) or for significant blood loss (≥1,500 mL)
2. Nursing-/pharmacy-initiated automatic substitution to higher doses of antibiotics for patients with a BMI ≥30 or weight ≥90 kg
3. Antibiotic prophylaxis added to preoperative checklist
4. Development of a list of surgeries requiring prophylaxis and recommended agents
5. Provision of premixed antimicrobial agents and improved availability in the operating room and pre-admission units
6. Education regarding cross-allergy with cephalosporins in patients with penicillin allergy
7. Implementation of a preoperative pause (March 2005)

increase in the percentage of patients administered an appropriate dose due to a greater proportion of patients (72% or 64 of 89) with a high BMI receiving the recommended antibiotic dose. Target levels were maintained for the selection of agent and for post-operative duration of prophylaxis, but the initial improvement in the number of patients who received an intra-operative dose of antibiotic when required returned to the baseline level of the initial review in 2002.

In the subset of patients administered the prophylactic dose of antibiotic prior to incision, the median time between administration and incision decreased from 59 minutes in 2002 to 25 minutes in both 2004 and 2006.

Discussion

The development and therefore prevention of SSIs involves a number of factors such as skin preparation, surgical technique and specific patient factors (Dellinger et al. 2005; Sessler and Akça 2002). Although surgical antibiotic prophylaxis is but one of these, giving the appropriate antibiotic at the appropriate dose within one hour of incision has been well documented to reduce the incidence of SSIs (Classen et al. 1992; Forse et al. 1989; van Kasteren et al. 2007) and should be expected by all patients undergoing surgeries in which prophylaxis is recommended. Conversely, an unnecessarily prolonged duration of prophylaxis increases the risk of antimicrobial-resistant organisms and adverse events (Harbarth et al. 2000; Kreisel et al. 1995).

Our baseline audit demonstrated that appropriate antimicrobial agents were administered and prophylaxis was correctly limited to 24 hours or less in 90% of the procedures we reviewed, and remained consistent throughout the study period. However, we found important deficiencies in the timing of the initial preoperative dose, as well as intra-operative redosing – an indicator not frequently evaluated in studies assessing surgical prophylaxis. Other studies have also demonstrated that surgical prophylaxis continues to be suboptimally administered in 25–50% of cases (Auerbach 2001; Matuschka et al. 1997; Silver et al. 1996; Webb et al. 2006). For example, in a review of over 34,000 surgical procedures in 2,965 acute care US hospitals, the appropriate antimicrobial agent was selected in 92.6% of procedures; however, timing was appropriate in only 55.7% of procedures, and only 40.7% of procedures had antibiotics discontinued within 24 hours of surgery (Bratzler et al. 2005).

Our quality improvement efforts focused on improving the timing, intra-operative administration and dosing of antibiotic prophylaxis. Having the anesthesiologist administer the antibiotic at the time of induction of anesthesia resulted in a significant improvement in the timing of the preoperative dose of prophylactic antibiotic (initially appropriate in 36% and improving to 68%) and a decrease in the median interval between antibiotic administration and incision (from 59 to 25 minutes). Although there may be some reluctance on the part of the anesthesiologists to assume this task, this method has also been shown to improve antibiotic administration in other studies too (Matuschka et al. 1997; Webb et al. 2006; White and Schneider 2007). We demonstrated a further increase in the number of patients receiving the antibiotics within the designated time following the introduction of the preoperative pause.

In addition, we observed a significant increase over time in the percentage of patients who received an appropriate dose of preoperative antibiotic. Administration of higher doses to patients with a larger BMI accounted for the majority of this improvement and was most likely related to increased awareness and our automatic substitution policy.

Our quality improvement efforts did not have a sustained impact on the percentage of patients who received intra-operative doses of antibiotics for long procedures or excessive blood loss, although the study was underpowered to detect small changes. One of the most important barriers was that no group (surgeons, anesthesiologists or nursing) was willing to take responsibility for monitoring this parameter. Clearly, a formal process, a mechanism and assignment of responsibility are required to improve this important aspect of surgical prophylaxis.

This study was not designed to measure the impact of improved antibiotic delivery on the risk of SSIs. A crude analysis of SSI rates during this time period suggested a non-sustained decrease in vascular surgery infection rates following these improvement initiatives. There was no discernible decrease in infection rates in other surgical procedures for which surveillance data were available. The causes of SSIs are usually multi-factorial, and reducing infection rates typically requires multi-faceted interventions. Nonetheless, a decrease in SSIs following an improvement in the timeliness of antibiotic administration has been observed in a number of recent studies (Dellinger et al. 2005; van Kasteren et al. 2007; Webb et al. 2006).

In summary, optimizing delivery of surgical antibiotic prophylaxis is an important patient safety goal. These findings demonstrate that significant improvements in the dosing and timing of preoperative antibiotic prophylaxis can be achieved through continuing quality improvement efforts involving multidisciplinary collaboration. HQ

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References

American Society of Health-System Pharmacists. 1999. "ASHP Therapeutic Guidelines on Antimicrobial Prophylaxis in Surgery." *American Journal of Health-System Pharmacy* 56: 1839–88.

"Antimicrobial Prophylaxis in Surgery." 2001. *Medical Letter* 43: 92–7.

Auerbach, A.D. 2001. "Prevention of Surgical Site Infections." In K.G. Shojania, B.W. Duncan, K.M. McDonald and R.M. Wachter, eds., *Making Health Care Safer: A Critical Analysis of Patient Safety Practices* (Evidence Report/Technology Assessment: No. 43. AHRQ Publication No. 01-E058). Rockville, MD: Agency for Healthcare Research and Quality.

Bratzler, D.W., P.M. Houck, C. Richards, L. Steele, E.P. Dellinger, D.E. Fry, P.M.C. Wright, A. Ma, K. Carr and L. Red. 2005. "Use of Antimicrobial Prophylaxis for Major Surgery: Baseline Results from the National Surgical Infection Prevention Project." *Archives of Surgery* 140(2): 174–82.

Classen, D.C., R.S. Evans, S.L. Pestotnik, S.D. Horn, R.L. Menlove and J.P. Burke. 1992. "The Timing of Prophylactic Administration of Antibiotics and the Risk of Surgical-Wound Infection." *New England Journal of Medicine* 326: 281–6.

Dellinger, E.P., P.A. Gross, T.L. Barrett, P.J. Krause, W.J. Martone, J.E. McGowan Jr., R.L. Sweet and R.P. Wenzel. 1994. "Quality Standard for Antimicrobial Prophylaxis in Surgical Procedures." *Clinical Infectious Diseases* 18: 422–7.

Dellinger, E.P., S.M. Hausmann, D.W. Bratzler, R.M. Johnson, D.M. Danial, K.M. Bunt, G.A. Baumgardner and J.R. Sugarman. 2005. "Hospitals Collaborate to Decrease Surgical Site Infections." *American Journal of Surgery* 190(1): 9–15.

Forse, R.A., B. Karam, L.D. MacLean and N.V. Christou. 1989. "Antibiotic Prophylaxis for Surgery in Morbidly Obese Patients." *Surgery* 106: 750–7.

Harbarth, S., M.H. Samore, D. Lichtenberg and Y. Carmeli. 2000. "Prolonged Antibiotic Prophylaxis after Cardiovascular Surgery and Its Effect on Surgical Site Infections and Antimicrobial Resistance." *Circulation* 101(25): 2916–21.

Kirkland, K.B., J.P. Briggs, S.L. Trivette, W.E. Wilkinson and D.J. Sexton. 1999. "The Impact of Surgical-Site Infections in the 1990s: Attributable Mortality, Excess Length of Hospitalization, and Extra Costs." *Infection Control and Hospital Epidemiology* 20: 725–30.

Kreisel, D., T.G. Savel, A.L. Silver and J.D. Cunningham. 1995. "Surgical Antibiotic Prophylaxis and Clostridium difficile Toxin Positivity." *Archives of Surgery* 130: 989–93.

Mangram, A.J., T.C. Horan, M.L. Pearson, L.C. Silver and W.R. Jarvis. 1999. "Guideline for Prevention of Surgical Site Infection." *Infection Control and Hospital Epidemiology* 20: 247–78.

Matuschka, P.R., W.G. Cheadle, J.D. Burke and R.N. Garrison. 1997. "A New Standard of Care: Administration of Preoperative Antibiotics in the Operating Room." *American Surgeon* 63(6): 500–3.

Scottish Intercollegiate Guidelines Network. 2000. *Antibiotic Prophylaxis in Surgery* (SIGN Publication No. 45). Edinburgh, Scotland: Author. Retrieved August 10, 2007. <http://www.sign.ac.uk/guidelines/fulltext/45/index.html>.

Sessler, D.I. and O. Akça. 2002. "Nonpharmacological Prevention of Surgical Wound Infections." *Clinical Infectious Diseases* 35: 1397–404.

Silver, A., A. Eichorn, J. Kral, G. Pickett, P. Barie, V. Pryor and M. Dearie. 1996. "Timeliness and Use of Antibiotic Prophylaxis in Selected Inpatient Surgical Procedures." *American Journal of Surgery* 171: 548–52.

Swoboda, S.M., C. Merz, J. Kostuik, B. Trentler and P.A. Lipsett. 1996. "Does Intraoperative Blood Loss Affect Antibiotic Serum and Tissue Concentration?" *Archives of Surgery* 131: 1165–72.

van Kasteren, M.E.E., J. Manniën, A. Ott, B-J. Kullberg, A.S. de Boer and I.C. Gyssens. 2007. "Antibiotic Prophylaxis and the Risk of Surgical Site Infections following Total Hip Arthroplasty: Timely Administration Is the Most Important Factor." *Clinical Infectious Diseases* 44(1): 921–7.

Webb, A.L.B., R.L. Flagg and A.S. Fink. 2006. "Reducing Surgical Site Infections through a Multidisciplinary Computerized Process for Preoperative Prophylactic Antibiotic Administration." *American Journal of Surgery* 192: 663–8.

White, A. and T. Schneider. 2007. "Improving Compliance with Prophylactic Antibiotic Administration Guidelines." *AORN Journal* 85(1): 173–80.

Zanetti, G., R. Giardina and R. Platt. 2001. "Intraoperative Redosing of Cefazolin and Risk for Surgical Site Infection in Cardiac Surgery." *Emerging Infectious Diseases* 7(5): 828–31.

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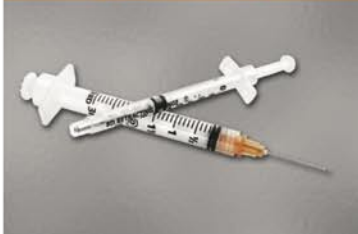

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