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Healthcare Quarterly

SPECIAL ISSUE

Papers

PATIENT SAFETY

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Human Factors in Action: Getting “Pumped” at a Nursing Usability Laboratory

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Implementing System Safeguards to Prevent Error-Induced Injury with Opioids

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Transfer of Accountability: Transforming Shift Handover to Enhance Patient Safety

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Adverse Events among Winnipeg Home Care Clients

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Editorial

Creating Safer Care

Is

safer healthcare possible? What needs to be done to fulfil this goal? Research on adverse events and improved reporting systems have elevated the issue of patient safety across Canada. But the work of creating care environments that encourage and sustain safety is more difficult than simply recognizing the problems. We are not the first to confront this. Two years ago, following the fifth anniversary of the Institute of Medicine report, a number of commentators lamented the failure to demonstrate much progress in the United States on the lofty goals enunciated in *To Err Is Human*. Our challenge in Canada is made even more daunting by the concurrent need to focus on other critical system issues such as improving access to care.

The good news is that the past year has seen a blossoming of efforts to improve patient safety in Canada. There is a growing recognition at senior policy levels that improvements in access to care are unsatisfactory unless we concurrently ensure that this care is safe and effective. The Canadian Patient Safety Institute and provincial safety and quality councils have articulated new goals and supported local improvements in quality and safety. But the most heartening developments are the accelerating efforts of clinicians and managers, along with researchers and others, to improve care for patients.

This issue of *Healthcare Quarterly* provides evidence that safer patient care is achievable. We have gathered papers outlining excellent work across Canada addressing this goal.

The papers are grouped by several themes. We begin with articles on *Identifying and Reducing Risks*. Many organizations are working to improve their assessment of incidents and adverse events. Even more challenging is moving from risk identification to improvement. Catherine Cronin outlines the use of the London Protocol in the analysis of critical occurrences in pediatric care in Winnipeg. Mark Daly describes how the analysis of sentinel events was translated into improvements in patient transport and the care for patients who experience a stroke in hospital at the McGill University Health Centre. Important information on risks can also be gleaned from staff. Debbie Barnard and colleagues at Capital Health in Edmonton report on their "Good Catch" program, which now generates over 100 reports per month on "near miss" events. Rosanne Zimmerman and colleagues at Hamilton Health Sciences Centre outline an innovative approach that builds local expertise in identifying and addressing patient safety issues. Patient Safety Triads are three-person groups formed from frontline staff and managers to coordinate unit-based safety efforts.

Similar patient safety problems are emerging in organizations across the country, and mechanisms are needed to share

this learning. Margaret Colquhoun and colleagues at ISMP Canada detail how they used hospital surveys on opioid use to spur improvements in medication use in hospitals in two provinces. Paula Beard and Linda Smyrski report on the development of provincial reporting and learning efforts that spread knowledge about incidents and improvements across institutions in Saskatchewan and in Manitoba.

Hospital-acquired infections remain a critical challenge for Canadian healthcare organizations. Two papers from Toronto hospitals report on successful efforts to reduce the incidence of such infections. Arladeen Tomiczek and colleagues at Toronto East General Hospital outline how they reduced the rate of *C. difficile* cases by 50%. Maryam Salaripour and colleagues at St. Michael's Hospital succeeded in reducing nosocomial MRSA by 60% and sustaining the decrease over several years.

Patient falls are another critical safety issue. Patricia O'Connor and others report on their efforts to transform nursing practice and organizational culture to reduce patient falls. Their work at the McGill University Health Centre built on the best practice guidelines on patient falls developed by the RNAO.

A second group of papers address *Human Factors and Work Redesign*. The transfer of patients between units, or transport to diagnostic departments, can pose serious risks. Rosmin Esmail and her colleagues developed and tested a patient transport decision scorecard to improve the safety of patients transported from the ICU to other parts of the hospital in the Calgary Health Region. Kim Alvarado and others at Hamilton Health Sciences Centre report on the development of guidelines to improve the communication of patient information at shift handover. Innovative work by Edward Etchells and colleagues using a human factors checklist to improve the programming of infusion pumps at Sunnybrook Health Science Centre and an insightful analysis by Sandra Gabriele of safety issues in medication label design provide examples of the need to promote a stronger awareness of the pervasive role of human factors influencing the safety of care.

Much of the effort to improve patient safety draws upon detailed knowledge of clinical practice and safety science. But much can be gained from involving patients and families too. In our section *Involving Patients and Families*, Bonnie Fleming-Carroll and others at the Hospital for Sick Children in Toronto report on their efforts to develop "Families as Partners in Patient Safety." Work to raise awareness and engage patients in improving safety is gaining momentum in several centres. Sudha Kutty and Sarena Weil at the Ontario Hospital Association provide information on the strengths and weaknesses of such strategies and, more specifically, the impact of the Patient Safety

Tips program in Ontario.

Effective and safe patient care depends upon reliable information. In the section *Using Information to Improve Safety*, Jennifer Turple and colleagues at the Halifax Infirmary and Dalhousie University report on the continuing problem of medication reconciliation. Computerized Physician Order Entry (CPOE) holds considerable promise, but such decision support programs have been difficult to mount and maintain. One success in this area is reported by Anna Greenberg and others at Cancer Care Ontario who have implemented CPOE for cancer medications. Still, changes in information systems pose risks as well as benefits. Andre Kushniruk and colleagues report on innovative work in assessing problems emerging from information system implementation and its impact on work flow.

One heartening development in work on patient safety in Canada has been the broadening focus on care outside of acute care hospitals. Our last group of papers reports on *Identifying Patient Safety Risks in Non-Acute Care Settings*. Ariella Lang and others summarize issues raised in an important roundtable discussion of the patient safety agenda in home care. A critical need in this agenda is information about the incidence and types of adverse events in home care. One of the first studies to report Canadian data comes from the work of Keir Johnson,

who adapted hospital-based research tools to assess adverse events in home care patients in Winnipeg. In another domain, Carol Fancott and her colleagues at the Toronto Rehabilitation Institute provide a profile of patient safety issues identified through qualitative research with staff at TRI.

Together these papers provide a snapshot of leading practices and critical knowledge from across the country, and by implication offer a challenge to others to investigate, adapt and implement these practices in their own organizations. The efforts outlined in this issue demonstrate that safer care is possible. But the work to translate these efforts into different settings and to spread safer practices across the country is still in early stages.



— G. Ross Baker

Professor, Department of Health Policy, Management and Evaluation, University of Toronto

Dr. Baker is the guest editor of this special issue of *Healthcare Quarterly* focused on Patient Safety.



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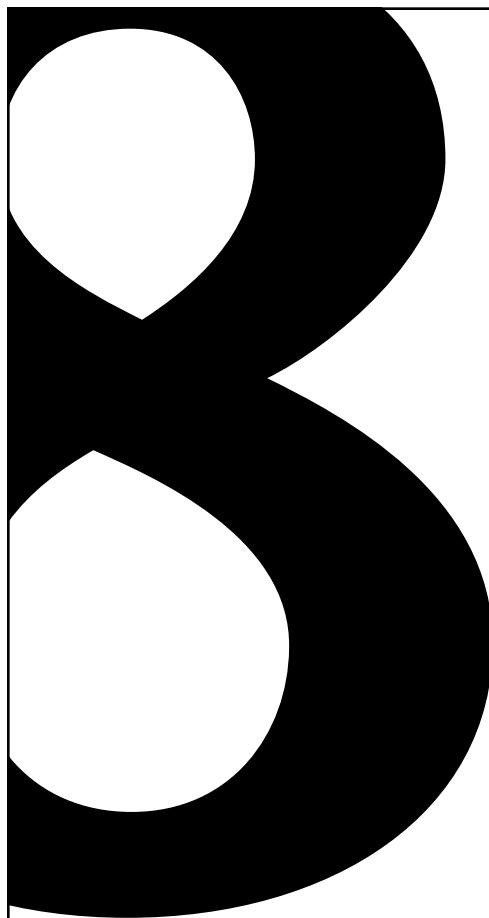
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News and Events

UNITED KINGDOM

Engaging junior doctors in patient safety campaign receives recognition for excellence

The National Patient Safety Agency's campaign to promote patient safety to doctors in training has received two awards from the Chartered Institute of Public Relations (CIPR).

Acknowledging the critical role played by senior clinicians such as Professor Sir Graeme Catto, President of the General Medical Council, who contributed to program, the judges said, "A key reason for the success of this campaign was the case study book in which 14 of Britain's most senior doctors shared personal stories of their own mistakes to encourage a more open culture. Also important was communication on a peer-to-peer basis targeting junior doctors through an independent doctors' website."

Partners integral to the campaign included the British Medical Association, the Medical Defence Union, Medical Protection Society and Opinion Leader Research. The Excellence Awards recognize and reward best practice in public relations throughout the UK and acknowledge personal and team achievement at the highest professional level.

Source: <http://www.npsa.nhs.uk>



AUSTRALIA

IT offers way to better aged-care practice

The Commonwealth Government is looking to the Internet to drive improvements in the quality and delivery of aged-care services nationwide, the Minister for Ageing, Senator Santo Santoro, recently announced. The Minister was announcing the Howard Government's agreement for the Joanna Briggs Institute to develop and maintain online clinical resources for the aged-care sector, at a cost of almost \$1.1 million over the next two years.

Under the agreement, the institute will develop online resources which will include a database of evidence summaries and will provide information sheets, best-practice guides, and database tools to help users apply evidence-based practice.

AUSTRALIA

Development of a Conceptual Framework for an International Patient Safety Classification

The World Health Organization's Alliance for Patient Safety has asked the APSF to lead the Working Group to develop the Conceptual Framework for an International Patient Safety Classification. The Working Group will develop and define the high level concepts to ensure that the Classification complies with the specifications required of all WHO Family of International Classifications.

WHO has commissioned another group to identify a list of critical concepts to be included in the classification.

Source: <http://www.apsf.net.au/news.php>

SPAIN

Spanish Medical and Nursing Scientific Societies pledge support to patient safety

A number of Spanish Medical and Nursing Scientific Societies pledged support to Patient Safety within the framework of the scientific conference on Quality and Patient Safety in Health Care, where the National Study on Adverse Events (ENEAS) was presented.

The participating societies supported a joint declaration named "Professionals for Patient Safety" where they expressed commitment for Quality and Patient Safety in the National Health System.

Key elements of the declaration are: the professional societies pledged support to the National and Regional policies and strategies on patient safety; they expressed commitment for improving the organizational culture towards patient safety, enhancing the communication to patients and patients' participation in their own healthcare processes, fostering the adoption of best clinical practices, building professionals' capacity in risk management, setting up adverse-events monitoring and reporting systems, and fostering risk management and research for patient safety.

Source: http://www.who.int/patientsafety/news/spanish_pl��es/en/index.html



Source: <http://www.health.gov.au>



World Alliance for Patient Safety: International Patient Safety Event Classification

The World Alliance for Patient Safety is embarking upon a consultation process (the "Delphi survey") for the International Patient Safety Event Classification (IPSEC). This process is designed to obtain vitally important feedback on the proposed conceptual framework, concepts and terms.

Practitioners and other experts interested in patient safety are invited to participate in the Delphi survey to ensure wide-ranging input. As a result of the feedback received, the IPSEC will be further revised. Field testing will commence in 2007. It is envisioned that the finalized version of the IPSEC will be available in 2008. ►To access the Delphi survey visit: <http://www.who-ipsec.org/>.

Source: http://www.jointcommission.org/PatientSafety/Delphi_Survey.htm

SINGAPORE

New safety reporting requirements for registered medicinal products

In February 2005, Singapore's Center for Drug Administration (CDA) released new guidelines on safety reporting requirements for registered medicinal products. The new guidelines apply to license holders who are responsible for bringing western medicinal products into Singapore. The guidelines define the types of safety-related reports that license holders are required to provide to the Pharmacovigilance (PV) Unit of the CDA and also define the timeline for which to do so. The new requirements cover three different types of safety reports: spontaneous suspected adverse drug reaction (ADR) reports, periodic safety update reports, and reports regarding regulatory actions or actions taken by companies due to safety issues.

Source: <http://www.who.int/patientsafety/news/pbm5/en/index.html>

Events

Halifax 6 - The Canadian Healthcare Safety Symposium - Safety Management: Changing the way we do things

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►More information - <http://www.buksa.com/halifax/>

The International Society for Quality in Health Care (ISQua) 23rd International Conference - Improving Healthcare: The Challenge of Continuous Change

October 22-25, 2006

London, UK

►More information - <http://www.isqua.org.au/>

Nursing Health Services Research Unit (NHSRU) 5th International Conference - Practice to Policy: Global Perspectives in Nursing

October 25-27, 2006

Hamilton, ON

►More information - <http://www.nhsru.com/>

29th Annual Health Care Quality & Patient Safety Conference - Quality: The Pathway to Success

October 28, 2006

Chicago, IL

►More information - <http://www.abqaurp.org/>

Practice Based Commissioning: Making It Work in Practice

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Harrogate, UK

►More Information - <http://www.neilstewartassociates.com/napc06/>

ESCMID-SHEA Training Course in Hospital Epidemiology 2006

November 25-28, 2006 - Baden/Vienna, Austria

►More information - <http://www.escmid.org>

Inauguration of the Global Patient Safety Challenge "Clean Care is Safer Care"

December 4, 2006

Muscat, Oman

►More information - <http://www.squ.edu.om>

2nd International Congress on Infectious & Tropical Diseases

December 4-7, 2006

Muscat, Oman

►More information - <http://www.moh.gov.om/icitd-oman/>

Patient Safety Officer Executive Development Program

March 7-14, 2007

Cambridge, MA

►More Information - <http://www.ihi.org>

CANADA

Using e-Therapeutics to Support Medication Safety

Improving the management of pharmaceuticals is important for the renewal of the healthcare system in Canada. Each year, preventable adverse drug events put the well-being of patients at risk and result in billions of dollars of cost to the healthcare system (Kidney and MacKinnon, 2001).

This gap in care – between the unsafe practices that are currently happening and the provision of optimal treatment to patients – is comprised of a number of factors. Inappropriate drug prescribing, inadequate monitoring and undertreatment all pose risks to the patient in an environment where drug therapy management has become increasingly complex.

In their 2005 *Annual Report to Canadians*, the Health Council of Canada recommended investment in unbiased, evidence-based drug information for physicians, pharmacists and patients as a way to help address this care gap. While healthcare providers are faced with an overload of information, many of these resources are out-of-date, don't reflect current practices or are influenced by industry.

Long recognized as a credible source of drug and drug therapy information, the Canadian Pharmacists Association has developed e-Therapeutics to respond to this call for unbiased, evidence-based information. e-Therapeutics was developed as a collaborative initiative involving a network of partners including: Health Canada, IBM Canada, Canada Health Infoway, Canadian Institute for Health Information, Nova Scotia and Alberta governments, and several national pharmacy, medicine and nursing organizations.

Delivered through a web portal with select content that can be downloaded to a Palm or Pocket PC device, e-Therapeutics gives practitioners access to the right information at the right time to make the right therapeutic decision. Therapeutic content is written by Canadian experts and rigorously reviewed by leading authorities in each clinical area, while drug information includes Health Canada-approved drug monographs. To this e-Therapeutics adds new drug safety information from Health Canada, a drug interaction analyzer (Lexi-Interact™), public drug plan coverage and links to references (Pub-Med), giving practitioners centralized access to the resources they need to inform their decision making.

e-Therapeutics has been developed using accepted health information standards and is designed to allow for integration in pharmacy dispensing systems, physician office electronic medical record systems and electronic health record applications. e-Therapeutics was made available to subscribers in April 2006.

In the 2006 *Report to Canadians* the Health Council of Canada has identified e-Therapeutics as a tool prescribers can use to improve drug therapy: "We urge prescribers to adopt this new tool to increase efficiency and accuracy of prescribing while preventing adverse drug events." ► For more information about e-Therapeutics please visit www.e-Therapeutics.ca or call 1-800-917-9489.

Kidney, T. and N.J. MacKinnon. "Preventable drug-related morbidity and mortality in older adults: a Canadian cost-of-illness model." *Geriatrics Today* 2001;4:120.

UNITED STATES OF AMERICA

AMA response to IOM report on reducing medication errors

"The American Medical Association is committed to improving the quality and safety of health care and we welcome the IOM report. Patient safety is a responsibility that all physicians take very seriously.

"We agree with the IOM that increased communication between patients and physicians is vital to improved health care quality. Providing new, easy-to-understand resources for patients to obtain drug information will also help minimize the opportunity for errors.

"The marketplace for health information technology in the physician office is still very much in its infancy. There is great interest by physicians, quality experts and patients to implement electronic health records, e-prescribing and other health information technology tools that may improve patient safety. Yet physicians face a dizzying array of choices when trying to purchase HIT, while struggling with high costs, interoperability and ease of use. Just this week, the first product certification tool to help physicians make EHR purchasing decisions was introduced. We're encouraged by these first, solid steps to help physicians make purchasing decisions, but there is much more work to be done before the majority of physicians have the capability to do e-prescribing in a comprehensive way that includes safety and security capabilities."

Source: <http://www.ama-assn.org>





Canadian Patient Safety Institute

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hat does it mean to make patient care safer? How do we take action on what we know? And what does it mean to us personally as we try to provide the best clinical care to patients?

If we have initially learned anything from other high-risk areas of service like the airlines, railways and nuclear plants, we are only at the very early stages in the journey of understanding what constitutes this important body of knowledge as it applies to healthcare. Clearly, without sound research – new knowledge concerning the nature of the problems we are trying to overcome and how to solve these complex human/system problems – we limit our ability to make the healthcare system safer for those we serve. It cannot be only “eliminating errors” (who’s perfect anyway?); as Charles Vincent reminds us in *Patient Safety* (2006), unsafe care for patients is “inherent in the very structures and processes of the healthcare system itself.” These are not, as some might argue, just human errors or mistakes we must accept as “risks of the business.”

The nature of human error and its relation to adverse events does not appear to be well understood. An example from another field is the recent tragic accident off the British Columbia coast. It was reported in the media that *Queen of the North* sank as a result of “human error,” as if this explained it all. That is far from the truth. Yet it is how some see it in healthcare as well. Sydney Dekker argues convincingly that “human error is not random. It is systematically connected to features of people’s tools, tasks and operating environment.” Furthermore, and most importantly, he points out, “human error is not the conclusion of an investigation. It is the starting point.”

We have much to learn about adverse events. This entails excellent people doing coordinated and methodical research focusing on the extent of the problem and the underlying issues creating unsafe conditions. For example, what is the extent of the unsafe conditions in home care, and if they are unsafe how extensive is the problem? Anecdotal reports from the field suggest that there are serious issues and further investigation is warranted. As we have seen from studying hospitals, we are only beginning to understand the real causes of the multiplicity of problems related to avoidable adverse events and their associated disability and death, and we are only at the early stages of applying solutions to reduce these.

We need to better understand these underlying causes and begin step by step to apply the growing body of knowledge to incrementally improve safety for our patients.

We have been able to admire the remarkable gains in the specialty of anesthesia as they have improved patient safety over many years, and now continue their efforts. In addition, through Safer Healthcare Now!, hospitals in particular are applying a set of six well-documented, evidence-based interventions, knowing

these will improve patient safety. In this regard we must evaluate (measure) whether in fact we are making a difference in our day-to-day application of improvements in care to assure ourselves, patients and the public that we can and are improving the safety of their care.

This journal is one vital foundational effort in knowledge transfer and sharing applications that we trust will help you continue your efforts.

This year we are partnering with the Canadian Council of Health Services Accreditation and the Health Council of Canada – both of whom consider patient safety a priority. We thank them for joining CPSI in this venture.

We also want to thank all those who have contributed to this journal, and even more so those who apply the learnings.

– Phillip Hassen, President and Chief Executive Officer,
Canadian Patient Safety Institute

Canadian Council on Health Services Accreditation

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he Canadian Council on Health Services Accreditation (CCHSA) is pleased to co-sponsor their second special issue of *Healthcare Quarterly* with the Health Council of Canada and the Canadian Patient Safety Institute. Whether a direct care provider, a board member or a member of a national healthcare association, we all have a role to play in ensuring a safer healthcare system.

Patient safety is fundamental to quality of care and is woven throughout our standards. In 2002, we recognized that a focused CCHSA patient safety strategy was essential. As a result the CCHSA Patient Safety Strategy was released early in 2003.

With the guidance of our Patient Safety Advisory Committee, established early in 2004 and comprising patient safety experts, national and international literature was reviewed to identify the major risk areas and best practices. Patient safety-related accreditation survey recommendations and the top compliance issues were also examined. The approaches being taken by other international accrediting bodies were considered.

The findings of these reviews, coupled with the escalating number of evidence-based safety practices, led to the development of a list of potential priority areas addressing patient/client safety. From this list, five Patient Safety Areas were selected for initial focus – Culture, Communication, Medications,

Workforce/Worklife and Infection Control. Six Patient/Client Safety Goals and 21 Required Organizational Practices (ROPs) were also developed, and publicly released in January 2005. Now, in 2006, the Goals and the ROPs have become an integral part of the accreditation program. They will be integrated into the accreditation standards over the next few years. CCHSA is conducting a comprehensive evaluation of the first six months of this implementation.

Patient safety is a priority at CCHSA, and our surveys show that Canadian healthcare stakeholders embrace this focus. We have seen and are encouraged by the inroads made in this area. However, we must ensure collectively that this issue remains at the forefront of health services.

Our strong relationship with both CPSI and the Health Council of Canada is essential to achieving our goal of a safer healthcare system. Effective partnerships with these and other important organizations will allow us to identify and set a course to our goal. Patient Safety is a critical focus we share, and together, with increasing collaboration, a safer healthcare system will be achieved.

At CCHSA we aim to raise the bar for excellence. Our commitment to improving patient safety and quality care is unwavering.



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

Health Council of Canada

The Health Council of Canada is proud to co-sponsor this second edition of *Healthcare Quarterly* specifically dedicated to issues of patient safety. We are all patients at different points in our lives, and we support all efforts to improve the quality of care Canadians receive.

The debate about healthcare renewal in this country remains largely focused on the question of access. The Health Council of Canada believes that we need to ask ourselves, "Access to what kind of care?" We need to make quality as important an issue as access. Patient safety, like access, is a crucial component of a quality healthcare system. In our 2006 annual report, *Healthcare Renewal in Canada: Clearing the Road to Quality*, the Health Council of Canada declared that the health of Canadians will not be improved by focusing solely on access to healthcare services.

The Canadian Patient Safety Institute's Safer Healthcare Now! campaign is an important step along the quality improvement pathway. In its 2006 annual report, the Council identified

other steps that might be taken in conjunction with the national campaign:

1. *Make accreditation for healthcare facilities mandatory.* Accreditation is a powerful lever to raise the quality of care and boost patient safety. It should be a condition of public funding.
2. *Require the public release of accreditation information.* To ensure accountability, healthcare facilities should publish the results of their accreditation reviews and explain their plans to improve patient safety and quality of care.
3. *Take a fresh look at how injured patients are compensated in Canada* and whether current insurance schemes inhibit the development of a culture of safety.
4. *Speed up the development of electronic information management systems* to support timely, evidence-based patient care.

The Health Council is currently immersed in these issues. We have undertaken a research project to better document accreditation practices and information disclosure across the country. And, with an eye to providing a forum for all perspectives to be shared, the Health Council of Canada organized a roundtable on patient safety and no-fault compensation in late September in New Brunswick. The participants included key players from within Canada, as well as experts from New Zealand, where no-fault compensation has already been implemented. We want to learn from their experience and perspectives when thinking about the Canadian system and context.

In June of this year, the Council also partnered with Canada Health Infoway to host a conference on implementing the commitment to an electronic health record for Canadians. We focused specifically on how an electronic health record improves quality and efficiency, the scale of investment required to make it a reality for all Canadians and the implementation challenges and corresponding strategies. The summary report can be found on the Council's website (www.healthcouncilcanada.ca).

This collection of papers generates new knowledge for all those tasked with the important work of improving patient safety and quality of care. The Health Council of Canada is pleased to contribute to further debate and discussion about these pivotal pieces needed to underpin a high-quality healthcare system.



— Cathy Fooks, Executive Director, Health Council of Canada



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Five Years of Learning from Analysis of Clinical Occurrences in Pediatric Care Using the London Protocol

Catherine M.G. Cronin

Abstract

A Protocol for the Investigation of Clinical Incidents (1999) was piloted on a Winnipeg high-risk neonatal service in 2001, and was subsequently adopted as the investigative tool of choice at the Winnipeg Regional Health Authority (WRHA). The paper describes the pilot and subsequent experience with the updated London Protocol (2004) in the WRHA Child Health Program.

Themes include: tightly coupled systems; multiplicity of contributory factors; medication safety; predominance of "near misses"; authority gradient; professional accountability; partnerships; and implementation challenges.

The London Protocol is an invaluable tool for review of critical occurrences and near misses. To maximize impact on patient safety, healthcare organizations must involve partners and develop expertise in human factors and change management.

Background

Reason (2001) defined *error* as the "failure of planned actions to achieve their desired goal." He distinguished two types of error: *slips and lapses* and *mistakes*. *Slips and lapses* are failures of execution associated with attention failure; lapses are internal events associated with memory failure. *Mistakes* are failures of intention. Actions go as planned, but the plan is wrong.

Mistakes may be *rule-based* or *knowledge-based*. *Rule-based*

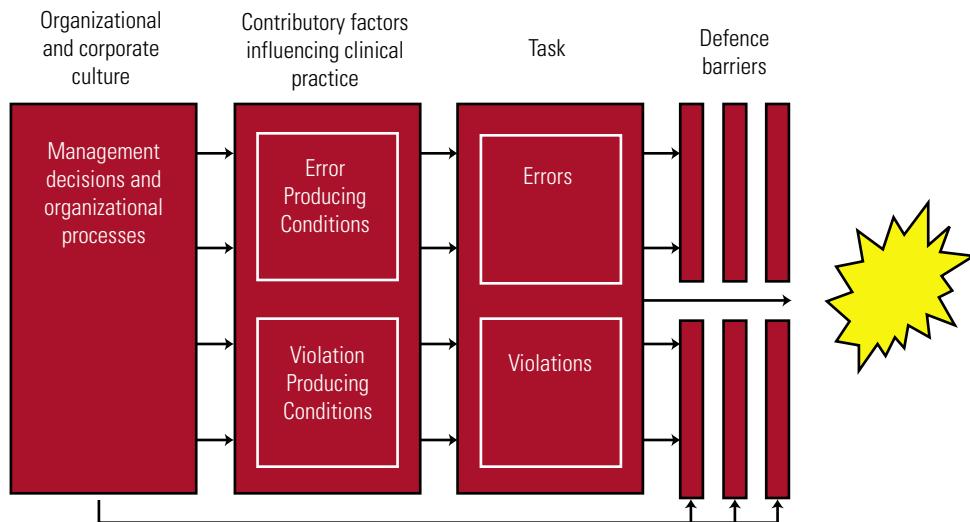
mistakes include failure to apply good rules and application of bad rules; *knowledge-based mistakes* occur when problems must be solved on the spot, without the help of preprogrammed solutions. The operator may be inexperienced, or may use an incorrect mental model (confirmation bias).

Violations are not errors, but deviations from safe operating practices, rules or standards. They include *routine violations* (cutting corners), *optimizing violations* (furthering personal goals) and *necessary or situational violations* (when rules hinder performance).

Active and *latent failures* must be distinguished. Negative outcomes of active failures are often immediate, but adverse consequences of latent failures may not occur for years. In healthcare, *active failures* are unsafe acts (errors or violations) by clinicians at the "sharp end" of the system. *Latent failures* often occur in the boardroom (e.g., budget cuts leading to suboptimal staffing).

Reason's organizational accident model (Figure 1), described in his classic, *Human Error* (Reason 1990), is founded on learning from complex industries. The model is the basis of *A Protocol for the Investigation and Analysis of Clinical Incidents* (Clinical Risk Unit 1999) and the London Protocol (Taylor-Adams and Vincent 2004). The Protocols provide structure for investigating and analyzing clinical incidents: after identifying Care Management Problems (active failures), reviewers consider contributory factors and organizational context. Table 1 itemizes factors that may contribute to error in healthcare.

Figure 1. Organizational accident model



Source: Adapted from Reason (1990).

Goldmann and Kaushal endorsed the Protocol in their discussion of a systematic approach to human factors to medicine (Goldmann and Kaushal 2002).

In this paper I describe five years of experience with these Protocols in the Child Health Program at WRHA.

Phase I: Pilot Study

Methods

The Protocol (Clinical Risk Unit 1999) was piloted between September 2001 and March 2002 on an academic tertiary neonatal service. All nontrivial occurrence reports were reviewed. The author conducted individual private interviews with personnel, based on involvement and fan-out from initial contacts, using the checklist to augment the information.

Results

Eight of twelve reported occurrences were investigated. Up to eight interviews (average 4.75; see Table 2) were required, lasting 20–60 minutes each. No patient harm occurred; there were four “near misses.” Occurrence reports were filed within 11 days. Figure 2 shows the distribution of contributory factors. All occurrences had one or more systemic contributory factors. Few occurrences were related to single, individual factors, consistent with the observations of Leape (1994). Five were nocturnal, involving understaffing, delay or difficulty accessing medical staff. In two cases, acuity and poorly planned physical plant contributed to inadequate patient surveillance. Team dysfunction, behavioural issues and lack of respect for colleagues were

Table 1. Framework of factors influencing clinical practice

Factor Types	Influencing Contributory Factors
Institutional context	Economic and regulatory context
Organizational and management factors	Financial constraints Organizational structure Strategic goals Policies and procedures Safety culture
Work environment factors	Staffing and skill mix Workload and shift patterns Design, availability and maintenance of equipment Administrative and managerial support
Team factors	Verbal and written communication Supervision Openness Team leadership and structure
Individual factors	Knowledge and skills Competence Physical and mental health
Task factors	Task design Availability and use of protocols Availability and accuracy of test results
Patient factors	Condition (complexity and seriousness) Language and communication Personality and social factors

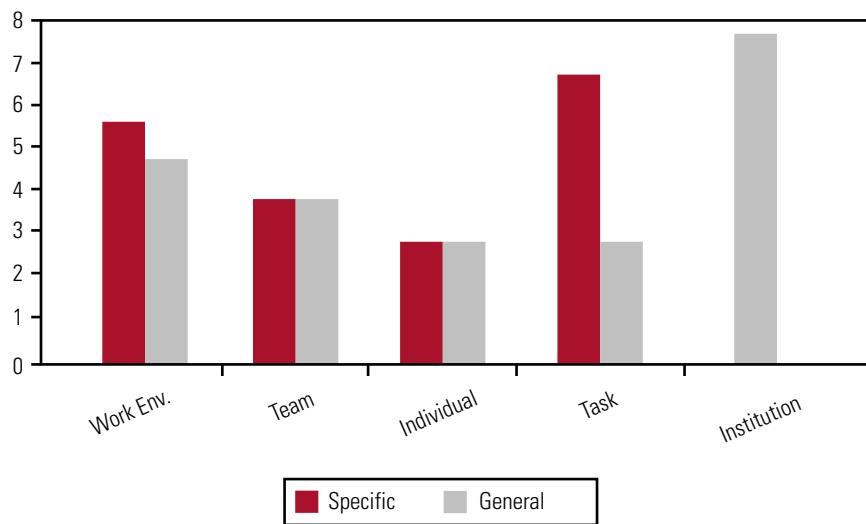
Framework Source: Clinical Risk Unit (1999).

observed in several cases. The interviews validated staff concerns, and made it easier to find and implement solutions.

Table 2. Number of interviews required to determine contributory factors for each occurrence

Occurrence	Number of Interviews
1	2
2	2
3	5
4	3
5	6
6	8
7	4
8	8

Figure 2. Frequency distribution of contributory factors



Source: Clinical Risk Unit (1999).

Phase II: Policy Development and Implementation

Regional policies were developed and implemented on reporting, management and disclosure of occurrences (Winnipeg Regional Health Authority [WRHA] 2002a, b, c). Critical Clinical Occurrences, as defined by policy, include near misses and

require formation of a Review Team within 48 hours. An individual designated by the relevant Vice-President chairs the Review Team, which must meet within five days, and conducts a review, using the Protocol, within 30 days. When an in-depth systems analysis is required, a status report is required within 30 days. Rollout of these policies included an educational strategy and development of a Regional Occurrence database.

Concurrently, Manitoba Health developed a congruent policy governing all Manitoba RHAs. It became apparent that lack of legal protection was a significant barrier to openness. WRHA worked with government to address this issue, resulting in new legislation amending the *RHA* and *Manitoba Evidence* acts (*Bill 17 2005*), currently awaiting Royal Assent. Regional policies are currently under revision.

Phase III: Rollout of the Protocol within the Child Health Program, WRHA

The Child Health Program at WRHA, based at Children's Hospital, Winnipeg, provides secondary and tertiary care to the children of Manitoba, Kivalliq, and northwest Ontario. Since 2002, the Child Health Quality Team has led or participated in 30 reviews of critical clinical occurrences and near misses involving children. Review teams are multidisciplinary

and may include community partners and families. A database of recommendations and actions is maintained. Reviews are used as learning opportunities and staff debriefings are provided. A synopsis of lessons learned follows.

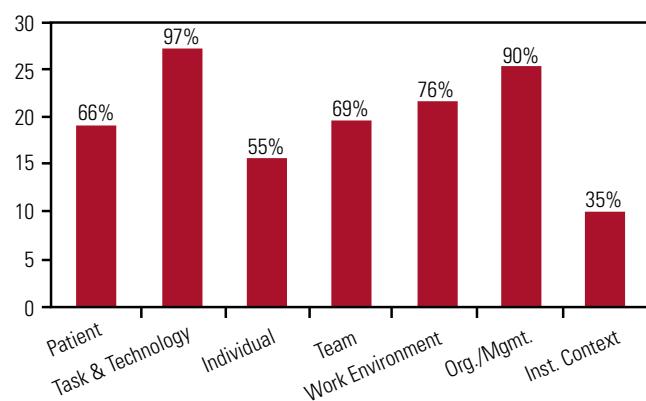
Lesson 1: Acute pediatric care is a tightly coupled system with multiple high-risk processes. All occurrences reviewed occurred in inpatient areas. Eight (27%) occurred in emergency or intensive-care units, in which patient acuity and complexity are high. These environments share many characteristics of high-risk processes, in which failure is likely to jeopardize safety: variable input, complexity, lack of standardization, tight coupling, heavy dependence on human intervention, time constraints and a hierarchical orientation.

Several reviews highlighted tight coupling of different components of patient care. For example, an apparently simple event (a change in the formulation of dopamine), was not perceived as significant by pharmacy staff, but had significant ramifications in PICU (the need to use an unfamiliar IV infusion pump).

"Tightly coupled systems work best when they operate with well established rules and procedures and when staff work hard to coordinate and adjust their activities through constant two way communication. A downside ... is that they can be quite fragile – the consequences of a small, innocuous error, omission, decision or action in one system can be rapidly transferred to the other. Operators in tightly coupled systems must always think in systems terms and must actively consider how a change in their system might affect the other system." (Michael Rodgers, Human Factors Leader, WRHA, personal communication, 2006)

Lesson 2: Critical occurrences usually have multiple contributory factors. We analyzed 30 reviews conducted since program-wide implementation using the taxonomy of the London Protocol (2004), which identifies seven categories of contributory factors but does not distinguish between specific and general factors. Once again, multiple contributory factors were the norm (Figure 3). In 97% of cases, task and technology factors were present. Next-commonest were organizational and management factors. In 66% of cases, patient complexity was a significant factor. Individual (staff) factors contributed to 55% of occurrences. There was *no* occurrence in which the actions of one individual were the only contributing factor.

Figure 3. Frequency distribution of contributory factors, Child Health Program, 2002–2006



Framework Source: Clinical Risk Unit (2004).

A patient with cancer, fungal and bacterial sepsis and multiple organ dysfunction became hyperkalemic while receiving multiple intravenous infusions including antibiotics and electrolytes. The active failure was administration of excess potassium, due to inadvertent use of the electrolyte solution

(intended to correct hypokalemia) as the infusion vehicle for medications. The process involved multiple sequential tasks and complex decisions, magnifying the probability of error. Operator inexperience, coupled with supervisor distraction, contributed to an incorrect decision. Overlying this situation was an unclear understanding of the supervisory role of instructors and mentors.

The London Protocol provides structure for interviews and the collateral search for information, but the complexity of human factors science requires expertise to tease out contributory factors, root causes and the context in which they occurred. Dekker (2002) reminds us to avoid hindsight, always considering the context in which decisions were made.

Medication error was the issue in 50% of occurrences reviewed. Active failures included incorrect medication, incorrect patient, incorrect route, medication preparation and dispensing.

Lesson 3: Medication error is the commonest category of active failure in acute pediatric care. Medication error was the issue in 50% of occurrences reviewed. Active failures included incorrect medication, incorrect patient, incorrect route, medication preparation and dispensing. Latent failures encompassed a broad spectrum of contributing factors, including lack of pharmacy expertise on clinical teams and reliance on paper-based ordering systems. One review led to the first healthcare FMEA investigation in Manitoba, which proved pivotal in identifying and driving change.

Errors related to resuscitation (including failure to rescue in a timely way) were, at 13%, the second-commonest category of active failure. Contributing factors included nighttime, knowledge deficits and an authority gradient. In two cases, existence and use of a rapid response team might have prevented harm.

Patient identification problems accounted for 13% of active failures. One case of wrong patient surgery occurred. In a near miss, an incorrect limb band was placed on a baby's foot; the physical characteristics of the band contributed.

Lesson 4: Most errors that reach the patient do not cause harm. The Canadian Adverse Events Study (Baker et al. 2004) showed a 7.5% incidence of adverse events and a 40.8% incidence of triggers in adult hospitalized patients. *There are no such data for Canadian children.* In this series, 79% of occurrences reached

the patient, but only 35% caused harm. High-reliability systems are characterized by detection and recovery systems for error and by collective preoccupation with the possibility of failure. There is a high awareness of failure in our program (Sinclair 2000), and we are encouraged by the willingness of staff to report occurrences and participate in reviews.

... professionals are accountable for their actions. We found several deliberate rule violations, including "cutting corners" in order to get the job done and occasional "optimizing violations" (self-interest). We discovered no dysfunctional rules.

Lesson 5: The authority gradient is alive and well. "Authority gradient" refers to the balance of decision-making power (Agency for Healthcare Research and Quality [AHRQ] 2006). The term was first used in aviation. Pilots and copilots may not communicate effectively in stressful situations if they differ in perceived experience, expertise or authority. While an authority gradient is necessary for role clarity and decision making, leaders must establish norms appropriate to the training and experience of team members (a responsibility referred to as Crew Resource Management). Cosby and Croskerry (2004) described the contribution of authority gradients to medical error.

This series includes four cases in which an authority gradient played a part. It was observed between nurses and physicians, and between junior and senior physicians. The management of multidisciplinary teams is particularly challenging in an academic environment, in which team members constantly rotate and there is diversity of expertise, training and cultural background. Addressing this issue may require multidisciplinary team learning and simulation beginning at the undergraduate level. The Israel Center for Medical Simulation (www.msr.org.il) has been a leader in this field.

Lesson 6: Accountability matters. Blame is counterproductive in the face of genuine error. Nevertheless, professionals are accountable for their actions. We found several deliberate rule violations, including "cutting corners" in order to get the job done and occasional "optimizing violations" (self-interest). We discovered no dysfunctional rules. Managing rule violations requires performance management, involving education, audit, reinforcement and sometimes discipline.

Lesson 7: The learning organization engages its partners. Healthcare is a complex adaptive system interacting with other

systems. Contributory factors may originate outside healthcare and must be addressed at their origin.

A student nurse erred in a very complex task. The review led to an examination of student supervision and a revised affiliation agreement with educational institutions.

A case of child abuse led to collaborative work with child welfare agencies on stronger communication protocols and advocacy with Government.

The literature is equivocal on the effects of open-disclosure policies on litigation (Kachalia et al. 2003). Physicians in particular are reluctant to discuss adverse events with patients and quality committees, due to fear of litigation. Insurers counsel that only facts should be disclosed, and only to committees under the umbrella of legal protection (Beilby 2004, 2005). The National Steering Committee on Patient Safety (2002) recommended that *Evidence Acts* and related legislation be reviewed and revised if necessary to ensure that data and opinions associated with patient safety and quality improvement discussions, related documentation and reports are protected from disclosure in legal proceedings. This is now under way in Manitoba.

Lesson 8: Writing recommendations is easy; implementation is challenging. Frequently, important contributing factors to adverse events originate outside the organization and remediation is outside the span of control of the team. The partnerships necessary to address external contributory factors are not formed overnight and require time investment and relationship-building over years.

Challenges occur within organizations too. In a complex adaptive system, every change has the potential to cause problems elsewhere in the system. Experience at WRHA suggests that access to a human factors consultant is invaluable in guiding the team to ask the right questions, to correctly analyze the root causes and contexts uncovered and to craft credible recommendations that will be adopted.

The challenge of obtaining buy-in and action from management has been noted in many industries.

One investigator described how the writing and inclusion of recommendations is heavily determined by who is ... on the committee assessing the recommendations for implementation. Language may be adjusted or changed, some recommendations may be left out in order to increase the chances for others. ... [T]he road from investigation to implementation ... is largely a political one. ... Really good investigations may reveal systemic shortcomings that necessitate fundamental interventions which are too expensive or sensitive to be accepted. (Dekker 2002)

In our experience, reviews leading to successful change are usually conducted within microenvironments, in collaboration with dynamic clinical teams. When there is need for broad systemic change, an individual who has the authority and the will to drive that change must be involved as early as possible. Our organization now involves senior leaders in all critical occurrences within 48 hours, and prior to sign off on the final report. A risk rating is assigned to each recommendation and individuals accountable for implementation and a time frame for action are identified.

Conclusions

The Child Health Program at WRHA has conducted reviews of critical clinical occurrences and near misses since 2001. We have learnt much about human factors, the nature of error in an acute pediatric care environment, organizational culture, interdependencies between organizations, legislative context and change management. The London Protocol has proven a useful platform for structuring the investigations, supplemented by experience, expertise and other management tools.

About the Author

Dr. Catherine M.G. Cronin is a Professor and Associate Head of the Department of Pediatrics and Child Health at the University of Manitoba. She leads the Child Health Quality Team and the WRHA Standards Committee. She is also a surveyor with the Canadian Council on Health Services Accreditation.

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Implementing a Good Catch Program in an Integrated Health System

Debbie Barnard, Marilyn Dumkee, Balvir Bains and Brenda Gallivan

Abstract

In 2004, the Canadian Adverse Events Study (Baker et al. 2004) determined the incidence rate of adverse events (AE) in Canada to be 7.5%. This translates to approximately 185,000 for the almost 2.5 million annual hospital admissions in Canada. The study noted "close to 70,000 of these AEs were potentially preventable."

In March 2005, a "Good Catch" program was implemented in Edmonton's Capital Health Region, one of the largest integrated health regions in Canada, as part of the region's comprehensive system of reporting, analyzing and managing incidents, adverse events and near misses.

Introduction

In 2004, the Canadian Adverse Events Study (Baker et al. 2004) determined the incidence rate of adverse events (AE) in Canada to be 7.5%. This rate translates to approximately 185,000 AEs for the almost 2.5 million annual hospital admissions in Canada. The study noted "close to 70,000 of these AEs were potentially preventable" (Baker et al. 2004).

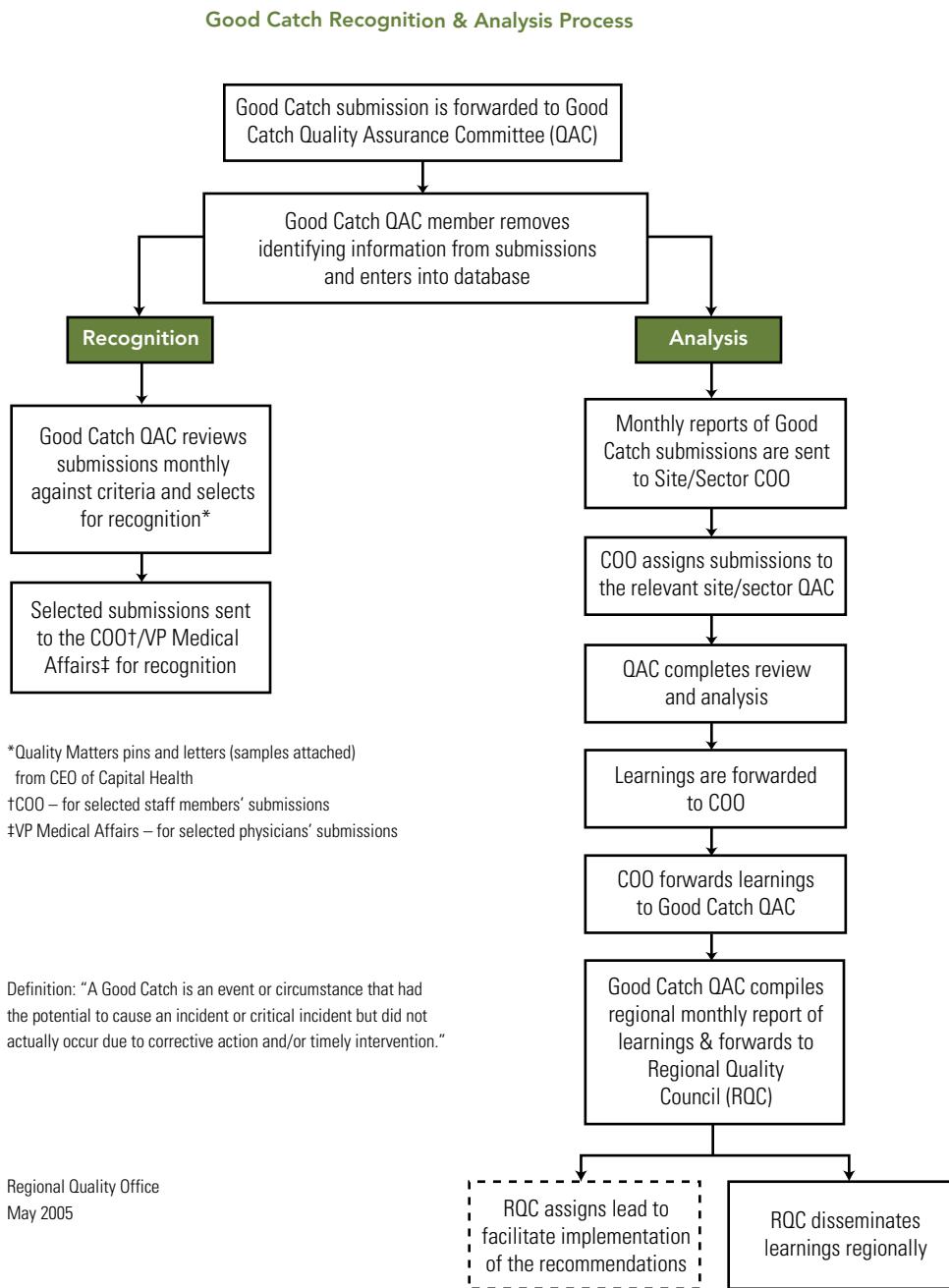
In the quest to enhance its safety systems, in March 2005 Capital Health (CH), one of the largest integrated health regions in Canada, implemented a Good Catch program. It is a part of the region's comprehensive system of reporting, analyzing and managing incidents, adverse events and near misses. A *Good*

Catch is defined as an event or circumstance that has the potential to cause an incident or critical incident but that did not actually occur due to corrective action and/or timely intervention.

Previously, the CH paper-based incident reporting system included the ability to report Good Catches, but there had not been emphasis on reporting and analyzing Good Catches or near misses. So the region recognized that an opportunity existed to further strengthen the quality culture of Capital Health while recognizing staff and physicians for their contributions to quality by implementing a Good Catch program.

In the article "Understanding Medical Error and Improving Patient Safety in the Inpatient Setting" (Shojania et al. 2002), three other reasons why healthcare organizations should want to focus on developing systems similar to Good Catch are highlighted:

- Near misses occur three to three hundred times more often than adverse events.
- The fact that no harm has come to the patient means there are none of the emotional/psychological barriers associated with actual events, especially the potential threat of legal action.
- Analysis is not encumbered by hindsight bias, the recognized tendency to judge care as inappropriate when it results in an adverse outcome.

Figure 1. Overview of Good Catch program

Good Catch was implemented in Capital Health in an effort to increase reporting, continue to enhance the culture of safety and provide the health system with the opportunity to proactively identify and implement risk reduction strategies in areas that could cause harm to patients and/or staff. The program endeavours to build an environment that fosters safety reporting with the intent to prevent system breakdowns before they occur,

Safety Program. The membership represents the diverse sites and sectors of the region from acute care to community-based service and primary healthcare. Currently the group is led by two co-chairs, the Vice-President for Medical Affairs and the Vice-President & Chief Liaison Officer, who is administratively responsible for quality and patient safety for Capital Health.

Once the proposal was approved by RQC, a team developed the

ultimately reducing the overall number of incidents and adverse events.

Figure 1 provides an overview. The program was designed with two major components: recognition and analysis. All submissions are received by the Good Catch Quality Assurance Committee. This group is responsible for evaluating each submission against defined criteria. The criteria include: impact of patient safety, quality of patient care, service and potential for regional impact. At least two to four staff (including physician partners) are selected for recognition every month, and each staff member submitting a Good Catch gets a letter of thanks from the QAC. Every Good Catch is analyzed at the site and regional levels to try to determine what happened, why it did and what potential processes might be implemented to prevent an actual incident. Learnings from the analysis are presented to the Regional Quality Council for region-wide dissemination.

Implementation

A proposal was presented to the Regional Quality Council (RQC), the group responsible for the overall strategic guidance of Capital Health’s Quality and Patient

program. The team was led by the Director of Regional Quality, and the Vice-President and Chief Liaison Officer was assigned the role of Executive Sponsor. The team included Regional Quality consultants (two nurses and an educator), a Health Information Analyst and a Public Affairs representative along with a Business Support Analyst who monitored the budget.

The team created a Project Management Plan to guide development and implementation. The plan included defined tactics for program design, execution (including education and communication), monitoring and evaluation. The team developed a Toolkit for the execution phase of the program. Feedback from key stakeholders indicated this strategy was the most valuable and was credited with much of the team's success.

The manager's Toolkit included posters, forms, information mailers and paycheque stuffers. A copy of the Good Catch Poster is displayed in Figure 2. The team also replicated the

opened a detailed Good Catch Toolkit that included handouts and an electronic presentation that described the objectives, goals and program strategy, a Good Catch definition, the process for submitting a Good Catch, selection and recognition criteria and suggestions for unit-level implementation.

The team also made presentations to all key management staff across the entire region on the Toolkit and answered questions over a three-month period prior to the program kickoff. The Good Catch program was also highlighted in all newsletters circulated in the region, both at the site and at regional levels.

The majority of reports received are related to medication administration, and this correlates with the actual incident reporting data in the region over the past few years. Consequently, medication safety has been identified as one of the primary focus areas for the Quality Improvement Program.

Figure 2. Good Catch poster



Good Catch Toolkit on the Regional Quality intranet site, which gave staff and physicians at all sites ready access to all the program materials.

To ensure consistency across the region, the team also devel-

Results

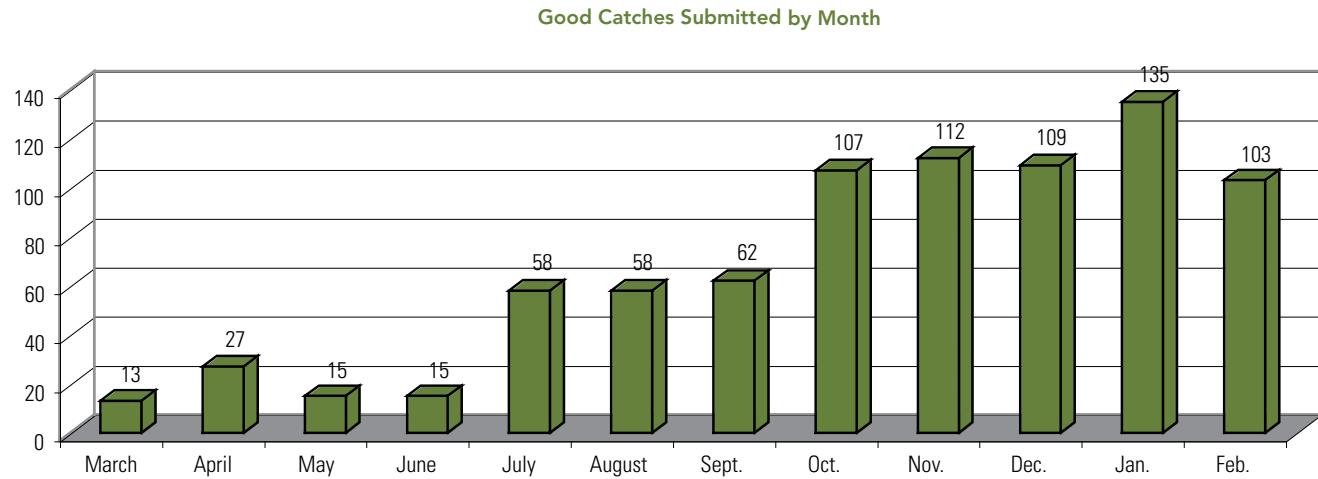
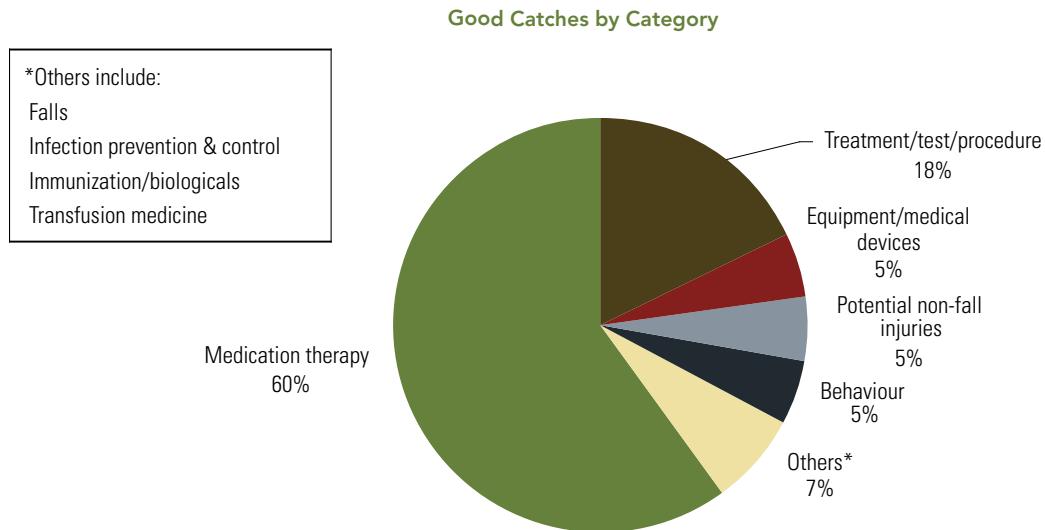
The team defined and communicated a comprehensive summary of the Good Catch process to all key stakeholders in the region to ensure that everyone was aware of their responsibilities for each component of the process, from reporting and analysis to dissemination of learnings.

During the first month of the program, 13 reports were received, but there has been a steady increase; from October 2005 to February 2006 reports received ranged from 103 to 135 per month. Figure 3 displays Good Catches submitted from March 2005 to February 2006. Reports have been received from all disciplines with an approximate distribution for nursing at 64%, pharmacy at 26%, lab at 5%, diagnostic imaging at 4% and physicians at 1%.

The majority of reports received are related to medication administration, and this correlates with the actual incident reporting data in the region over the past few years (see Figure 4). Consequently, medication safety has been identified as one of the primary focus areas for the Quality Improvement Program.

From March 2005 to February 2006, 77 Good Catches have been selected for special recognition. Each staff member who is selected for recognition receives a Capital Health "Quality Matters" pin and a letter of recognition from the CEO and the Vice-President for their site or sector. Physician partners receive a letter of recognition that is also signed by the Vice-President for Medical Affairs. All staff members who report a Good Catch receive a formal note of thanks.

To ensure that the review and the analysis of Good Catches are as thorough as possible, a Good Catch Review Tool (see Appendix 1) was developed. It incorporates all the elements used when performing a root cause analysis, such as:

Figure 3. Good Catches by month, March 2005–February 2006**Figure 4. Good Catches by category, March 2005–February 2006**

1. What happened?
2. Why did it happen?
3. How can it be prevented from happening again?

The reports are aggregated and reviewed quarterly by site and then by region. A Risk Priority Matrix is used to determine events that require immediate follow-up and a more in-depth analysis. The Matrix includes a review of severity and probability.

Limitations and Lessons Learned

To ensure that CH found and maintained a balance between accountability, system transparency and protection for staff reporting incidents, prior to launching Good Catch the CH legal counsel reviewed the entire program. On guidance from legal counsel, the Good Catch Selection Committee was designated as a Quality Assurance Committee (QAC) and all Good-Catch-related discussions at the site and the regional level are conducted by the appropriate QACs. The staff and physician

Figure 5. Some kinds of positive changes implemented

Good Catch Examples	Action/Follow-up	Hierarchy
In the ICU Pyxis both MgSo4 10 cc multidose vials and Midazolam 10 cc multidose vials are very similar in appearance – both have green and navy blue strips on white labels.	Manufacturer has changed labelling to alleviate confusion – all old stock replaced and returned.	Strong
Patients inadvertently connect to air flow meter when oxygen required.	RAH currently leading Regional initiative to implement force function to prevent misconnections.	Strong
Patient on a puréed, level-3 fluids diet order. Nursing staff noted he received a dinner roll on his lunch tray and removed it.	Regional Nutrition and Food Services have discussed with specific staff and at general staff meeting. Bun position on tray has been changed to ensure that a bun from the upper tray cannot fall off onto the lower tray.	Intermediate
Sterile water solution for injection was mistakenly placed on a renal replacement therapy cart. Anticoagulant for dialysis looks very similar to the dialysis anticoagulant trisodium citrate 1 premixed bag.	IV solutions are now stored separately from the dialysis solution.	Intermediate
Specimens received in the lab from the ward unlabelled.	Team selected this as a Proactive Risk Assessment Demonstration Project. Recommendations to follow.	Weak
In netCARE (electronic health record), under "Blood Work" when you look at a Type and Screen it has the phrase "Blood Available Until" and a date. When you look at a crossmatch it also has a phrase "Blood Available Until" and a date. This refers to how long the sample is good for, not how long the crossmatch or type and screen is good for. Staff read that to mean there was blood available for transfusion in the blood bank for the patient.	Wording changed to improve clarity of the phrase "Blood Available Until" and reflect that this is sample availability only.	Weak

partners agreeing to be recognized for a Good Catch submission are – in order to protect their privacy – not associated with details of the actual Good Catch or any subsequent improvement. For all reporting and discussions at the regional level, Good Catches are stripped of any identifying information about patients, healthcare providers and patient care units.

The team found that this element of the program design was important to staff and physicians, as it ensured protection under Section 9 of the *Alberta Evidence Act*.

Conclusion

Due to the Good Catches reported during the last year from March 2005 to February 2006, many opportunities for improvement of patient safety and care have arisen throughout the region. Figure 5 includes a sample of the kinds of positive changes that the region has implemented as a result of the Good Catch program. Some changes have included working with manufacturers; in one incident the manufacturer had changed the labels of a medication, so the region worked with it to

Due to the Good Catches reported during the last year from March 2005 to February 2006, many opportunities for improvement of patient safety and care have arisen throughout the region.

replace all the old stock to avoid the "lookalike" drug mix-up. In another instance the "bun" placement on the tray was changed by Regional Nutrition and Food Services to avoid buns falling from one tray to another on the delivery cart.

The program has also facilitated the uptake of patient safety science in the region. Two new projects are under way, with one team performing a proactive risk assessment to look at the issue of specimen labelling and another investigating force function mechanisms available to prevent inadvertent misconnections of patients to air instead of oxygen.

The team continues to refine the program in response to the comments received from key stakeholders. Planning is under way aimed at: reducing the cycle time from when a Good Catch is reported to when actual feedback and action is received by staff in the care areas; increasing the capability in the region to use the analysis and learning tools, that is, proactive risk assessment and root-cause analysis; consistently identifying regional improvement priorities and acting upon them; and consistently communicating lessons learned in an efficient and timely manner across the region and, when indicated, provincially and nationally.

To view Appendix see <http://www.longwoods.com/product.php?productid=18373&cat=452>

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The McGill University Health Centre Policy on Sentinel Events: Using a Standardized Framework to Manage Sentinel Events, Facilitate Learning and Improve Patient Safety

Mark Daly

Abstract

Promoting a culture of safety within organizations includes translating the lessons learned from sentinel events into concrete changes that will improve patient safety. In May 2005 the McGill University Health Centre Policy on Sentinel Events was implemented to provide a standardized framework to manage these events and promote that culture of safety. This framework helped implement a number of changes to improve patient safety. The O₂ Ticket to Ride project ensures cross-disciplinary responsibility for the transportation of oxygen-dependent patients to diagnostic testing areas. The Code Stroke Algorithm was developed to expedite the sequence of events from the time the stroke symptoms are observed to the time the CT scan is carried out.

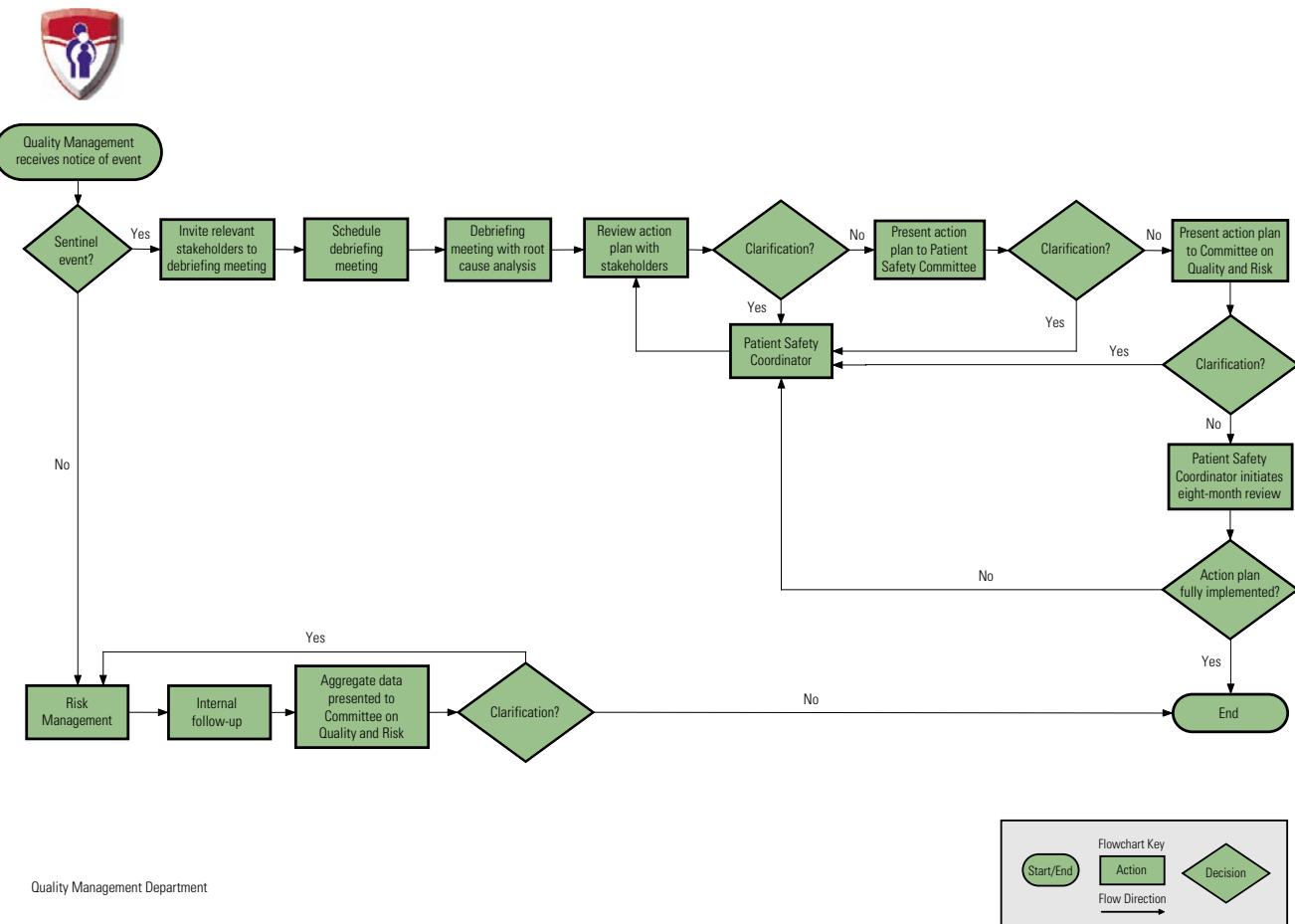
Background

In May 2005 the McGill University Health Centre Policy on Sentinel Events was developed and implemented. This policy provides a standardized framework to manage the sentinel events. It promotes a culture of safety by ensuring that an objective process focused on identifying system issues and not assigning individual blame is respected. The Joint Commission on Accreditation of Healthcare Organizations (2002) describes

a *sentinel event* as “an unexpected occurrence involving death or serious physical or psychological injury, or risk thereof. ... Such events are called ‘sentinel’ because they signal the need for immediate investigation and response.” Sentinel events present us with an opportunity to learn. However, in order to gather the information required to learn, we must first design a credible framework (Figure 1) to review the events systematically.

Our sentinel event process consists of the following steps:

1. *Confirm that it is a sentinel event.* Once the event is reported, it is reviewed by the following individuals: Director/Associate Director of Professional Services, Director of Clinical Operations/Nursing, Director of Quality Management, Patient Safety Coordinator, the attending physician, and the department/nurse manager.
2. *Invite clinical staff, administrators and support staff to the debriefing meeting.* The Patient Safety Coordinator works with the department/nurse manager to identify the staff at the “sharp end,” in addition to other relevant stakeholders such as administrators, laboratories, security, transport, call centre.
3. *Schedule the meeting.* Our goal is to schedule the debriefing meeting within 14 calendar days from the time Quality

Figure 1. Sentinel event algorithm

Management is notified of the event. The main goals of the debriefing meeting are to:

- Ensure that participants have consistent and factual information
 - Discuss contributory factors
 - Develop recommendations and an action plan
4. *Review recommendations and action plan with all stakeholders.* Within 7 calendar days from the debriefing meeting, the participants are provided with the draft minutes and action plan for approval. Once this is approved, a final version is circulated to the participants in addition to the appropriate director or associate director.
5. *Present to the Patient Safety Committee.* A denominative summary of the events and action plan is presented to the Patient Safety Committee for review and comment. This multidisciplinary committee includes the Director and the Associate Director of Professional Services. Table 1 describes the full committee membership.

Table 1. MUHC Patient Safety Committee membership list

Director of Quality Management	Multidisciplinary Council representative
Executive Secretary: Director of Quality Management	Council of Physicians, Dentists, and Pharmacists representative: Associate Director of Professional Services
Director of Professional Services	Nursing Council representative
Director of Clinical Operations and Nursing	McGill Medical Simulation Centre
Acting Director, Health Network Development	Human Resources representative: Occupational Health and Safety
Legal counsel	Patient Safety Coordinator
Associate Director of Nursing Pediatric site	



Figure 2. Sentinel event user's guide

MUHC POLICY AND PROCEDURE User's Guide

Please keep all documentation and/or material relevant to the sentinel event

Timeline	Required Action
Immediate	<p>Stabilize and treat patient/victim, provide information and appropriate support</p> <p>Notify one representative from each of group 1 and group 2 and group 3:</p> <ol style="list-style-type: none"> 1. Nurse Manager or Assistant Nurse Manager or Resource Nurse Manager 2. Attending Physician or Physician-in-charge of unit or Clinical Teaching Unit Director 3. Department manager or delegate <p>Appropriate representative from either Nursing, Physician, or Department provide information, including the measures taken up to this point, and appropriate support to patient/victim and significant others</p> <p>Provide support to staff</p> <p>Notify Security and/or Administrator-On-Call if appropriate</p>
Within 2 Hours of the incident	<p>Nurse Manager/delegate or Department Manager/delegate collects names/contact information of all staff and other witnesses involved</p> <p>Nurse Manager/delegate or Department Manager/delegate collects preliminary information using the optional pre-formatted data collection tool (to be developed as a complementary tool to the incident report form)</p>
Within 1 Working Day from the date the incident occurred	<p>Nurse Manager contacts the Director of Clinical Operations/Director of Nursing and appropriate Associate Director of Nursing if necessary</p> <p>Responsible Physician contacts Director/Associate Director of Professional Services</p> <p>Department Manager contacts the appropriate Director</p> <p>Nurse Manager and/or responsible Physician and/or Department Manager contact Quality/Risk Management at local 35663</p> <p>Incident report completed and sent, with any other relevant data/information, to Risk Management at F6.10 (RVH/MCI/MNH), F1.38 (MCH), T8.105 (MGH)</p> <p>Decision is made if it is a sentinel event (MUHC Policy on Sentinel Events, V.3)</p> <p>Risk Manager contacts l'Association des hôpitaux du Québec</p> <p>Physician contacts CMPA if required</p> <p>Professionals contact their appropriate professional order if required</p> <p>Disclosure to the family according to the MUHC Policy on the Disclosure of Accidents to Patients, Patients' Representatives, Parents, or Guardians</p>
Within 7 calendar days from the day the incident is reported to Quality/Risk Management	<p>First debriefing meeting is scheduled</p> <p>Necessary communications are initiated should it be determined that a sentinel event occurred (MUHC Policy on Sentinel Events, V.4)</p>
Within 14 calendar days from the day the incident is reported to Quality/Risk Management	First debriefing meeting occurs
Within 7 calendar days of the first debriefing	Draft minutes and action plan circulated to debriefing participants
Within 14 calendar days of the first debriefing	Debriefing participants provided feedback on draft minutes and action plan
Within 21 calendar days of the first debriefing	Final minutes and action plan circulated to all debriefing participants
Within 8 months from the time the incident is reported to Quality/Risk Management	Follow-up meeting with debriefing participants to review status of action plan

6. Present to the Committee on Quality and Risk Management.

Once the Patient Safety Committee is satisfied with the summary and action plan, it is presented to our Committee on Quality and Risk Management. This is a Board committee, which fulfils the requirement of Bill 113. The Quebec National Assembly enacted Bill 113 in 2002. One of its requirements is that all institutions form a risk management committee (Gouvernement du Québec 2005).

7. Initiate an eight-month review. This provides an opportunity to discuss with the stakeholders the status of the recommendations, to identify any challenges and to develop a strategy to overcome the identified challenges.

The Patient Safety Coordinator is responsible for managing the sentinel event process and ensuring the above steps are completed. In addition, he or she also acts as the link between the staff who participate in the debriefing process and the senior leaders within the organization (e.g., the Patient Safety Committee and the Committee on Quality and Risk Management).

One unique feature of our Policy on Sentinel Events is the one-page User's Guide (Figure 2). This supplemental tool was developed to assist our staff, including those working evenings/nights/weekends, when faced with a potential sentinel event. It summarizes the required communications, steps and timeline to follow immediately and in the short term, and ensures long-term follow-up.

From February 1, 2005 to March 31, 2006, 71% of the recommendations resulting from sentinel events have been implemented (see Table 2).

The Policy on Sentinel Events helped initiate a number of changes to improve patient safety including the two pilot projects dubbed O₂ Ticket to Ride and Code Stroke Algorithm. The former ensures cross-disciplinary responsibility for the transportation of oxygen-dependent patients to diagnostic testing areas. The latter was developed to expedite the sequence of events from the time the stroke symptoms are observed to the time the CT scan is carried out.

Table 2. Sentinel event statistics, February 1, 2005–March 31, 2006

Number of sentinel events with recommendations	16
Total number of recommendations	65
Number of recommendations implemented	46
Percentage of recommendations implemented	71%

Case Study 1: O₂ Ticket to Ride

Problem

The transport attendant was returning an oxygen-dependent patient from a diagnostic area to the inpatient unit. Just prior to arriving on the unit, it was noted that the patient was unresponsive. Upon arrival the patient was immediately given oxygen, responded well and suffered no deleterious effects. Once the patient was stabilized it was discovered that the portable oxygen cylinder was empty when the patient arrived from the diagnostic testing area. A preliminary investigation highlighted the need to clarify the responsibility of the various participants at each transition point, and the process when transporting oxygen-dependent patients from their inpatient unit.

Process

A debriefing meeting was scheduled to review the system components and identify the contributory factors. Attendees at the debriefing included clinical staff, physicians, administrators and support staff. The goal of the meeting was to review the current practice for transporting oxygen-dependent patients, identify the challenges and develop an action plan to improve the situation and minimize the likelihood of a recurrence.

Several attendees had been involved in previous discussions concerning this topic. A number of issues still existed, which led to spirited discussion. Daryl Conner (1992) describes covert and overt resistance; this was an excellent example of overt resistance. The participants put their cards on the table and described their frustrations in trying to resolve this issue. Overt resistance is often perceived as a negative activity; however, it can be a powerful tool, providing information enabling you to identify and prioritize your challenges in order to implement a change in practice.

Intervention

The outcome of the meeting was the creation of a smaller workgroup that included nursing, physicians, radiology and the unit coordinator group. A pilot project was discussed that would include all patients being transported to radiology from two internal medicine units at one of the MUHC adult sites. The working group defined the criteria to be included in the tool. Once this was done, a draft document was produced and circulated to the Clinical Teaching Unit directors and all staff involved. In addition, guidelines were written in order to ensure that all stakeholders understood their role in the process.

The project was presented to the Patient Safety Committee and Committee on Quality and Risk Management according to the Policy on Sentinel Events.

The nurse professional development educator carried out in-service training to nursing staff and unit coordinators. The

chief radiology technologist was responsible for informing this group about the project and ensuring appropriate training took place, if required.

Tool

The O₂ Ticket to Ride “ticket” is a two-sided form. It is printed on blue paper to differentiate it from the myriad of white sheets in the patient’s chart. The colour also serves as a visual cue to remind staff that the tool is being used to prevent a possible “code blue” from occurring when preparing an oxygen-dependent patient for transport. One side includes the information that must be completed prior to the patient’s departure by either the Nurse or the Radiology Technologist. This includes the date the patient goes to radiology, the departure time from the unit, the name of the departure unit (internal medicine or radiology), the destination, the type of oxygen device, the number of litres per minute of oxygen, the amount of pressure remaining in the cylinder, *the time the cylinder must be changed* and the initials of the Nurse or the Radiology Technologist. The reverse side includes a chart that describes how long the oxygen will last on the basis of the flow administered to the patient and the amount of pressure remaining in the cylinder.

Evaluation

Evaluation of the project will be focused in two areas: process and outcome. The first measures compliance with using the tool. The Assistant Head Nurse will keep a master list of the oxygen-dependent patients. This list will be reviewed against the completed O₂ Ticket to Ride forms to evaluate if the tool was used each time an oxygen-dependent patient was transported to radiology. In addition, risk management will be asked to review the incident reports received from the two areas to identify any possible incidents involving patients lacking oxygen in transit during the pilot phase.

The pilot project has recently been completed and data analysis is under way.

Case Study 2: Code Stroke Algorithm

Problem

An inpatient was suspected to be exhibiting signs of a stroke. It is important to note that the patient’s admitting diagnosis was not related to a neurological condition, and therefore the patient was not admitted to a neurology ward. Upon consultation by the neurology service, it was decided that the patient required a computerized tomography (CT) scan to determine if tissue plasminogen activator (tPA) was a treatment option. The communication process at the time was not centralized, so the call centre received several independent calls to contact the radiology resident, the CT scan technologist and the transport attendant. A delay occurred from the time the CT scan was

ordered until the time that it took place. The patient received tPA and was admitted to the intensive-care unit. The event was considered a sentinel one, and a debriefing meeting was scheduled within two days.

Process

Similarly to the O₂ Ticket to Ride project, attendees at the debriefing included clinical staff, physicians, administrators and support staff.

Intervention

The key issue identified was the need to expedite the communication process. During the debriefing meeting a small working group, including radiology, nursing, transport and the call centre, was created to develop a strategy. Because of the large number of clinical staff required to provide patient care, the call centre suggested that a group page be implemented to reach the key stakeholders in one call instead of multiple calls or pages. This was the impetus for the development of the code stroke algorithm (Figure 3).

The project was presented to the Patient Safety Committee and Committee on Quality and Risk Management according to the Policy on Sentinel Events.

The algorithm will be piloted for one year on all 15 inpatient units at one of our adult sites.

The Tool

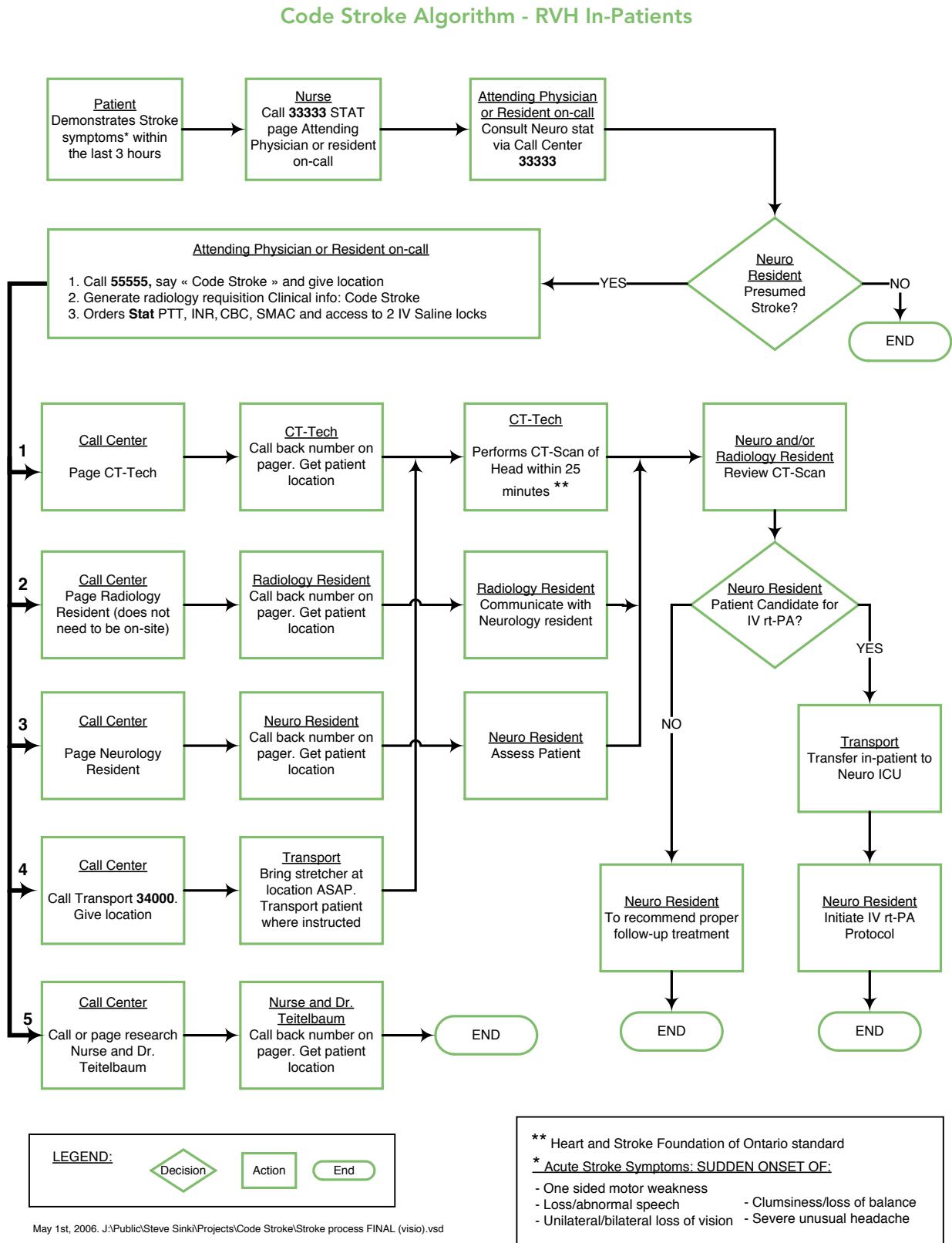
How does the algorithm work?

Once nurses observe the sudden onset of signs and symptoms of stroke, they immediately call the on-call physician. They consult with the neurology resident on-call. Once it is confirmed that the patient may be having a stroke, the on-call physician places a call to the Call Centre indicating a “Code Stroke.” At the same time, the on-call physician orders various STAT blood tests, including PTT, INR, SMAC and CBC, so that the results will be available when the CT scan is completed. The operator initiates the group call to simultaneously notify the CT technologist, transport, the stroke program research nurse and the physician leader, the neurology resident and the radiology resident. The research nurse is notified to ensure that other available research protocols are discussed if the patient is not a candidate for tPA treatment. The second call to the neurology resident confirms that the Code Stroke sequence has been initiated.

Evaluation

For each Code Stroke called, the Clinical Nurse Specialist will convene a debriefing meeting to review the process. In addition, because the CNS is involved with all stroke patients, she or he will also review those cases in which a Code Stroke should have been initiated. Evaluation criteria will include the total number of codes called, the overall time it takes from initial call to initia-

Figure 3. Code stroke algorithm



tion of CT scan and the response times of the treating physician, neurology and radiology residents, transport and the CT technologist from their initial call.

On the basis of the guidelines published by the Ontario Heart and Stroke Foundation, the goal is to initiate the CT scan within 25 minutes of the time the stroke symptoms are observed.

Lessons Learned

1. *A standardized framework, such as the Policy on Sentinel Events, bridges the gap between the unit-based staff and the senior leaders and improves organizational learning.* As a result of implementing our policy, we have put in place a mechanism that facilitates bidirectional communication. Information regarding a sentinel event is shared up and down the organizational hierarchy from the unit-based level to the Patient Safety Committee and Committee on Quality and Risk.
In addition, by managing the process in a standardized way, we can ensure that organizational learning and knowledge transfer occurs at all levels within the organization.
2. *A standardized framework clarifies the expectations of the participants.* The Policy on Sentinel Events and User's Guide describe in detail the expectations for the unit-based staff, department/nurse manager, Risk Manager, physicians, and Director/Associate Director of Professional Services when faced with a sentinel event.
3. *When someone is "engaged" in the process: Grab them!* Internal champions were one of the keys to both projects being implemented. They possessed the ability to enlist the support and assistance of their peers. In addition they had a willingness to contribute to resolving the system issue and improving patient safety.
4. *A nonpartisan facilitator keeps the group focused on system issues and not on trying to assign individual blame.* When an adverse event occurs, it is rarely the result of just one factor but rather a chain of events. Unfortunately there is usually at least one staff member at the sharp end. As a nonpartisan facilitator, the Patient Safety Coordinator lends an objective lens to the sentinel event process by addressing the anxiety that might be experienced by the staff at the sharp end and directing the conversation toward the system issues. Bennis (1997) described four competencies of a successful change agent: broad knowledge base, ability to listen/observe, sensitive/mature and authenticity of your behaviour with the message. These are also valuable qualities for Patient Safety Coordinators in their role of promoting a culture of safety within the organization.
5. *Communication is improved when clinical staff, physicians, administrators and support staff participate in the debriefing process.* Although both cases represented clinical issues, in order to evaluate the system components it is necessary to include all the "system" participants to review the problem. The sentinel event debriefing provides a unique forum that

challenges the "silo" mentality of problem-solving by initiating cross-disciplinary discussion in a face-to-face environment. Participants work together to analyze the event in addition to identifying, and addressing, the potential challenges involved in implementing a sustained change in practice.

The working group that developed the O₂ Ticket to Ride project included the unit coordinators from the clinical unit. These individuals are responsible for coordinating patient testing and transport. Their expertise in the operational aspects of the project improved the process for the staff on their units.

Including transport in the initial debriefing for the Code Stroke Algorithm was vital to the success of getting the patient to the CT scan area as quickly as possible. Expanding the working group to include the Call Centre allowed us to capitalize on their expertise in communication technology to contact the various players in the most efficient way possible.

These two pilot projects are excellent examples of what can happen when a standardized framework, including multidisciplinary participation, is used to review an adverse event. In both cases the various stakeholders identified their challenges, worked together to address them and implemented a change in practice that will improve patient safety.

For the O₂ Ticket to Ride form see Online Appendix at <http://www.longwoods.com/product.php?productid=18374&cat=452>

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Implementing System Safeguards to Prevent Error-Induced Injury with Opioids (Narcotics): An ISMP Canada Collaborative

Margaret Colquhoun, Christine Koczmara and Julie Greenall

Abstract

Institute for Safe Medication Practices Canada (ISMP Canada) is involved in collaborative initiatives focusing on opioid safety in two Canadian provinces: Ontario and Alberta. Baseline survey responses from these provinces indicate opportunities for improvements to the opioid system that might be applicable nationally. Information about the Ontario project and preliminary analysis of follow-up survey results from that province are shared here, to increase awareness and create further national impetus for the enhancement of safeguards in the use and management of opioids.

Background

Opioids (narcotics) are “high-alert medications,” defined as medications with a higher risk of causing patient injury when errors occur (Institute for Safe Medication Practices 2005). “Narcotic accidents are among the most frequent of all serious incidents reported” (Cohen 1999: 5.35). Within the ISMP Canada database, opioids are the class of drugs most frequently reported in medication errors causing harm (Institute for Safe Medication Practices Canada 2006). Reports from other countries have also identified opioids as a class of medications frequently involved in preventable adverse events causing patient harm (Hicks et al. 2004; Smith 2004). With an increasing focus on patient safety

in Canada and movement toward outcome measurements (Baker et al. 2004; Forster et al. 2004; Safer Healthcare Now 2005), awareness of medication errors associated with opioids can also provide a collective, national impetus to enhance opioid safety and thus prevent opioid-associated errors.

Opioids are administered by various routes: oral, enteral, rectal, subcutaneous, intramuscular, intravenous, neuraxial (i.e., epidural or spinal) and transdermal. They are available in a variety of dosage forms, including tablets, capsules, liquids, suppositories, injectables, and patches. Suffixes indicating immediate or sustained release are common, but they can be confusing (e.g., IR for immediate release, CR for controlled release, SR for sustained release, XR for extended release). The names of some opioids sound alike, which can result in mix-ups between what is ordered and what is administered (e.g., morphine and hydromorphone; fentanyl and sufentanil; oxycodone and Oxycontin®). Furthermore, opioid products are supplied by a small number of manufacturers in Canada, leading to situations in which multiple strengths of drugs with sound-alike names, in similar packaging, are stored together in patient care areas.

Current medication systems are designed to ensure accurate verification of narcotic counts but not necessarily the safe and appropriate use of these drugs. Known safeguards that have

been implemented for the dispensing of other categories of medications, such as unit-dose packaging, order verification by pharmacy and preparation of specific parenteral doses, are often not in place for opioids. Pharmacy staff are conscientious about ensuring that patient care areas have “enough stock”; current prescribing practices can lead to the stocking of a large variety of opioid medications; and administration practices commonly require a single practitioner to identify, prepare and administer an opioid without redundant checks. All of these factors can result in few barriers (low “fault tolerance”) to prevent errors from reaching the patient.

Ontario Opioid Safety Project

Ontario was the first Canadian province to establish a province-wide support service to assist healthcare organizations to enhance safety in the use of high-alert medications. The Medication Safety Support Service (MSSS) is a joint initiative of the Ontario Ministry of Health and Long-Term Care and ISMP Canada. MSSS projects are led by ISMP Canada with the support of a multidisciplinary provincial advisory committee, composed of representatives from the professional colleges and associations of medicine, nursing and pharmacy. The first MSSS project focused on elimination of concentrated potassium chloride, and resulted

in reduced availability of this high-alert drug in patient care areas by Ontario hospitals (Institute for Safe Medication Practices Canada 2003). The MSSS potassium chloride project enhanced national awareness and action (McKerrow et al. 2004).

The current MSSS project focuses on opioids, with the goal of reducing the risks associated with the distribution and use of these high-alert medications in Ontario hospitals. It is hoped that sharing the methodology and preliminary analysis of the project results will generate national awareness and action similar to that which occurred with the potassium chloride project.

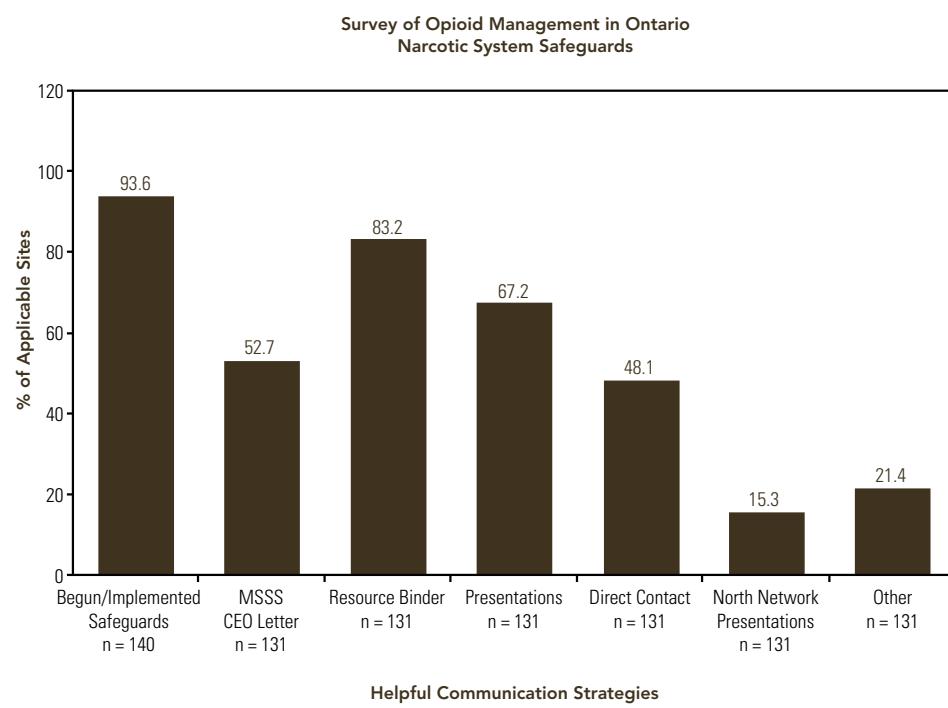
Project Rationale and Background

In July 2003, ISMP Canada hosted a conference at which Ontario hospital representatives identified opioids as a top concern in medication safety. Central nervous system drugs are the class most frequently involved in medication incidents, with opioids most frequently implicated (Marshman et al. in press). In a review of 32 deaths related to medication errors investigated between 1999 and 2003 by the Office of the Chief Coroner of Ontario, Flynn and Greenall (2004) found that 14 of the deaths (44%) involved opioid medications. A review of numerous articles describing opioid-related errors (Institute for Safe Medication Practices Canada 2005), and two high-profile

opioid-related deaths that were investigated by the Office of the Chief Coroner of Ontario (Chief Coroner, Province of Ontario 2000, 2001), provided additional impetus for the project.

A survey based on known best practices for handling of opioids was developed to assess the current management of these medications in Ontario hospitals. The five-page survey was electronically distributed by the Ontario Hospital Association to every Ontario hospital in January and February 2004. Responses were submitted online or via fax to ISMP Canada. Seventy-five percent of Ontario hospitals (165) responded to the baseline survey. Results indicated that there were opportunities to implement system changes to reduce risks associated with opioid use.

Figure 1. Survey of opioid management in Ontario



Source: Used with permission from Institute for Safe Medication Practices Canada.

The survey findings were used to create priority recommendations (see Appendix A). A resource binder was created, compiling information about opioid errors, underlying systems issues and practical strategies and resources, some of which were provided by Ontario hospitals. Recommendations were directed toward short-term and attainable changes that would be relevant to most acute care facilities, rather than longer-term strategies such as automation and computerization. Importantly, the project was intended to contribute to organizational culture change, shifting the focus from individual practitioners as the safety net to systems supporting individuals in safer practice.

The resource binder was distributed directly to representatives of 91 Ontario hospital sites at a workshop in January 2005. Resource binders were mailed to hospitals that were unable to send representatives to the workshop. In addition, multiple communication strategies, such as telemedicine presentations, letters to hospital chief executive officers and direct contact with hospitals by telephone and e-mail, were used to supplement the resource binder and assist hospitals to implement the recommendations. Ontario hospitals were urged to implement the priority recommendations and additional strategies to address potential problems in the management of opioids.

Results

One hundred forty Ontario hospitals (64%) responded to a follow-up survey distributed in November and December 2005. Almost all (94%) of the respondents indicated that they had started to implement recommended safeguards in their narcotic distribution systems. Respondents noted that the variety of communication strategies employed by ISMP Canada had been helpful in implementing system changes (Figure 1).

Of 140 follow-up survey respondents, 131 (94%) have begun or already implemented opioid system safeguards. These respondents also indicated the useful communication strategies employed by ISMP Canada.

Progress is being made in implementation of the priority recommendations. For example, the availability of high-potency opioids as stock items in patient care areas decreased from baseline. Specifically, a 46% reduction in stocking of morphine 50 mg/mL and a 66% reduction in stocking of hydromorphone 50 mg/mL in medical and surgical areas were reported (Figures 2 and 3). Figure 4 illustrates the implementation of several suggested strategies to reduce higher-potency items in patient care areas, such as review of narcotic storage areas, purchase of premixed agents and preparation of parenteral opioids in the pharmacy rather than in patient care areas. There also appeared to be a strong commitment to changes in opioid distribution practices that require additional time and resources, for example, standardization of concentrations of parenteral opioid solutions (Figure 5).

Another priority recommendation for Ontario hospitals is

the implementation of independent double-checks (IDCs) for patient-controlled analgesia (PCA) infusion pumps. The working definition of a non-automated IDC is “a process in which a second practitioner conducts an individual verification” (Institute for Safe Medication Practices Canada 2005). Information and strategies for IDCs are based on human factors engineering principles, and practical examples are included in the resource binder. For example, a report of a usability test for an IDC process and a checklist for a PCA infusion pump are provided. The survey results indicate that Ontario hospitals are implementing IDCs with PCA and other infusion pumps (Figure 6).

The follow-up survey also provided Ontario hospitals with the opportunity to provide further information about changes they had made or were in the process of making. Ninety-four Ontario facilities provided qualitative comments, 80% of these indicating they have made or are in the process of making *multiple* changes. Most frequently identified changes relate directly to the ISMP Canada recommendations and the practical strategies that were highlighted in the opioid resource binder. These include revision of narcotic administration records to incorporate safe design principles; reduction in numbers of opioid stock items in patient care areas; reorganization of patient care area opioid stock; standardization of opioids used for pain management; and enhanced differentiation of long- and short-acting opioid oral products at the point of selection. Many of the respondents’ comments provided insight into the specific changes being made:

Dedicated education time for nursing on pilot units related to narcotic and patient safety; 4 hour education sessions for more than 2000 hospital staff.

Hydromorphone 10 mg/mL only on one nursing cart and clearly labelled “high potency for palliative patients.”

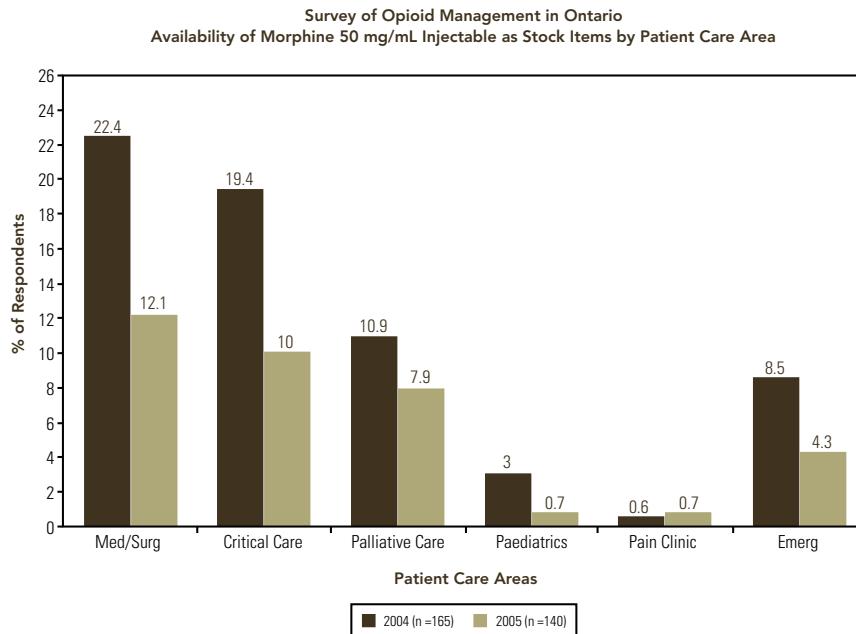
Increased frequency of narcotic delivery to daily to alleviate nursing concern of running out of stock (narcotic requisition trial).

Purchasing narcotics in unit dose where possible, i.e., control packs – it is safer than scanners and less chance of error.

Narcotic safety working group established and currently working on issues around storage, labelling, distribution, education.

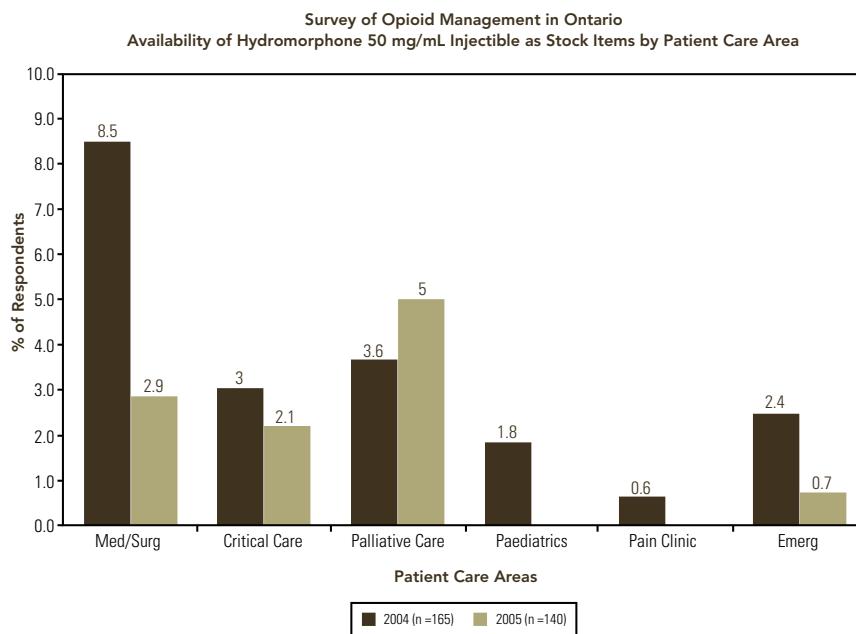
Interpretation of the Ontario results is limited by the nature of the project and the survey methodology: the hospitals responding to the survey were de-identified, making it impossible to know how many hospitals participating in the repeat survey had participated in the initial survey. In addition,

Figure 2. Change in availability of morphine 50 mg/mL (injectable) as stock in patient care areas in Ontario hospitals



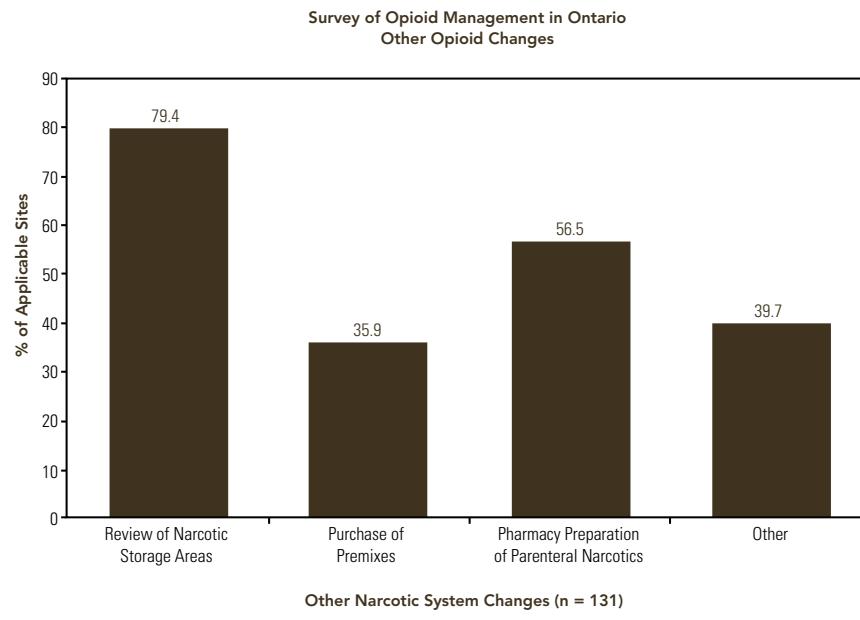
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Figure 3. Change in availability of hydromorphone 50 mg/mL (injectable) as stock in patient care areas in Ontario hospitals



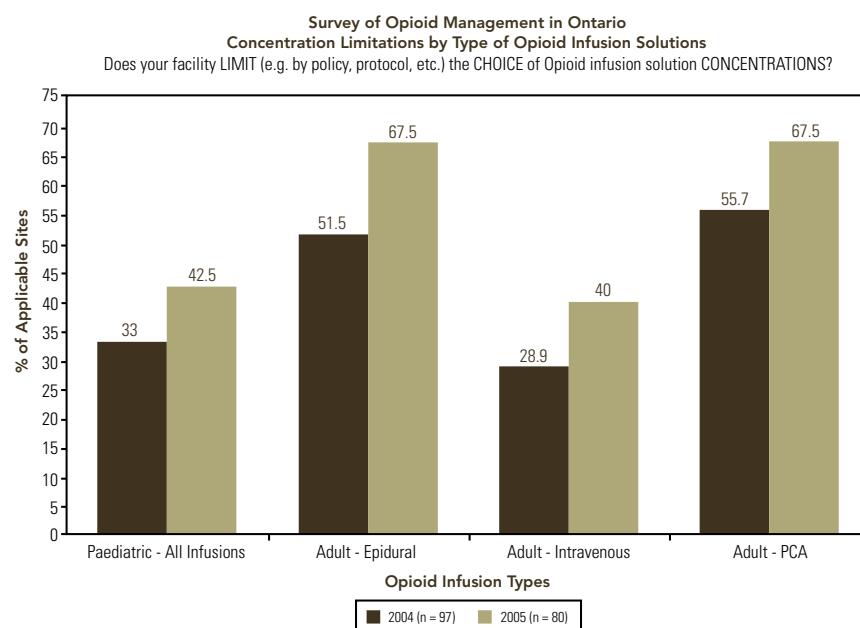
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Figure 4. Strategies in Ontario hospitals to reduce availability of higher-potency opioids in patient care areas



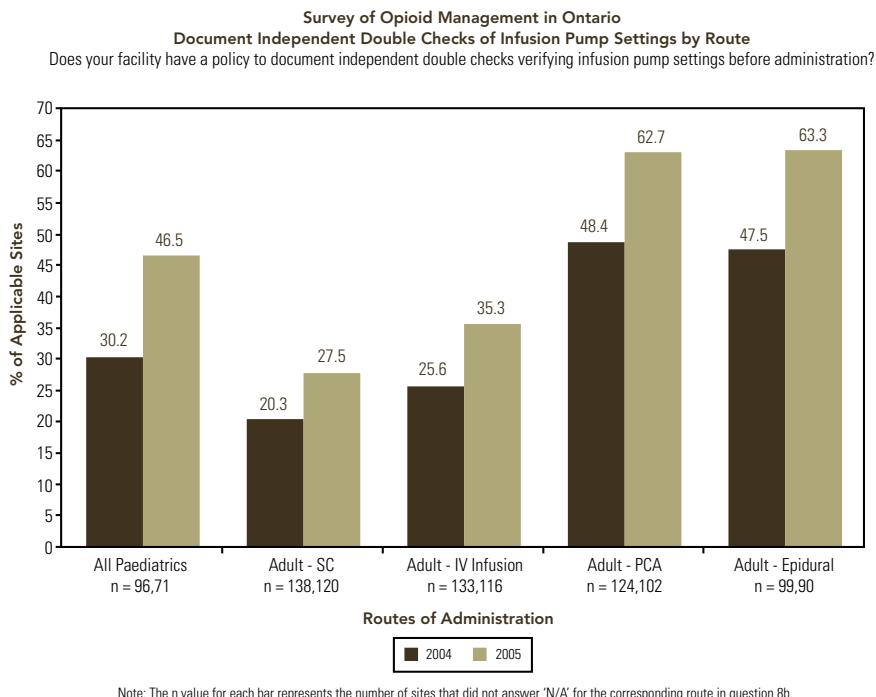
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Figure 5. Change in limitation of narcotic solution concentrations by Ontario hospitals (standardization)



Source: Used with permission from Institute for Safe Medication Practices Canada.

Figure 6. Comparison of baseline and follow-up surveys: policy to document independent double-check of infusion pump settings in Ontario hospitals



Source: Used with permission from Institute for Safe Medication Practices Canada.

respondents' interpretation of the questions might have varied, information was provided voluntarily and the accuracy of the information was not verified through other means. However, the comparisons between the baseline and follow-up survey responses and the qualitative responses provide an overview of opioid use in Ontario hospitals indicating positive changes are being made.

Alberta Opioid Safety Project

Building on the Ontario MSSS project, the Health Quality Council of Alberta and the Alberta regional directors of pharmacy, assisted by ISMP Canada, began work on opioid safety as part of the Alberta Medication Safety Collaborative in 2005. A preliminary survey of opioid practices was conducted in July and August 2005. Many of the opportunities identified in the Ontario project were also identified as priority areas in Alberta (e.g., reducing availability of higher-potency opioids and standardization of opioid solutions). At a May 2006 workshop, representatives from all Alberta health regions unanimously chose opioid safety as a top priority from a list of medication safety initiatives. A follow-up survey to measure changes in practice in Alberta is anticipated.

Conclusions

Opioids are potentially lethal, commonly prescribed high-alert medications that are widely available as floor stock in hospitals. Many opioid products have look-alike packaging and labelling, and they may require complex administration procedures. Ontario and Alberta have taken decisive steps to improve system safety related to the management of opioids in facilities. Comparison of Ontario baseline and follow-up survey responses indicate that changes are being made, but more remains to be done. The authors believe that the opioid project successes achieved to date are largely related to:

1. Multidisciplinary and province-wide partnerships and collaboration
2. Practical information, rationale for change and clear recommendations provided in an easy to use reference (binder), and presented at multiple workshops around the province
3. The province-wide Medication Safety Support Service collaborative model
4. Measuring outcomes based on pre- and post-survey responses related to opioid system best practices

Unlike the initiative to improve safety aspects of concentrated potassium chloride, enhancing safety with opioids is a broader and more complex issue. It involves an entire class of medications delivered by a variety of routes and methods, and thus requires greater multidisciplinary collaboration and longer-term efforts by multiple stakeholders, including the pharmaceutical industry. Other provinces are encouraged to focus on system-based safety initiatives for opioid use similar to those undertaken by Ontario and Alberta. There is great potential for healthcare providers across Canada to collaborate and share findings and resources to enhance patient safety through improved management of opioids.

To view Appendix see <http://www.longwoods.com/product.php?productid=18375&cat=452>

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Taking Aim at Fall Injury Adverse Events: Best Practices and Organizational Change

Patricia O'Connor, Joann Creager, Sharon Mooney, Andrea Maria Laizner and Judith A. Ritchie

Abstract

Fall injuries represent a huge healthcare, social and financial burden to the Canadian population. In 2004, the McGill University Health Centre (MUHC) was awarded recognition as a National Spotlight Organization for Implementation of the Registered Nurses Association of Ontario Best Practice Guidelines (BPGs). That same year, the author and co-leader of the Best Practice Guideline Program began the CHSRF Executive Training in Research Application (EXTRA) Program with the goal of reducing falls injuries, one of the most common adverse events in the MUHC and in acute care in Canada. This demonstration project used multiple strategies to strengthen a culture of safety and improve performance relating to adverse events, including: pilot testing several evidence-based falls prevention interventions (autumn 2005), training teams of champions to work across multiple sites, developing an infrastructure to support organizational change, modifying existing quality indicators to become benchmarkable, conducting a cost analysis of falls prevention, evaluating pre- and post-pilot surveys of organizational climate and obtaining initial baseline measures of the safety climate within the organization. Positive patient, practitioner and organizational outcomes suggest that falls safety prevention is feasible in large, complex healthcare organizations – and that safety is both a moral and a financial imperative. Next stages of the BPG

program include full rollout, and measuring sustainability via a formal outcome evaluation study.

Background

Falls are the sixth leading cause of death in Canada, account for 20% of all injury-related deaths among seniors in Canada, and add an estimated annual direct cost of \$2.4 billion (Canadian Institute for Health Information 2002). The incidence of falls among elderly hospitalized patients is greater than that among older persons living in the community. Several researchers (Morse 2002; Halfon et al. 2001) have reported a range of fall rates (per 1,000 bed days) as 2.2 to 7 in acute care hospitals, 11.0 to 24.9 in long-term-care hospitals, and 8.0 to 19.8 in rehabilitation hospitals. Injury rates have been reported to be 29–48% of falls, with 4–7.5% resulting in serious injuries. Many hospital falls are judged to be preventable: an Australian study found that 62% of hospital falls were preventable (Wilson et al. 1995). Research on falls prevention in acute care is limited, but there is compelling evidence from systematic reviews, meta-analyses and primary research studies in nursing homes and community-dwelling seniors demonstrating that falls can be prevented through timely risk detection and appropriately skilled management (Hanger et al. 1999; Close et al. 1999; Leipzig et al. 1999; Lord et al. 2003; Healey et al. 2004; Hill et al. 2004; Bischoff-Ferrari et

al. 2005; Gillespie et al. 2003; McClure et al. 2005). The major fall risk factors are diverse, and many – balance impairment, muscle weakness, excessive or suboptimal medication use and environmental hazards – can be modified.

Falls are the most commonly reported incident at the McGill University Health Centre (MUHC), an organization that is a merger of five acute care teaching hospitals (four adult, one pediatric). Approximately 1,150 falls are reported annually at the MUHC; 33% result in injury causing harm and 1.4% cause permanent injury. There is no information on the annual economic impact of falls at the MUHC, aside from settlement costs. Between 2001 and 2004, settlement costs totalled \$4.6 million for 15 cases, and in 2005 there was an accidental death related to a fall. Another indirect fall-related cost involves use of constant observation (about \$1.7 million per year at MUHC).

The Issues

While some units had already implemented excellent falls prevention measures, a systematic, evidence-informed organizational approach to falls prevention was lacking at MUHC. This posed important risks related to patient safety, legal liability and financial burden. The size (12,000 staff) and complexity of the merged organization, a history of strong cultural differences between sites, and the lack of benchmarked fall performance indicators were key issues.

In 2003, as part of the quality and safety initiatives of the MUHC Nursing Department, three nurse-sensitive outcome indicators were targeted for improvement: falls, pressure ulcers and pain management. In January 2004, the department was designated as one of nine national spotlight organizations for the implementation of the Registered Nurses Association of Ontario Best Practice Guidelines (RNAO BPGs) (2006). In August 2004, O'Connor began a two-year Fellowship in the Canadian Health Services Research Foundation's EXTRA (Executive Training in Research Application) Program. Her intervention project focused on fall injury reduction and strengthening a culture of safety through collaboration with the newly created Falls Prevention Task Force co-led by Creager and Mooney. The results of these collaborations are reported here.

Goals. The interdisciplinary falls prevention program, begun in autumn 2004 with the launch of a falls prevention task force (FPTF), had two goals: (1) implement a falls prevention best practice guideline in order to achieve a 20% reduction of in-patient fall injuries by 2007 and (2) utilize numerous multilevel strategies to increase organizational awareness of patient safety and adverse events, and strengthen a culture of safety.

Approach

We used the PARIHS conceptual framework to guide our knowledge transfer work. The model, Promoting Action on Research Implementation in Health Services (Kitson et al.

1998; Rycroft-Malone et al. 2004), proposes that three factors influence successful uptake of evidence into practice: the nature of the *evidence* being used, *contexts* that are receptive to change and the appropriateness of the *facilitation* strategies utilized.

A key resource for facilitating practice changes was the large cohort of nurse educators and clinical nurse specialists who had experience with knowledge transfer. While some units had falls prevention programs, clinicians on many other units had low awareness of the prevalence of falls risk and of appropriate interventions.

Implementing Best Practices

Assessing organizational readiness for change is a first step for successful change management. Feedback during preliminary BPG awareness workshops revealed widespread nurse enthusiasm to improve basic nursing practice. There was multilevel buy-in for falls safety changes from the CEO and board of directors to the managerial ranks and Council of Nurses quality committees. A key resource for facilitating practice changes was the large cohort of nurse educators and clinical nurse specialists who had experience with knowledge transfer. While some units had falls prevention programs, clinicians on many other units had low awareness of the prevalence of falls risk and of appropriate interventions. There was no single tool in wide use for risk assessment or documentation of prevention efforts. As a recently merged institution, leadership had little experience with effectively introducing practice change across multiple sites. These factors indicated the need for a clear, multipronged implementation plan.

Undertaking such large and complex change is impossible without considerable infrastructure support. The RNAO "spotlight" designation provided \$100,000 in funding, used primarily to ensure paid release time of unit staff for education, an important condition for manager buy-in. The RNAO falls prevention BPG, based on critical appraisal of existing evidence, provided a "ready to go" product from a credible source. Other supportive features included: (1) executive co-leadership of the BPG Program, and creation of a BPG steering committee, (2) workshops to train facilitators such as our "advocates" (change agents who work across sites providing coaching and guidance) and "unit-based champions," (3) embedding researchers and senior managers on each task force – an innovation that brought rigour and practicality to the teams, (4) linking these efforts with existing quality and practice committees, the nursing Executive and the Council of Nurses and (5) multiple communication strategies.

Table 1. Pilot unit interventions and methods of evaluation

Evidence-Based Interventions	Measurement/Evaluation
<ul style="list-style-type: none"> • Morse Fall risk assessment: admission & transfer • Individualized risk profile, matched with interventions, completed on admission, transfer, change in status and after a fall • Use of universal falls prevention precautions • Post-fall debriefing • Environmental & equipment audits • Medication audits of unit prescribing practices • Staff training • Patient and family education 	Focus groups: 3 intervals Chart audits Environmental audits Staff Surveys (Edwards et al. 2004) relating to: <ul style="list-style-type: none"> • Organizational culture of change • Organizational support for BPG • Assessment and management of falls risk • Safety climate • Perceived worth of BPGs • Educational and support processes

An interdisciplinary falls prevention task force, developed in 2004, was responsible for: (1) identifying baseline fall rates, (2) selecting performance indicators and targets (autumn 2004), (3) piloting falls prevention interventions on four units for 6–8 weeks (autumn 2005), (4) evaluating and communicating the results and (5) recommending changes for diffusion (winter-spring 2006) and rolling out the implementation across the hospital. The pilot units included two internal medicine units and two long-term-care units.

The summary of the falls prevention interventions that we promoted and our methods of evaluation are listed in Table 1. The Morse Falls Risk Assessment Tool (1997) was used to provide a simple, valid and reliable measure of fall risk based on specific risk factors. These evidence-based practice changes were promoted through formal, falls prevention interactive learning activities, and use of decision-support pocket tools and posters and other incentives (BPG buttons, bags and lanyards). The task force co-chairs supported the unit-based champions throughout the piloting process via frequent unit meetings to discuss progress and troubleshoot.

Multiple Strategies to Strengthen a Culture of Safety

Improving patient safety is primarily a culture change. Many healthcare organizations are treating adverse events as a technical challenge, but the larger challenge lies in transforming the work and the patterns of behaviour that have developed around the work (Baker 2005). Creating and sustaining a culture of safety occurs when organizations place as high a priority on safety as they do on production (fiscal performance). In addition to implementing best practice guidelines, our strategies were aimed at increasing awareness, developing a falls safety business case and improving corporate monitoring systems.

Increasing Safety Awareness. Several methods were used to increase safety awareness. Surveys pre- and post-implementa-

tion of the falls BPG on four pilot units elicited staff perceptions regarding: organizational culture, support for BPGs, safety climate, worth of the BPGs, changes in practice and educational support. Multiple knowledge exchange sessions were held on a range of safety issues (adverse events, falls prevention, sentinel events, root cause analysis, workplace quality indicators). We targeted multiple groups in these sessions: the public, CEO, Board of Directors Quality Committee, executive teams, managers, clinical nurse specialists, educators, practitioners, pharmacy, technical services and groups with quality mandates.

Developing a Business Case for Falls Safety. Another aspect of our falls prevention program included tabling a business case (cost analysis) for falls prevention to senior management and the Board of Directors Quality Committee. Rather than undertaking a lengthy study with matched controls to determine the MUHC fall injury costs, our approach was more pragmatic. We projected costs based on existing evidence about the following factors: physician service costs, average increased length of stay for fall injuries in acute care, average costs for hip fracture injuries, fracture rate within the MUHC, costs for safety equipment and estimated avoidable patient days based on potential rates of fall injury prevention. An audit of falls prevention equipment was also conducted across the five sites to identify and cost needed resources. Multiple external funding sources were sought to support best practice implementation.

Modifying Corporate Reporting of Falls and Fall Injuries. Comparing fall rates among different institutions was difficult because of varying definitions, reporting methods, types of settings and populations and lack of risk adjustment. In 2004, the MUHC was reporting fall occurrences, not fall rate, making external benchmarking comparisons difficult. The most commonly used statistic allowing benchmarking comparisons to measure falls is the “fall rate,” the number of falls per 1,000 patient days. Our falls severity measure included categories too

numerous and overlapping. In Quebec, incidents are currently reported by means of a single-page provincial reporting tool, which is inadequate for assessing whether falls prevention practices were in place when the fall occurred. Representatives of the falls task force and the MUHC Quality Department together focused on revising internal fall reporting systems, modifying the provincial tool and reducing gaps in accurate identification of fall adverse events.

Results

Piloting Best Practice Guideline

Falls and Fall Injuries. Table 2 shows the results of fall rates and injury rates in the five-month period prior to and after the pilot implementation of the falls prevention BPG. While falls did occur on all four units, the more significant improvement was in the rate of fall injuries. On units 3 and 4, the fall rates increased slightly, but they remained quite low, and there were significant improvements in injury rates. All post-pilot fall injuries on units 1–3 resulted in only minor injuries (bruising/abrasions), and the six falls occurring on unit 4 resulted in no injuries.

Table 2. Fall and fall-injury rates: 5 months pre- and post-piloting

	Fall Rate		% Falls with Injury	
	Pre-pilot	Post-pilot	Pre	Post
Unit 1	4.7	4.5	47%	6%
Unit 2	6.9	6.8	24%	28%
Unit 3	1.9	2.9	40%	14%
Unit 4	1.3	1.8	50%	0%

Focus Group and Chart Audit Results. Audits showed the Morse tool was usually completed at time of admission and after a transfer. Staff found it easy to complete. There was some variability in scoring during training sessions, resulting in descriptive prompts being added to the charting tool. Feedback from nurses illustrated the usefulness of the Morse tool – for example, “It catches my attention” and “It leads me to see the patient earlier – at the start of the shift.” An individualized risk factor documentation tool, designed by the task force to chart fall interventions linked to patient risk factors, was seen as too time-consuming and detailed by practitioners on the acute care units. The reformatted and re-piloted version has received very favourable reviews, and has been prepared for wide implementation. The CATT tool denotes the times for assessment – Change in status, Admission, Transfer or after a Tumble (fall)

Staff perceived a fairly open culture for change (2.7–2.8 /4), the highest ratings being given for: morale, openness of team to try new things and having a feeling of “Let’s get things done” and that their manager was an advocate for nursing in the hospital.

– and includes a Morse score, risk profile and fall intervention charting. Interdisciplinary debriefings following falls occurred more consistently in the long-term-care areas, and staff on all pilot units indicated they were much more aware of the interventions that needed to be modified. In most cases the appropriate interventions were in place.

Ongoing facilitation provided by the advocates and task force co-chairs and the internal support from the unit-based champions were seen as crucial by staff and managers alike. These interactions, largely informal but frequent, allowed for problem-solving when obstacles were met, ongoing encouragement and high visibility for the project. Given the constant barrage of competing priorities for staff at the unit level, they found the regular positive feedback and communication essential.

Staff Surveys. Survey results are expressed with simple mean score ranges for the four units. Staff perceived a fairly open culture for change (2.7–2.8 /4), the highest ratings being given for: morale, openness of team to try new things and having a feeling of “Let’s get things done” and that their manager was an advocate for nursing in the hospital. Lowest scores related to work overload. Organizational support for the BPG was rated slightly higher (2.9–3 /4), the best scores being given for: management support of the BPG, nurses’ belief they had the time/training to learn to use the BPG and readily adopting the changes required. Lowest scores related to inadequate supplies/equipment to implement the BPG. Staff perceptions of safety climate were positive, with small increases post-pilot (3.8–4.1 /5). The acute care units had a somewhat more negative perception of worth (6.8–8 /10) and facilitation (2.6–2.9 /4), possibly due to unwieldiness of the original falls risk factor assessment tool designed for the pilot units. Nurses perceived improvements in their ability to assess and manage 13 fall risk factors post-pilot. The units infrequently reviewed medications with pharmacists and physicians – an important target area for interdisciplinary collaboration. Limitations of these results include a lower response rate for two units post-pilot, and nonmatching staff responding pre- vs. post-pilot.

Environmental, Equipment and Medication Audits. Our audits identified faulty equipment/patient furniture posing fall hazards. In long-term-care units, clutter from patients’ personal

belongings was the most common problem. There was a significant lack of appropriate fall risk reduction equipment on all pilot units – for example, bedrail bumper pads, wedge cushions, bed and chair alarms and nonskid socks. During the pilot we were successful in obtaining funds from the hospital foundation and volunteers to purchase safety devices for these units. Polypharmacy, defined as taking more than five medications, was very common (97% of patients) and there was significant use as well of benzodiazepines and antidepressants (59%).

Results of Strategies to Strengthen Culture of Safety

Knowledge Exchange Sessions. While difficult to fully evaluate the results, the high attendance rate at the many safety sessions was significant and feedback, though informal, was very positive. Another important result was buy-in from the unions, including their financial support for advancing the best practice guideline implementation program and requests to have presentations at their union–management meetings. Sessions held with managers, and the various safety audits in particular, resulted in greater awareness of the potential to reduce falls.

Business Case for Fall Safety. Bates (1995) estimated the cost for falls occurring in acute care as averaging \$4,230 (in 1995, in US) for physician services, with lengths of stay extended an average of 12 days. VHA statistics for hip fracture injuries after a fall indicate an average cost of \$34,000, and an increased length of stay of 17 days. Assuming approximately 11 MUHC hip fractures/year based on current rates, this represents an annual cost of approximately \$374,000. The identified cost for new fall safety equipment is approximately \$200,000 (\$5,000/unit). It becomes clear that the preventable cost associated with one year of fall injuries exceeds the cost to properly outfit all care units. There are even more important savings vis-à-vis patient days if adverse events such as fall injuries were reduced (improving access for other care). The MUHC's current rate of 33% fall injuries (378 falls) – and potentially lengthened stays of 12 days – represents 4,554 avoidable patient days. Assuming at least half of these falls were preventable, this would mean 2,277 bed days potentially available for other admissions. An important consequence of performing the various audits (environmental, equipment, fall safety devices) and involving many managers was the managers' increased awareness of the potential to reduce falls.

Obtaining adequate resources for falls prevention was a key priority. Funding obtained includes: (1) \$75,000 from the Canadian Nurses Foundation and partners for a formal evaluation study of further BPG implementation, (2) \$200,000 received from the provincial Ministry of Health for work reorganization relating to best practices and (3) \$55,000 from MUHC Foundations for falls safety equipment purchases. These funds allowed the recent hiring of a project manager – a

much-needed support. An evaluation of patient beds was also conducted in collaboration with the falls task force, resulting in a long-term replacement plan and partial funding to begin replacement.

Modified Corporate Reporting of Falls and Fall Injuries. Table 3 illustrates the conversion of fall occurrences into a falls rate and percentage of falls with injury, for the combined adult and pediatric sites. Rate comparisons, internal and with external benchmarks, are now possible. The anticipated fall rate reductions following the introduction of BPGs will only be evident in 2006–2007, when rollout is occurring across many units.

Conclusions

Our experiences confirmed work by others (Bero et al. 1998; Solberg et al. 2000) that effecting organizational changes requires the use of multilevel, bundled interventions – and it is a messy process. Staff indicated falls prevention is a priority in their practice, and that the BPG content and processes used were valuable. The results suggest improvements in practice and in patient outcomes. It is clear that commitment to reducing falls involves: changing staff and client behaviour, systematic organizational changes, coalition-building and closing the gap between corporate safety values and operationalization to the front line. Ultimately, safety is both a moral and a financial imperative, requiring dedicated resources for basic equipment, information systems, learning activities and paid release time of clinically expert change agents who are needed for the ongoing facilitation of practice changes. This is crucial, as competing priorities easily dissipate the focused attention required to sustain such changes. The alignment of this best practices initiative with key corporate safety priorities has encouraged many clinical leaders from different disciplines to begin working in a more systematic and cohesive manner. A systematic review of evidence on sustainability of innovations (NHS Modernization Agency 2002; Greenhalgh et al. 2004) confirms these variables as key to successful change.

Table 3. MUHC fall and fall injury rates, 2002–2006

Indicator	02–03	03–04	04–05	05–06
Number of falls	1,375	1,157	1,146	1,099
Patient days (PD)	369,266	363,461	352,306	356,933
Falls rate (# falls/1000 PD)	3.7	3.2	3.3	3.1
% of falls with injury	25%	34%	29%	30%
% of falls with severe injury	0.3%	0.95%	1.3%	0.9%

Lessons Learned

Factors affecting successful change at MUHC included: extensive stakeholder analysis and engagement including support departments such as finance, technical services/housekeeping, and risk management in addition to the usual frontline clinical disciplines and executive levels; ongoing training of champions at the unit and cross-site level; creating infrastructure to support organizational change; and clear timelines. Manager buy-in was key; it required many rounds of consultation, and flexibility in making adjustments while setting realistic limits. Breakdown in communication in such a large system was common and needed constant attention. Access to resources was an obstacle, and sources both external and internal were still required. Embedding both researchers and senior managers on the falls task force was an innovation that brought rigour and practicality to the teams. Having appropriate systems in place to evaluate the effectiveness of change provides critical feedback throughout the system to support sustainability. Celebrating successes and small, incremental wins at every possible step has been a deliberate strategy, along with continuous communication of results both internally and internationally.

Future Directions

The new corporate monitoring systems will allow for more accurate rate comparisons internally and with external benchmarks. In 2006–2007, pediatric and adult data will be reported separately. Plans are under way to streamline fall injury reporting, noting presence/absence of injury and percentage with severe injury. Recommendations have also been made for improving the provincial incident reporting system. Medication management as it relates to reducing risk of falls is an area requiring further practice review.

Despite the many challenges, we have made remarkable progress, and have concluded that the pilot implementation was successful. We have seen many unanticipated benefits, as new leaders are emerging with stronger skills in project management, flexibility and collaboration, political awareness and public relations, and knowledge transfer. We also are seeing an improvement in the discourse in the organization toward a culture of evidence-based decision-making and patient safety.

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Enhancing Patient Safety through the Management of *Clostridium difficile* at Toronto East General Hospital

Arladeen Tomiczek, C. Stumpo and James F. Downey

Abstract

In 2005 Toronto East General Hospital experienced a steady increase in the number of *C. difficile* cases diagnosed within the hospital. This was identified as a patient safety issue, and several areas of the hospital came together to address the problem. Pharmacy immediately started a medication review of past cases. Environmental services took the lead on the environmental cleaning, and a process was put into place with Infection Control so that housekeeping knew of every room that contained a patient with *C. difficile* and enhanced cleaning could be practised. Staff, including nursing, housekeeping and porters, were educated on *C. difficile* and the methods of transmission. A business case was developed for a disposable bedpan system, and this was approved by the senior team. A new washable product was tried out with success for the overhead patient light pulls and bathroom call bell systems. Infection rates were shared with staff through a variety of venues. As a result of the initiatives, the hospital has seen a decrease of 50% in the rates of *C. difficile*. A bonus was that our MRSA rates dropped as well.

Introduction

In recent years, there have been multiple reports of *Clostridium difficile*-associated diarrhea (CDAD) causing severe colitis and high case fatality rates in healthcare institutions (Pepin et al. 2004; Morris et al. 2002; Dallal et al. 2002). Some of

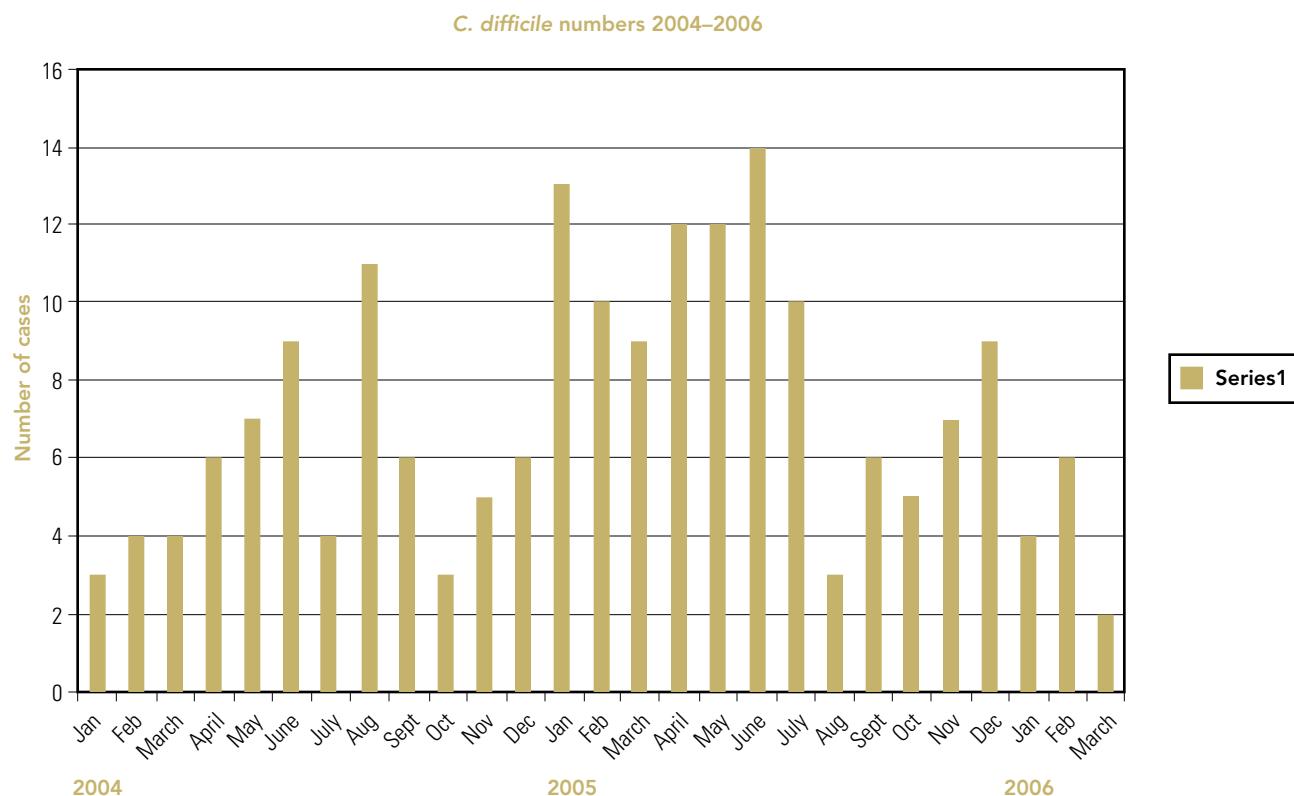
the recent reports involve *C. difficile* strain NAP1-027, which hyper-produces toxin leading to more severe, prolonged and/or relapsing disease (Warny et al. 2005). Pepin et al. (2004) have described their experience in Sherbrooke, QC, which has highlighted the severity of disease due to the new strain. The use of fluoroquinolones in the hospital environment is an important risk factor for the development of *C. difficile* disease (Pepin et al. 2005).

C. difficile is a gram-positive spore-forming bacillus that produces toxins that can cause disease in healthy patients, often following the administration of antibiotics. Some other factors that increase risk of CDAD are recent abdominal surgery, older age, chronic underlying illnesses and the use of bowel-motility-altering drugs. *C. difficile* produces spores that are difficult to eradicate and spread easily on equipment and healthcare workers' hands in the hospital environment.

Many hospitals have noticed increased numbers of cases in the past several years. This report outlines the Toronto East General Hospital experience with the management of increased numbers of cases of *C. difficile* noted between May 2004 and December 2005 in a 550-bed community teaching hospital.

Data Collection

The Toronto East General Hospital Infection Prevention and Control Service has collected surveillance statistics on *C. diffi-*

Figure 1. *C. difficile* cases identified at Toronto East General Hospital, 2004–2006

case rates. Before 2004 baseline rates were four or five cases per month. However, over the course of 2004, more and more cases were detected, scattered throughout the hospital with no obvious link between them. Between April and June 2004, the total number of cases identified doubled within our facility (Figure 1), but then numbers dropped back to baseline levels. Because of reports of increased numbers of severe cases from other local institutions (personal communication), the situation was carefully monitored.

However, from January to June 2005, the number of cases of CDAD increased further, to two to four times baseline levels (Figure 1). At this point, it became clear that intervention was necessary.

Interventions

The Infection Control Service convened a meeting that included various services, such as: facilities (building maintenance), housekeeping, laboratory, nursing, pharmacy and portering. A brainstorming session was held in an effort to evaluate all aspects of the issue with a particular focus on patient safety. All involved

parties felt they had contributions to make in the management and control of CDAD in our facility and eagerly responded to the challenge.

Facilities

The method of cleaning bedpans was a “toilet wand” spray system attached to the back of the toilets. Spray from this wand during the cleaning of bedpans resulted in splashing and aerosolization of fecal material. Also, this cleaning method uses only water and so fails to fully eliminate bacterial and spore loads. We believe this to have been a contributing factor to the development of the increased numbers of cases.

Facilities and Infection Control worked together to evaluate acceptable options for bedpan cleaning. These options included a closed-system bedpan washer and a macerator system with disposable bedpans and urinals. A decision was made to advocate for the purchase of the macerator system. A business plan was developed for the purchase and installation of this system hospital-wide. The business plan was presented to management and approved; the first unit was installed in September 2005.

Housekeeping

Wards with the most CDAD patients were identified to the housekeeping department. Infection Control worked with housekeeping to identify high-risk/high-touch surfaces where transmission might occur, and enhanced daily cleaning of these surfaces was initiated. Terminal cleaning was done through the hospital of all medical and surgical patient care units that had had cases of CDAD.

A process was developed to notify housekeeping coordinators of any room that contained a patient diagnosed with CDAD. The identified rooms were terminally cleaned whenever an affected patient was discharged from the hospital or had recovered.

The Infection Control Service reviewed cleaning practices with all housekeeping staff. As well, education concerning CDAD, focusing on the modes of transmission and why high-quality cleaning is so critical, was developed for housekeeping personnel by the Infection Control Service.

The Infection Control Service conducted a review of patient rooms to identify ways *C. difficile* could be harboured and transmitted from patient to patient. Light pull cords and bathroom pull cords were identified as high-touch surfaces that were not easily cleaned and through which transmission might occur.

Infection Control

Policies and procedures related to the care of patients diagnosed with *C. difficile* were already available both in hard copy on each nursing unit and on the hospital intranet site.

All staff were encouraged to access these policies and procedures in an effort to have consistent utilization of best-practice techniques throughout the hospital.

An information fact sheet for patient and families was also available. Staff were encouraged to distribute these to all sick patients and family members whenever CDAD was a potential concern. Public Relations assisted by having this information translated from English to the six most common non-English languages used in the local community and at the hospital (Cantonese, Greek, Italian, Tagalog, Tamil, Urdu).

The Infection Control Service conducted a review of patient rooms to identify ways *C. difficile* could be harboured and transmitted from patient to patient. Light pull cords and bathroom pull cords were identified as high-touch surfaces that were not

easily cleaned and through which transmission might occur. The overbed lights were designed with short beaded chain pull cords. These cords could not be reached by most patients, and multiple types of extender cords had been attached by nursing staff to allow patients access to their light cords. Bathroom pulls were also made from a similar cord-like material. All of these makeshift cords were nearly or totally impossible to clean, often being pieces of cloth material. The Infection Control Service championed the purchase of new light pull cords made of a vinyl material that is easily cleaned and disinfected. A business plan was developed, approval was obtained from management and the vinyl cords were installed throughout the facility.

Laboratory

Clostridium difficile toxin testing is not done by the onsite TEGH microbiology laboratory. Instead, stool specimens are sent to the local Public Health Laboratory for testing. This results in longer turnaround times for testing and results. In view of this, isolation precautions were initiated for all patients at the onset of diarrhea symptoms, until the diagnosis was made.

Microbiology lab staff pointed out that a significant number of stool samples were submitted to the microbiology laboratory in inappropriate collection containers, usually making testing impossible. A reference pictorial guide, suitable for posting on patient care units, was developed and distributed throughout TEGH. This has been used by the nursing staff as a reference when they collect stool samples from patients with diarrhea.

Nursing

The Infection Control Service developed an education package for nursing staff that focused on the chain of transmission, and the prevention of infections. Handwashing was emphasized. The use of dedicated equipment for all patients suspected or diagnosed with CDAD was implemented so as to minimize potential for spread.

Nursing staff stated that no process was in place for the routine cleaning of IV poles. A system was developed that allowed for the cleaning of IV poles whenever a pole was removed from any patient's room and before it was reassigned to a new patient. Any IV poles used for patients on isolation precautions were identified and given enhanced cleaning.

Pharmacy Services

Pharmacy undertook a review of antibiotic exposure in all patients with a positive stool toxin assay for *C. difficile* for the six-month period of January to June 2005. Antibiotic exposure for the two months prior to a positive assay was determined for all cases in this time period. The association of each antibiotic to *C. difficile* disease was calculated as number of cases per 1,000 days of antibiotic treatment. The data was difficult to interpret, because some patients had had more than 10 antibi-

otic exposures in the two months prior to the development of *C. difficile* disease, making it impossible to determine the offending agent. Overall, cephalosporins (ceftriaxone, cefazolin) and fluoroquinolones (moxifloxacin, ciprofloxacin) were most commonly associated with CDAD. However, the relative risk of using these drugs was only slightly increased, as they are commonly used antibiotics. Therefore, no formulary changes were recommended on the basis of the antibiotic review.

Portering

Porters were given education by the Infection Control Service specific to the transport of isolation patients throughout the facility. Signage for transport of isolation patients within the facility had previously been developed so a refresher training program on best practice was developed and implemented.

The portering staff identified that wheelchairs and stretchers were not being cleaned on any routine schedule. Also, it was pointed out that there was no process to identify wheelchairs that had been used to transport isolation patients. Infection Control worked with the portering pool to develop an identification system for soiled wheelchairs and stretchers. A process was then developed that ensured regular cleaning and labelling of cleaned equipment. All such equipment is now cleaned on a rotational basis.

Other Challenges

Most hospitals built over 15 years ago were built without significant Infection Control input and are not equipped with bedside handwashing stations. Bathrooms are usually small, and are often shared. In most hospitals, only a few private rooms with private bathrooms are available, and most of these are used to isolate patients with a communicable condition (i.e., CDAD or other conditions requiring isolation). Some hospitals have so few single rooms that patients with communicable conditions must be cohorted, making the probability of transmission higher. This makes the control of transmission of disease in older hospitals extremely difficult. At TEGH, an Infection Control representative now sits on the hospital planning and design committee and is involved with all construction and renovation.

Bleach is a well-known sporicide, and is the preferred cleaner for CDAD cases. Unfortunately, many find its odour unpleasant and irritating to the upper respiratory tract. Our initial response was to choose diluted bleach solution as our cleaning agent, but after one hour it became apparent that staff and patients were unable to tolerate the odour. We began to use an accelerated hydrogen peroxide-based cleaner, and this was better tolerated.

Conclusion

Since Fall 2005 we have noticed fewer cases of CDAD, and since January 2006 we are back to baseline (Figure 1). The ongoing installation of the bedpan macerator system has been extremely

popular, especially with the nursing staff. Our augmented cleaning strategies for rooms with patients having CDAD, and the equipment and approach used to treat these patients, now remains as standard practice. As a bonus, our numbers for cases of methicillin-resistant *Staphylococcus aureus* have dropped by 30 to 50%. It is believed this is due to better comprehension and best practice in the care of patients with isolatable conditions.

It is clear that a multifaceted strategy involving members of multiple hospital departments has paid off in the control of CDAD cases. Staff in many different care roles have demonstrated a commitment to a safe and healthy environment for our patients. Patient safety is a priority at Toronto East General Hospital, and staff were very pleased to have had an opportunity to prove it.

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A Multidisciplinary Approach to Reducing Outbreaks and Nosocomial MRSA in a University-Affiliated Hospital

Maryam Salaripour, Pat McKernan, Roslyn Devlin
and the Infection Prevention and Control Team

Abstract

Endemic MRSA (methicillin-resistant *Staphylococcus aureus*) colonization and infection has been shown to increase morbidity, length of stay and hospital cost. Prevention of transmission demands innovative approaches.

Descriptive statistics were used to determine high-incidence units. On admission, patients with a history of previous admission to a healthcare institution within the past six months were screened for MRSA. Point prevalence studies were carried out on units with more than two nosocomial (hospital-acquired) MRSA patient isolates within a four-week period. A multidisciplinary team from Infection Control and clinical units determined potential contributing factors. Recommendations included increased organism-specific education for staff, environmental cleaning and elimination of sources of transmission. Control charts to monitor nosocomial incidence rates were provided to those units that historically had a high prevalence of MRSA infections and colonization. Compliance with the infection control isolation guidelines and screening guidelines was monitored by the service.

There was a 60% decrease in nosocomial MRSA between 2000 and 2001. Unit feedback was extended throughout the hospital. This decrease has been sustained since 2001 with annual rates per 1,000 patient-days of 0.61 for 2000, 0.21 for 2001, 0.24 for 2002, 0.25 for 2003, 0.35 for 2004 and 0.19 for 2005.

Introduction

Healthcare-associated infections (HAIs) represent a major source of avoidable morbidity and mortality. A recent survey identified the need for a focus in infection control strategies as one of the top 10 strategic issues/challenges facing acute care hospitals in Ontario (Adalsteinn et al. 2005).

Canadian data published by Zoutman et al. (2003) estimated over 220,000 cases of HAIs per year in healthcare settings, resulting in more than 8,000 deaths. Methicillin-resistant *Staphylococcus aureus* (MRSA) is a major cause of nosocomial (hospital-acquired) infection and colonization, resulting in substantial morbidity and mortality (Cosgrove et al. 2003), and costing the Canadian healthcare system an estimated \$42 million to \$59 million annually (Kim et al. 2001). Although the rate of MRSA isolates in Canada is significantly lower than in hospitals in the United States (40%), Japan (80%) and some European countries (Verhoef 2001), a significant and steady rise in the percentage of *Staphylococcus aureus* isolates resistant to methicillin has occurred, increasing from 0.95% in 1995 to 10.39% in 2003 (Public Health Agency of Canada 2005).

The Canadian Infectious Diseases Society and the Canadian Association of Medical Microbiologists have outlined best practices for treatment, surveillance and infection control strategies (Simor et al. 2004). Cooper et al. (2004) agreed that the appropriate practice of infection control protocols is associated with reduction of nosocomial transmission of MRSA. However,

they identified the need for more research in recognizing the individual value of each preventive intervention to decrease nosocomial MRSA. Other studies have called for a multidisciplinary and strategic collaborative effort in identification, and institution of prevention and control measures such as appropriate use of antibiotics, screening on admission, active surveillance and concentrated control measures (Struelens 1998).

However, the application of techniques used regularly in quality improvement strategies, such as statistical process control charts and feedback, and their effect on nosocomial rates of MRSA, has not been frequently reported. Recently, a tripartite group, representing the British Society of Antimicrobial Chemotherapy, the Hospital Infection Society and the Infection Control Nurses Association, recommended surveillance for MRSA with feedback to staff and hospital administration as one of the cornerstones of an effective program to control and prevent nosocomial MRSA infection (Coia et al. 2006).

In 2001, after a comprehensive risk assessment and review of infections due to MRSA as well as colonization rates at St. Michael's Hospital, the Infection Prevention and Control Service (IP&C) made a strategic decision to align intervention strategies to prevent the spread of MRSA with the long-term strategic risk management goals of the organization. We examined, designed and implemented three major risk response options: preventing risk, controlling risk and risk financing. However, the major focus was on the concept of risk communication and exchanging findings with stakeholders. We utilized a risk management conceptual framework (Figure 1) for developing the strategic plan to reduce the rate of MRSA infection and colonization adapted from the risk management process steps detailed originally in the Australia/New Zealand Standard in risk management (National Health Service 1999). We also incorporated strategies from the quality improvement literature, such as those described by Langley et al. (1996), that emphasized the continuous nature of improvement. The major innovation to standard infection control strategies was structured communication with frontline workers, senior administration and other

stakeholders of quantitative data with respect to care outcome, practice standards, the role of the environment and economic impact on a regular basis. The effect of surveillance and timely reporting as an agent of reduction of HAIs was confirmed in the literature as we moved into the second year of this plan (Curran et al. 2002).

A problem-solving paradigm based on an educational model (Bagayoko et al. 2000) was used to plan out the roadmap against the risk management strategies. This paradigm considers the following five factors as major contributors to developing proficient problem-solving analyses: (1) knowledge base – understanding the knowledge level and disseminating a standard and evidence-based knowledge, (2) skills base – the capability in translating the knowledge into actions, (3) resource base – human and material were both considered, (4) strategy or experience base – the translation and the order in which the tasks were operationalized, (5) behaviour base – defined as the self-discipline that encourages the knowledge and the skills.

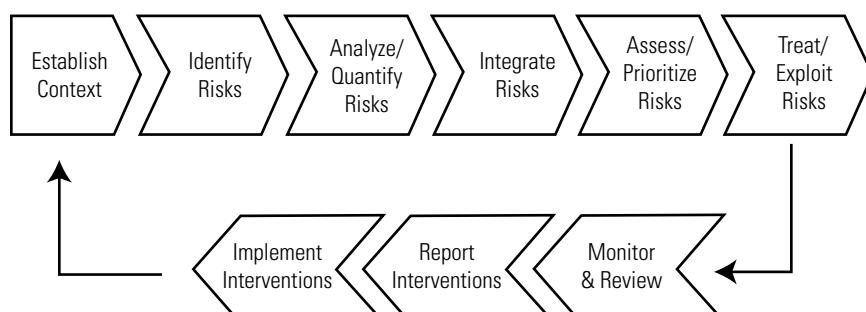
Methods

The high-risk and high-incidence units were initially identified by retrospectively analyzing patients identified as being colonized or infected with MRSA utilizing the Microbiology Laboratory reports and Infection Prevention and Control surveillance data. Nosocomial cases were defined as cases identified by culture taken more than 72 hours after admission. Patients that were identified as having MRSA within 72 hours of admission were termed as having MRSA POA (present on admission). We interpreted MRSA POA cases as representing the burden of disease for each unit and the risk management challenge facing units when preventing nosocomial cases.

The incidence rates per 1,000 patient-days were calculated by unit, and a hospital-wide comparison was done in order to benchmark similar units against each other as well as externally. We identified those units with a high rate of nosocomial MRSA as well as units with high number of MRSA positive patients on admission. Unit-specific extracted data were next evaluated for special or common-cause variations using Statistical Process Control Charts. Risk management quarterly reports were initiated and sent electronically to all patient-care-area managers and medical leadership commencing in January 2001. Unit-specific discussions to identify special or common sources for nosocomial spread were initiated by the IP&C. A multidisciplinary team, including the Medical Director of the unit affected, the Clinical Leader Manager, the Program Director, a senior frontline

evaluated for special or common-cause variations using Statistical Process Control Charts. Risk management quarterly reports were initiated and sent electronically to all patient-care-area managers and medical leadership commencing in January 2001. Unit-specific discussions to identify special or common sources for nosocomial spread were initiated by the IP&C. A multidisciplinary team, including the Medical Director of the unit affected, the Clinical Leader Manager, the Program Director, a senior frontline

Figure 1. Risk Management conceptual framework to decrease the incidence of MRSA at St. Michael's Hospital



nurse, housekeeping and environmental hygiene services, an Infection Control Practitioner (ICP), the Medical Director of IP&C, the Director of Risk Management & Quality Improvement, the microbiology laboratory, and representatives of engineering/planning (when applicable), identified root causes, intervention measures and long-term preventive actions. When outbreaks occurred, trends of transmission were mapped on a floor plan of the affected unit to better understand the possible common sources and reservoirs.

The following interventions were introduced as a result of these meetings:

- Routine screening of all patients with a history of admission to a healthcare facility within the previous six months (this was later extended to 12 months) for MRSA (and vancomycin-resistant enterococci [VRE]) within 72 hours of admission.
- Assignment of an Infection Control Assistant to generate a daily list of new admissions and call the clinical units to remind them to culture the high-risk patients for MRSA and VRE.
- Active surveillance for patients with MRSA delegated to one Infection Control Professional (ICP) in order to provide an organization-wide picture of the incidence of MRSA and

trends of admission in real time.

- Early identification of the contacts of a positive case and screening of those cases for MRSA twice, at least one week apart.
- Point prevalence studies conducted in units with three or more nosocomial cases in a four-week period or two or more nosocomial cases in a four-week period in an open-concept unit (defined as outbreak condition).
- Revamping of the MRSA policy and procedures related to it, including entering and exiting the patients' rooms under precautions, the environmental cleaning protocol and a transport policy.
- Development of a decolonization/eradication protocol for colonized patients. This was formulated by a team consisting of infectious disease specialists, a pharmacist, an internal medicine specialist from a high-incidence unit, the Medical Director of IP&C and an infection control practitioner. The protocol included both local and systemic antibiotics, bathing with antiseptic soap and follow-up cultures to ensure eradication of MRSA.
- Knowledge transfer and targeted education of staff about the prevention and control measures to limit the spread of this organism in the environment. These sessions were designed to pass on organism-specific information in a short (30-minute) face-to-face format. During the educational sessions skills and behavioural concerns were addressed and a practical demonstration of the use of personal protective equipment was conducted.
 - Education of both patients and family members to prevent the spread of the organism.
 - Development of visual aids and signage to remind healthcare workers at the site of the isolation about the precautionary measure.
 - Prevention of transient carriage of MRSA through a hospital-wide hand hygiene campaign. This included updating and redesigning the hand hygiene signage, installing more waterless hand sanitizers in the patient care areas and hand hygiene demonstrations.
 - Providing a daily electronic list of rooms of the patients under precautions to the housekeeping supervisors in order to emphasize the cleaning resources to be assigned to those areas.

Figure 2. Identification of the high-risk/high-incidence units at St. Michael's Hospital

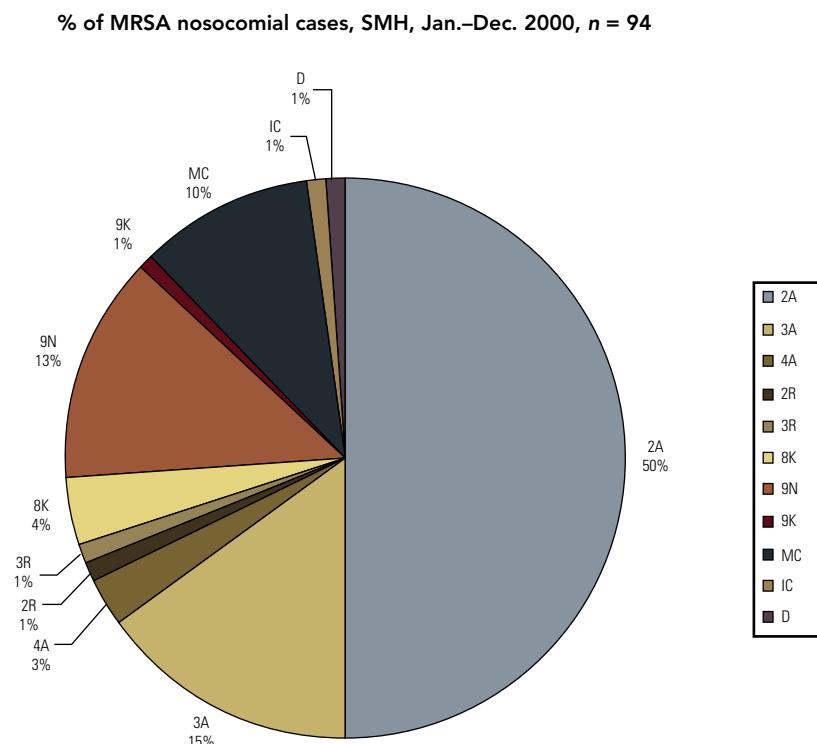
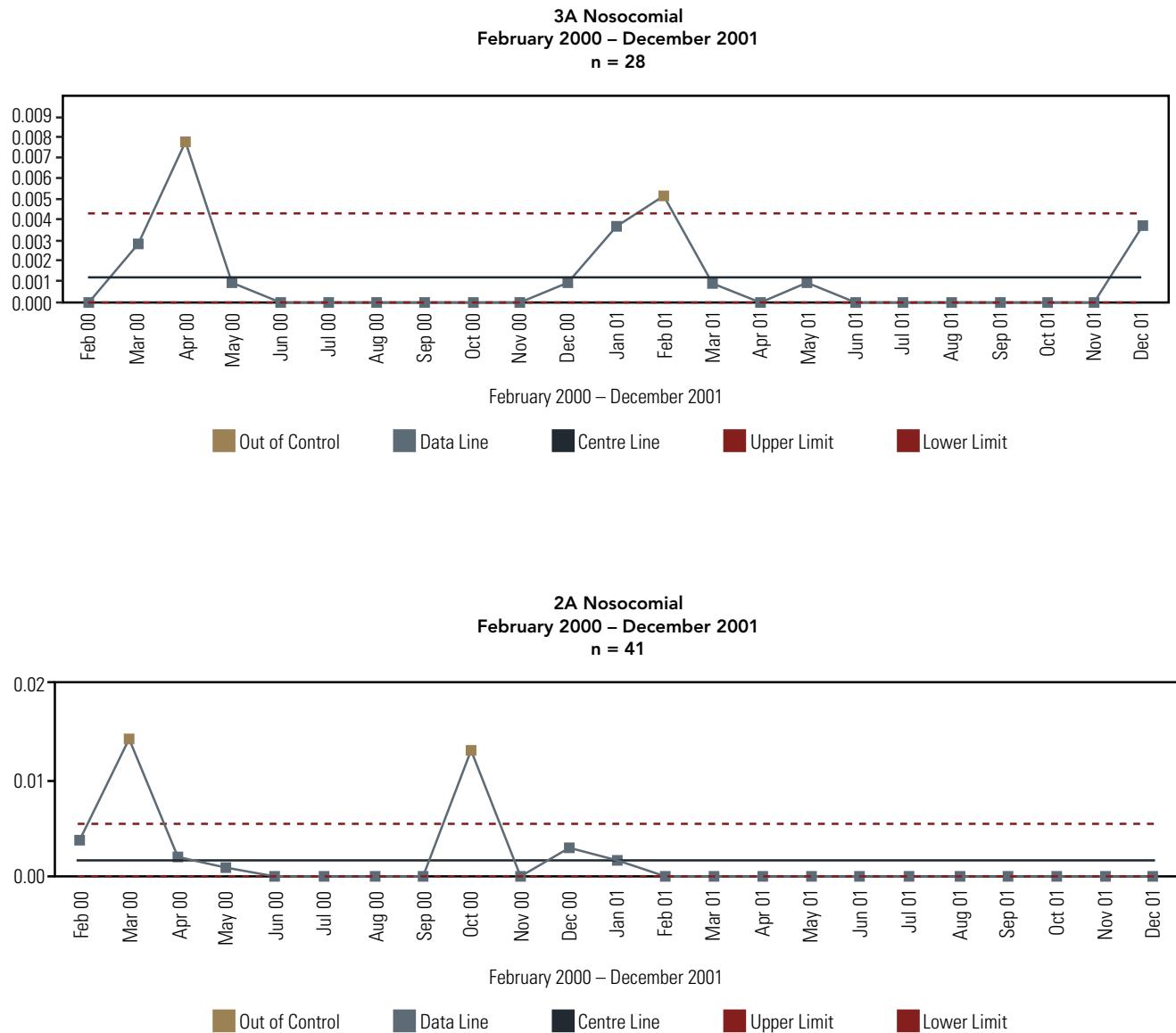


Figure 3. Use of statistical process control charts to identify special or common-cause variation in high-risk/high-incidence units at St. Michael's Hospital



- Provision to stakeholders of the estimated costs of a patient colonized or infected with MRSA as calculated by Kim et al. (2001).

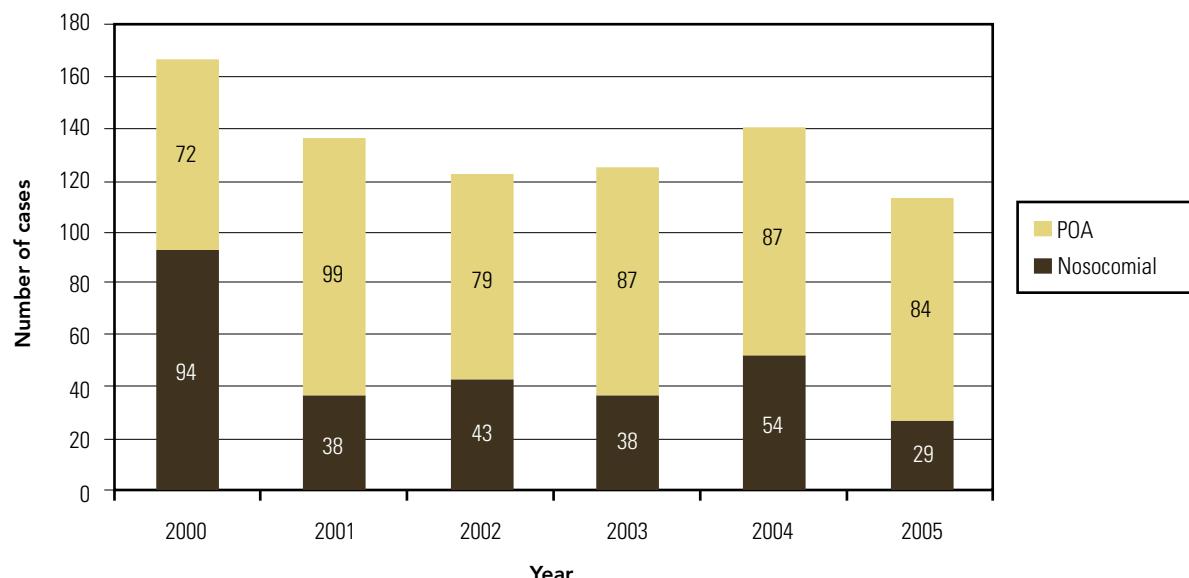
This approach was enhanced by the implementation of an Infection Prevention and Control Competency-Based Certification program in 2003. The goal of the program was to enhance patient and staff safety and facilitate the continuous development of infection control competence, and to practise

compliance among all healthcare providers (Salaripour et al. 2004).

We utilized the Z-test with approximation to determine the significance of the decrease in the rate of MRSA both over time and in comparison to the benchmark.

Results

In March 2001 a hospital-wide impact analysis of the burden of MRSA was conducted. Both nosocomial cases and those

Figure 4. Comparison of the total nosocomial and POA cases of MRSA from 2000–2005 at St. Michael's Hospital

considered POA were identified; units with a high rate of nosocomial transmission were also identified (Figure 2). Data for the two highest-risk units were further assessed using statistical process control charts (SPC) to detect special or common-cause variation (Figure 3). Nosocomial transmission on high-risk units was outside the control limit, set at 2 standard deviations from the mean, during the periods February–March 2000, October–November 2000, and February–March 2001.

During the first year of the implementation of this strategy, a 60% hospital-wide drop in the incidence of nosocomial transmission was noticed, decreasing from 0.61 per 1,000 patient-days for the year 2000 to 0.21 per 1,000 patient-days in 2001. The number of isolates detected on admission increased by 38% in the first year (Figure 4) as a result of the screening and detection procedures implemented. Despite the fact that no outbreaks were noticed during the first 13 months after the institution of this feedback methodology, the majority of cases still originated in the high-risk units (identified as 2A and 3A on Figure 2). Continuous use of the policies and procedures described above coupled with quarterly feedback to all units has successfully sustained the decrease in the rate of nosocomial transmission across the hospital.

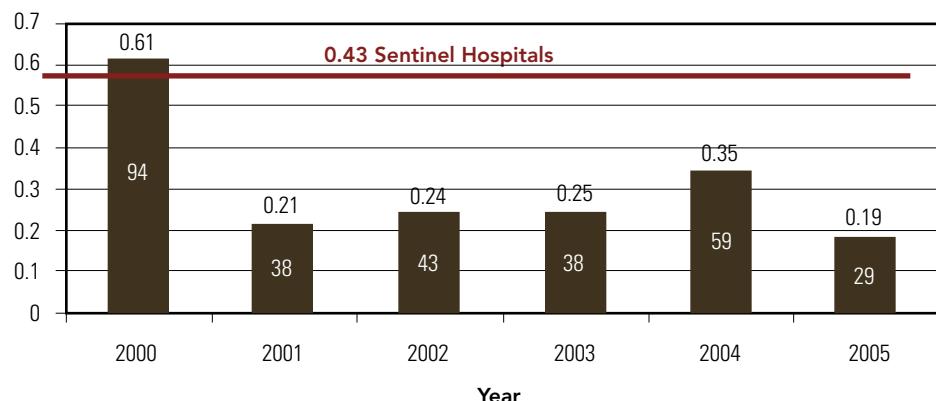
The rate per 1,000 patient-days of nosocomial MRSA was 0.61 for year 2000, 0.21 for year 2001, 0.24 for year 2002, 0.25 for year 2003, 0.35 for year 2004 and 0.19 for 2005 (Figure 5). The rates in each year from 2001 to 2005, at 0.43 per 1,000 patient-days, were significantly lower than the target ($p < 0.01$) (Simor et al. 2001, Table 1) and significantly lower than the internal benchmark rate of 0.61 in 2000 ($p < 0.001$).

Over time, the high-risk units were merged, and the one combined unit has become one of our success stories, with a nosocomial MRSA rate of 0.01 as against the hospital rate of 0.19 and the benchmark rate of 0.4 per 1,000 patient-days. This unit still has the largest burden of patients considered POA MRSA.

Discussion

Establishing a systematic method of feedback and follow-up is sometimes more challenging than the intervention. However, only by doing so is effective information constantly provided to both frontline workers and leadership (Gandhi et al. 2005). Curran et al. (2002) demonstrated that the use of statistical control charts and monthly feedback to medical staff, ward managers, senior managers and hotel services resulted in a 50% reduction in the overall MRSA rate and an associated decrease in variability within departments. Our findings supported this observation by demonstrating a sustained decrease in the rate of nosocomial transmission within our institution. It became apparent that senior administrators of the high-risk units were unaware of the severity and depth of the problem as it related to their units. There was a misconception among administrators and health workers that the rate of infection was the same for all clinical units. Our first unit breakdown presentations raised many questions and the senior administration of the units became fully supportive of efforts to decrease their incidence levels. These presentations also highlighted the risk financing aspect of the MRSA problem at the unit level. A special commitment to early identification and adherence to the admission screening policy was noticed in high-risk units. This

Figure 5. Demonstration of decrease in rate/1,000 patient-days of MRSA from 2000–2005 at St. Michael's Hospital



was supported by delegating the task of reminding units of the need for admission screening based on the daily new admission list to an infection control assistant.

The success of our program was due, in large part, to unit-specific short in-services that were customized to attract the interest of each clinical unit on the basis of the culture of the service. These educational sessions were designed to emphasize the practical aspects of the prevention and control measures, appealing to the ethical commitment of the healthcare workers and their role in advocating a safe practice as well as a review of evidence-based standards and the latest literature. In July 2003, our hospital made it a mandatory requirement for all staff to be certified in infection control through a competency-based program for infection control practices. A survey of staff revealed that those who have gone through the certification felt more confident when caring for patients under precautions (Salaripour et al. 2004). Other workers have examined the use of process feedback rather than outcomes feedback. MacDonald et al. (2004) demonstrated a decrease in the MRSA rate from 1.9 to 0.9% using performance feedback of hand hygiene. Cromer et al. (2004) examined the impact of implementing a method of feedback and accountability related to contact precautions compliance and showed a reduction in facility acquired MRSA from 0.69 per 1,000 patient-days in 2001 to 0.478 in 2003. Notably, neither of these methods achieved the low levels achieved at St. Michael's Hospital using a multifaceted approach that incorporates feedback to clinical units.

Access to the microbiology laboratory and a short turnaround time for specimen processing was another contributing factor that led to our success. Effective use of the microbiology laboratory in assisting the IP&C programs for surveillance and efficient epidemiological interpretations and investigations is an essential tool required to build a solid foundation for an IP&C program (Emori and Gaynes 1993; Franklin et al. 2004).

One of the deficiencies of our method was the lack of segregated and intervention-specific measurements. Studies to evaluate the effect of each intervention may help assist prioritizing the future selection of action plans. However, similarities between our results and those of Pittet provide evidence that the complexities tied into a change process require implementation of multimodal and multidisciplinary approaches to effectively achieve a culture change (Pittet 2001). Despite the lack

of outbreaks in the high-risk units that historically have had increased nosocomial transmission, sporadic clusters have been noticed in the recent years, mostly in the open-concept units. Our next step will be to focus our efforts on effective infection prevention and control practices in such units. The comprehensiveness and interactive nature of our multipronged strategy that demands active multidisciplinary participation of all stakeholders is considered key to our sustained and successful achievement.

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Reporting for Learning and Improvement: The Manitoba and Saskatchewan Experience

Paula Beard and Linda Smyrski

Abstract

Both Saskatchewan and Manitoba have embarked on major provincial quality improvement endeavours that include a mandatory reporting and learning process aimed at enhancing patient safety by reducing the potential for recurrence of critical incidents. This move from a voluntary, less comprehensive process signals a commitment from policy makers that substantial improvements to safety will occur only when adverse events are addressed systemically within the healthcare system.

Saskatchewan took the lead with the passage of legislative requirements to report, investigate and share learnings arising from critical incidents as of September 15, 2004. Manitoba is due to implement similar requirements in 2006. The focus of legislation in both provinces is aimed at reporting for learning in order to strive for further improvements in patient safety.

By empowering staff and physicians to actively participate in risk identification and mitigation, both provinces have become leaders in patient safety. Saskatchewan and Manitoba have taken an innovative and collaborative approach to strive for substantive system changes, seeking out best practices in the areas of quality and patient safety.

Background

Both Saskatchewan and Manitoba have embarked on major provincial quality improvement endeavours that include a mandatory reporting and learning process aimed at enhancing patient safety by reducing the potential for recurrence of critical incidents. This move from a voluntary, less comprehensive process signals a commitment from policy makers that substantial improvements to safety will occur only when adverse events are addressed systemically within the healthcare system.

Saskatchewan took the lead with the passage of legislative requirements to report, investigate and share learnings arising from critical incidents as of September 15, 2004. Manitoba is due to implement similar requirements in 2006. The focus of legislation in both provinces is aimed at supporting a more secure environment for reporting and investigation and an environment of openness that promotes learning and sharing of important safety information. This article is the story of how two provinces are coordinating and striving for patient safety improvement.

Saskatchewan

In late 1997–early 1998 it was clear to officials within Saskatchewan Health, Health Districts (now Regional Health

Authorities), Regulatory Authorities and other concerned individuals in the Saskatchewan healthcare system that they could ill afford to lose the regionally learned lessons. Themes emerged in critical incidents throughout the province, and officials became concerned that without provincial coordination of information similar incidents would occur in each of the Districts. The process for collecting and analyzing the critical incident information varied across the system.

At this time Saskatchewan Health, in partnership with a number of stakeholders, initiated several patient safety activities. Additionally, regional pockets of expertise were developing. These activities came together over the next few years to become a robust and well-coordinated provincial undertaking to improve patient safety by sharing information and resulting lessons learned about critical incidents.

An early theme provincially identified in Saskatchewan was the potential for critical incidents to occur as patients were transferred from one region to another for continuing care. The attempt to address issues related to these handoffs led to an important effort coordinated by Saskatchewan Health with the assistance of several stakeholders from Regions throughout the province. The Department convened the Interdistrict Transfer Process Working Group to develop a process for the standardized movement of patients between health regions based on the available and required resources. The Saskatchewan Interdistrict Transfer Process was completed and approved for use in June 2000. It provides clear guidance on the steps involved in moving patients within (and when necessary outside) the province to receive the appropriate services.

During the same period, the newly appointed Risk Manager for the Regina Health District, Carolyn Hoffman, attended an Institute for Healthcare Improvement (IHI) Conference at which Patrice L. Spath spoke persuasively on the merits of root cause analysis. The impact of Hoffman's IHI experience was significant and facilitated the introduction and implementation of a Critical Incident Review Policy. The implementation of this policy complemented the District's work on updating and simplifying the occurrence reporting process. The District's first critical incident review was facilitated by Hoffman in the mental health setting in 1998. It immediately became clear that this was a tool to bring together the previously disparate risk management activities of the District and move toward a culture of patient safety.

Manitoba

In Manitoba, the deaths of 12 children sparked the Sinclair inquest, which five years later resulted in the Thomas recommendations to "identify institutional arrangements and procedures that would provide Manitobans with a stronger guarantee of competent, safe and ethical healthcare in the future" (Sinclair 2000; Manitoba Health 2001). Collaborative work has been

and continues to be undertaken, resulting in the development and implementation of many actions where risk to the safety of individuals has been identified. A quality and risk management network was established and continues to provide valuable support to the provincial patient safety agenda. These champions and other stakeholders were instrumental in the development of eight provincial policies. In response to the Thomas recommendations, several policies were specifically designed to promote openness in reporting critical incidents and learning from mistakes, and to provide support for providers and patients in dealing with critical incidents.

Roadblocks as Catalysts for Change and Improvement

Concurrent to Hoffman's activities in the Regina Health District, the Assistant Deputy Minister of Saskatchewan Health and her staff were making plans to bring stakeholders together for the inaugural meeting of the Provincial Critical Incident Review Working Group. This group had originally assembled representatives from various-sized regions, the Registrar with the College of Physicians and Surgeons, the Executive Director of the Saskatchewan Registered Nurses Association, and select staff from Saskatchewan Health. Initial efforts of this working group were focused on the development of a provincial policy to facilitate the sharing of local critical incidents, and the results of the accompanying reviews, at a provincial level. It quickly became apparent that the *Saskatchewan Evidence Act* (Canada 2006) would create a barrier to this type of sharing. Regions were concerned that they would lose the protection provided to their reviews by sharing the findings. By 2001 it was clear that the existing legislative protections would need to be extended to the Minister so that maximum benefit could be attained through sharing the reports. The focus then became the development of appropriate language in the *Regional Health Services Act* (Canada 2002) to enable the sharing of lessons learned. The language contained in the Act, accompanying Regulations and the Saskatchewan Critical Incident Guideline (Canada 2004) was developed through broad and frequent consultation with stakeholders over the next three years, coming into effect on September 15, 2004.

Subsequent to the release of the Thomas recommendations, a somewhat similar movement arose in Manitoba as quality stakeholders voiced similar concerns. Consequently, and also in response to national and international recommendations, amendments to provincial legislation were proposed. The *Regional Health Authorities Amendment and Manitoba Evidence Amendment Act* received Royal Assent in June 2005. When proclaimed into force (at a date yet to be established), it will amend both the *Regional Health Authorities Act* and the *Manitoba Evidence Act* to require the disclosure, reporting and investigation of critical incidents and to provide legislated

protection from use in legal proceedings for information generated in carrying out the required reporting and investigation activities (Government of Manitoba 2005).

The legislation will protect the confidentiality of records and information, including opinions and advice obtained, compiled or otherwise prepared for the purposes of investigating a critical incident – while protecting the rights of individuals affected by an incident, by requiring them to be fully informed of what had actually occurred.

Results to Date

In 2001 Saskatchewan Health began gathering statistics about the voluntary reporting of critical incidents, and during that period fewer than 30 critical incidents were reported. Over time, the definition of *critical incident* and the development of the reporting guideline assisted regions in identifying when a critical incident had occurred. Reporting of critical incidents increased only slightly during the development stage, when reporting was voluntary. After introduction of the legislation, reporting increased significantly, 162 incidents being reported for the 2005/06 fiscal year. More importantly, the Region's consciousness of these types of events was raised.

Here is a breakdown of the 162 critical incidents reported to Saskatchewan Health:

- Surgical events (11) – 6.8%
- Product or device events (13) – 8.0%
- Patient protection events (14) – 8.6%
- Care management (89) – 54.9%
- Environmental events (32) – 19.9%
- Criminal events (3) – 1.9%

In Manitoba, voluntary reporting of critical occurrences and critical clinical occurrences began in early 2003. The legislative amendments to the *Regional Health Authorities Act* and the *Manitoba Evidence Act* will strengthen the intake and notification process, and it is anticipated that there will be increased reporting. Manitoba Health will provide guidance to the regional health authorities and the provincial organizations in the reporting of critical incidents to clarify requirements and standardize reporting mechanisms.

But the primary purpose of reporting of critical incidents is to learn from the experience. Reporting does not improve patient safety; it is the response to the reports that leads to change.

Developing a Tool Kit

The development and delivery of the root cause analysis methodology was pivotal to building capacity for the recognition and review of critical incidents at the regional level. In February 2003 the first workshop was developed by Saskatchewan Health to assist efforts to spread patient safety provincially. In the subse-

quent three years, the tool continued to be refined, and the Department ensured that all regions were exposed to it. The introduction of the tool and reporting was simplified by the existence of Regional Quality of Care Coordinators (QCCs), who had a well-developed relationship with the Provincial Quality of Care Coordinators (PQCC) at Saskatchewan Health. The QCCs quickly became the access points for moving critical incidents and root cause analysis information within their regions and to and from Saskatchewan Health. Additionally the commitment was made by Saskatchewan Health to ensure that regions would be supported by the PQCCs through their initial endeavours to utilize the RCA tool in reviewing local critical incidents. In many cases the PQCC co-facilitated the first RCA conducted in the region with the QCC.

By September 2005 there was an overwhelming demand for training in the use of the root cause analysis tool, a hybrid of the Spath model first utilized in Saskatchewan by Hoffman and the Veterans Administration National Center for Patient Safety methodology (Hoffman et al. 2006; Department of Veterans Affairs 2005). Therefore, Saskatchewan Health approached the Canadian Patient Safety Institute (CPSI) to take on the continuing national spread of this tool. CPSI partnered with Saskatchewan Health and ISMP Canada. The workshop has since been refined and developed into what is now known as the Canadian Root Cause Analysis Framework (Hoffman et al. 2006). Workshops can be facilitated by qualified individuals at any one of the three partner organizations. Efforts are under way to develop a Train the Trainer Workshop to be delivered in late 2006 or early 2007.

In March 2005, Manitoba became the first province outside of Saskatchewan to pilot and provide support to its regions to attend the inaugural national workshop. Health authorities have begun to implement these methods to review processes and systems related to how critical incidents might occur or have happened. Using both Root Cause Analysis and Failure Mode & Effects Analysis methods, aggregated patient data are being utilized to improve patient safety and quality of care.

Saskatchewan Health collates and disseminates the information received related to reports of critical incidents in an effort to provincially share learnings through *Issue Alerts*. The information contained in the *Alerts* is gleaned from critical incident reports provided to Saskatchewan Health by Regions. Both parties work together to ensure that the information alluded to in the *Alert* is de-identified, and that recommendations are circulated appropriately to reduce the likelihood of harm to others. In the period between fiscal year 2002/03 and 2005/06, fifteen *Alerts* were released by Saskatchewan Health. These speak to topics such as the safe labelling and storage of fluids, labelling of solutions used in the perioperative setting, surgical count policies and telephone advice, among others.

At the time of the writing of this article, pending Proclamation,

Manitoba continues to encourage the reporting, investigation and notification to the Minister according to the current provincial policies. As a result of each region's commendable work in reporting and analyzing their critical incidents, opportunities for learning and improved patient/client care have been implemented. A few examples are comprehensive orientations, alerts about instruments and devices, safety inspections and education about equipment, review of staffing ratios, changes to services provided within emergency rooms and the sharing of safe medication practices.

In Manitoba, collaborative effort is under way to prepare for implementation of the legislative amendments, including policy revisions and frontline staff education. Provincial workshops are planned that will help support the regions with disclosure and the use of system analysis for their critical incident investigations. Manitoba is already benefiting from ongoing, collaborative conversations with Saskatchewan Health. Following Proclamation, Manitoba will need to consider mechanisms of communication that will best enable sharing of information to facilitate system learning.

The Saskatchewan experience, with Manitoba well positioned to follow, demonstrates that cooperation among stakeholders, and a real commitment to changing how the healthcare system recognizes and shares information about critical incidents, provides support to both the patient and the healthcare providers. All parties are impacted by critical incidents. Frequently the desire of all involved is aligned. "Make the experience valuable by learning from it." Saskatchewan and Manitoba have made more than a positive step in this regard. By empowering staff and physicians to actively participate in critical incident identification and analysis, both provinces have become leaders in patient safety. Saskatchewan and Manitoba have taken an innovative and collaborative approach to strive for substantive system changes, seeking out best practices in the areas of quality and patient safety.

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A Framework for Local Accountability for Patient Safety

Rosanne Zimmerman, Emily Christoffersen, Jill Shaver and Teresa Smith

Abstract

Despite numerous publications outlining the magnitude of patient safety issues, the literature provides limited strategies for organizations to develop comprehensive, effective patient safety programs. Hamilton Health Sciences (HHS) has created a framework to foster local accountability called Patient Safety Triads and Networks. The Networks operationalize patient safety initiatives, develop knowledge and improve patient safety culture in a collaborative interdisciplinary team model. They have proven to be an effective way to support patient safety at the local level and to integrate organizational and local work on patient safety.

Background

Many organizations are committed to patient safety; however, translating organizational commitment to local accountability for patient safety can be a challenge. In 2004, Hamilton Health Sciences (HHS) created and unveiled our patient safety model: Cornerstones, Connections and Caring (Figure 1). This model is based on the need for a balanced approach to the creation of an effective patient safety program. Four "cornerstones" need to be addressed to achieve this balance: Culture of Patient Safety and Accountability, Measurement and Improvement, Education and Professional Development, and Information and Communication. To translate these cornerstones into action, there are underlying infrastructures called connections. The

integration of the cornerstones and the connections ensures a strong patient safety program and optimal care for our patients.

The connections of the model include: coordinating roles for safety (Patient Safety Specialists); databases to track and trend adverse events, near misses and identified safety issues; committee infrastructure (a Patient Safety Steering Team); and Collaboratives, Innovation and Learning Centres and Patient Safety Networks. The Collaboratives represent the collaborative quality work that occurs within the organization. The Innovation and Learning Centres are areas where teams are supported by Quality Improvement Specialists in their ongoing improvement work.

HHS is a large, four-site tertiary care centre, which includes five hospitals and a cancer centre. We believe that patient safety is the responsibility of the 10,000 people who work at HHS in more than 100 units/areas. "A critical task of any executive is to build accountability into the systems they manage or lead; part of this task is to encourage individual employees to share that responsibility" (DiBella 2001). HHS has developed a framework to foster local accountability called Patient Safety Triads and Networks. Accountability for patient safety must exist at organizational and local levels to effect the needed changes in practice and culture. Delegation leads everyone to share accountability (DiBella 2001). This framework has enabled us to create consistent and sustainable improvements in patient safety.

Figure 1. HHS Patient Safety Model

Cornerstones, Connections and Caring



Intervention

Patient Safety Triads

Patient Safety Triads (PST) are unit- or area-based champions for patient safety. In clinical areas Triad members most often include a manager, a frontline staff member and a third member from the multidisciplinary team who is most often a physician. In service areas, membership includes a manager, a supervisor/leader and a frontline staff member. The configuration of the Triad membership ensures that the staff who provide care and work within the system, and those who have decision-making authority, are able to identify and address patient safety issues together.

When the Triads were developed, there was recognition that the diversity of areas represented might require customization of the structure. In this regard, two key considerations were suggested: (1) to ensure that a frontline staff member, who directly provided care to patients or service to support patient care, was part of the Triad and (2) to select opinion leaders who would enhance the strength of their team. At the time of this publication, there existed 91 Triads with more than 320 members.

In both clinical and service areas, PST members are identi-

fied as the “local point people” for patient safety, whose role is to develop an expertise in safety concepts, identify and manage local safety issues, assist with the spread of organizational safety initiatives, provide a connection between the frontline and the senior team and be a role model for patient safety culture.

The Patient Safety Networks were developed to support the Triad members in meeting these goals.

Patient Safety Networks

The Patient Safety Networks are comprised of multidisciplinary members from all hospital sites with a diverse mix of clinical and service area Triads. This type of interdisciplinary team development and communication has been shown to positively influence patient safety (Leonard, Frankel and Simmonds 2004). Due to the large number of Triad members, three Patient Safety Networks were developed to keep meetings to a manageable size and facilitate networking and group work. The Networks are coordinated and supported by the two Patient Safety Specialists.

The Networks meet once every two months for two hours, to communicate and share, develop patient safety expertise and obtain and provide support to further empower the members. “Change from learning is not an accidental event; there must be preparation, persistence and follow-up” (DiBella 2001).

Each Network meeting starts with an update of organizational patient safety initiatives and activities. There are opportunities for Triads to share successful initiatives and obtain ideas and support for challenges and barriers. Case studies of adverse events are presented, either by Triad members who have demonstrated the courage to share their own events, or as anonymous HHS case studies. Each case study is discussed to assess the system and human factor issues that led to the adverse event. This exercise assists in developing an open culture in which contributing factors and possible preventive measures are identified.

There is also a 30-minute “teaching moment” in which a specific principle of patient safety is presented, followed by group work applying the principles. Teaching moments include topics such as standardization, rapid tests of change, teamwork, change strategies and application of human factors principles in product acquisition and implementation.

At the end of each Network meeting, Risk Management, Pharmacy and Infection Control each present a five-minute synopsis of a key issue in their area.

Three additional strategies are used to enhance the effectiveness of the Triads and Networks. Every Network meeting is evaluated, and the feedback is used to develop future meetings. Also, the members are periodically asked to complete, before the next meeting, specific tasks related to patient safety. These simple tasks, which achieve easy wins, assist Triads that may be finding the work challenging. The third strategy is to provide, at each meeting, literature related to the teaching moment, which the Triads can use to create their own libraries of resources.

Discussion

The development of the Triads and Networks has created a framework of local accountability for patient safety with an infrastructure to support and continuously develop safety expertise throughout the organization. All four cornerstones of the patient safety model are supported within this framework.

Cornerstone: Culture of Patient Safety and Accountability

The formation of the Networks has further developed the culture of patient safety and local accountability within the organization. There are more than 320 individuals working together to lead patient safety improvement. Each area or unit has support and a clear process to address local patient safety issues. These areas and units are supported in their local work through the Networks. The Networks also identify trends in patient safety issues, which are then reported to the Patient Safety Steering Team.

Patient safety is hard work. The Networks provide an opportunity to share successes and struggles with colleagues within a comfortable safe environment and generate solutions for patient safety issues. The collaboration of disciplines, sites and clinical and service teams has created an awareness of and respect for the contribution that everyone within the organization makes to patient safety. The greatest accomplishment of the Networks has been the enhanced teamwork within and between disciplines, clinical and service areas and sites. "The strength of an integrated system is that its leaders can develop a framework for constant collaboration to occur. Safety requires collaboration amongst clinical groups and should be a goal of all those responsible for patient safety" (Frankel, Gandhi and Bates 2003: i33). The opportunity to develop relationships between areas and to understand the challenges faced by all parts of the team has been especially powerful.

Cornerstone: Measurement and Improvement

The open sharing and networking allows the Triads to share project work. For example, recently a project to improve the process for labelling of liquids on a sterile field was completed by diagnostic imaging in collaboration with perioperative services. Their work was presented to the Networks and has now engaged other areas faced with the same issue to adopt and learn from their project. A database of all Triad projects is maintained and made available to members, not only allowing them to learn from the experiences of others, but also to ensure that areas working on similar projects are able to connect and integrate their work.

Cornerstone: Education and Professional Development

The ongoing education and support within the Triads has created many experts in patient safety, who then share knowledge on their units and areas to further develop other staff.

The Networks offer a framework to access both internal and external resources. In addition, once a year the organization holds a day-long patient safety symposium for all the leaders at HHS. As recognized leaders in patient safety, all Triad members are included.

Cornerstone: Information and Communication

The Networks offer an opportunity to ensure access to information and sharing of organizational initiatives. Communication is often a big challenge in large organizations. To support this further, a bimonthly patient safety newsletter is disseminated to members, in a medium that readily lends itself to sharing within the units/areas.

Finally, the Networks provide a communication channel between frontline staff and leadership. Triad members attend "Patient Safety Leadership Walkarounds" with the senior leaders in their areas. This allows the leaders to be part of the dialogues with staff about patient safety. The Triads bring their concerns and challenges to the Networks, which are also communicated back to the Patient Safety Steering Team.

The Challenges

Three key challenges have been faced since the inception of the Triads and Networks in January 2005. The first is creating Network meetings that meet the needs of both clinical and service areas. This requires planning and reflection of the issues from multiple viewpoints. Often, due to the nature of the healthcare work, case studies are clinical in nature. Time must be taken to extrapolate their key principles and offer examples of how they apply to service areas.

The second challenge has been to engage physicians. Physician attendance at the Networks is limited, due to the time of the Network meetings and conflicting clinical commitments. While many physicians are engaged at the local level, their opportunity to network is limited. To address this, Triads have used different strategies: to tackle the key issues as seen by physicians, to integrate Triad meetings into existing meeting frameworks, and to collaborate with physicians in a consultative model whereby they provide input into initiatives and assist with creating support for these initiatives among their colleagues.

The third challenge has been to recognize the need for support and development of frontline leaders. Skills such as project management, quality improvement and change management require further support and education. These have been built into the planning of future Network meetings.

Lessons Learned

In November 2005, one year after the inception of the Networks, a "pulse check" was conducted with them to assess satisfaction with the current framework and determine opportunities for improvement. Members were asked to respond in small groups

to questions related to the Triads, the Networks and the organizational support for their roles.

Overall, the message was that the Triad members felt valued, excited and committed to their work. They also valued their Network meetings and felt the multidisciplinary, multisite model had created a more cohesive and collaborative approach across disciplines, programs/services and sites. The monthly evaluations of sessions were consistently rated as very good to excellent, and the areas most useful to the Triads were identified as the networking opportunities, the "teaching moments," the tools learned, and the sharing of projects, challenges and adverse events.

To further develop the Networks five areas of opportunity were identified.

First was the need to revise the team structure of some Triads. For some unit and service areas, the three-person model was working extremely well. For some of the larger areas, members expressed the need to increase the size of the Triad to accomplish the work. Some unit/area Triads have now developed into groups of four to seven. As well, some Triads have identified the need to add the educator, recognizing his or her important role in implementation of initiatives in their unit/area. Other Triads have decided to remain as a core group of three and have ad hoc members for projects as appropriate.

The second area of opportunity developed as the number of Triads increased across the organization. The members of the initial 45 Triads had received training on the basic principles of patient safety and human factors. When Triads doubled to 91 within one year, the new members identified the need for education. Repeat education sessions have now been provided to all members to review or acquire core knowledge.

The third opportunity relates to variation in the expectations for Triads, and the level of support for time and resources. This issue is currently being addressed.

The fourth area was clarification of the Triads' role as both "doer and communicator," and this message has now been clearly discussed with the Triad groups, and suggestions of how to fill that role have been offered.

The final issue, raised during the "pulse check," came as a surprise. The lack of support the Triads felt from their colleagues was almost universal. The Triads struggled daily with engaging their unit and area staff in their work. Multiple strategies and tools are presently planned to address this concern.

Conclusion

"For the healthcare industry as a whole to become highly reliable, organizations must move to a culture focused on safety" (Leonard, Frankel and Simmonds 2004: 32). The Patient Safety Triads and Networks have been a successful framework to enhance patient safety culture and to build local accountability for patient safety. Patient Safety Triad members identify

themselves as leaders in patient safety, and the growing number of improvement projects in progress has been impressive. Most importantly, ongoing collaboration in safety projects between and within programs has been evident. The commitment and excitement of the Triad members has been very inspiring, and it continues to gain momentum. The Networks continue to increase in membership, demonstrating an enhanced ownership, leadership and accountability for patient safety at HHS.

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Rosanne Zimmerman, RN, BHScN, MEd, Patient Safety Specialist at Hamilton Health Sciences, has had an integral role in the foundation of the Patient Safety Program at HHS and has a background in quality improvement, education and emergency nursing.

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Human Factors in Action: Getting “Pumped” at a Nursing Usability Laboratory

Edward Etchells, Cynthia Bailey, Ron Biason, Susan DeSousa, Laurie Fowler,
Karen Johnson, Catherine Morash and Catherine O’Neill

Abstract

We describe our experience with a Nursing Usability Laboratory, where human factors design principles were applied to common nursing procedures. Our first step was to develop a human factors usability checklist. We then used this checklist while observing 11 nurses completing two standardized tasks on a simulated patient: (1) programming an insulin infusion and (2) programming a heparin infusion. We found that a usability checklist can help to uncover systematic error-provoking conditions in nursing tasks, that immediate improvements can be made in nursing training and practice and that participant nurses found the process useful. This paper will be of interest to any hospital seeking to enhance safety by applying human factors design principles.

Background

A central concept in patient safety is to build a system of care that reduces the possibility for human error and prevents human error from causing patient harm. “Human factors” is the scientific discipline concerned with designing systems to meet the needs, limits and capabilities of the people who work in them. The application of human factors science is a logical step in the patient safety movement.

One important aspect of human factors science is the usability of medical devices. Human factors principles can be used in the design and development of medical devices, and in the ongoing evaluation of devices while in use. Usability testing can identify

unanticipated design problems with a relatively small sample of users (Kushniruk et al. 2004).

There are relatively few published examples of usability testing of medical devices (Making Health Care Safer 2001; Chiu et al. 2004; Nunnally et al. 2004). Human factors principles reduce programming errors with patient-controlled analgesia pumps, and improve efficiency (Lin et al. 1998; Gosbee 2004). Although usability should be a prime consideration in medical device selection, the process of device procurement may overlook vital usability considerations (Keselman et al. 2003). Fortunately, a growing number of institutions have adopted usability principles for device procurement and training (Gosbee 2004).

At Sunnybrook, our safety program is focused on three core areas: culture, reliable design and measurement. Our work on reliable design began by inviting two human factors consultants to provide advice. We developed a Human Factors course for staff that has been very popular and highly rated. This paper describes our initial experience in applying human factors usability principles to medical device use in a “Usability Laboratory.” Our overarching goals were

- (i) To develop a usability assessment method
- (ii) To apply this usability assessment method to existing clinical tasks
- (iii) To build expertise and teamwork in the assessment of device usability

Table 1. Selected features of the usability checklist*

A. General Human Factors Impressions
B. Feedback and Visibility of System Status
1. When you try to do things, how do you know you are successful? 2. Can you tell what to do next? 3. Do you know what the device is doing at any given moment? 4. If you are distracted, can you tell immediately where you've left off? 5. If you handed the device to someone, would it take them long to figure out where you've left off and what the device was doing? 6. Is status on startup obvious? If powered off, are settings lost or changed? 7. Does the device have a "default" setting? Is this status obvious?
C. Consistency with Other Devices and Experience
1. Does it act the same way as similar models do? 2. Are controls, labels, terminology and symbols consistent with other models? 3. Could any inconsistencies lead to error?
D. Functionality of Controls
1. Is it obvious what the controls do? 2. Do they work the same way in different circumstances? 3. Do you know what you have done when you press a button? 4. Do some buttons/switches look too similar to others? 5. Are they grouped/located in a logical manner? 6. Are some controls more critical than others? If so, how are they differentiated from other controls?
E. Displayed Messages
1. Is the message display big enough? 2. Can you understand the displayed messages? 3. Is the language simple and natural? 4. Is the information useful? Do you need more information? 5. Is it displayed long enough to be useful? 6. Can you tell how to recall messages once cleared from display?
F. Recognition and Recovery from Errors
1. Can you tell if you've made an error? 2. Can you tell what the error is? 3. Do you know how to fix it? 4. Are there cues (e.g., messages) to help you figure it out? 5. Are error messages understandable? 6. Is it possible to connect the device apparatus (lines, tubes, etc.) incorrectly? 7. Is it obvious if you do? Will the device still function?
G. Ease of Use
1. Is it obvious how you operate the device? 2. Does the device provide cues to help you use it?
H. Readable and Understandable Labels and Warnings
1. Are you able to easily see or hear important labels and warnings? 2. Is the language on the label/warning understandable? 3. Do you need technical knowledge in order to understand it? 4. Are connection ports and fittings labelled clearly?

*The complete checklist is available from the authors.

Our specific objectives for this initial pilot study were

- (i) To develop a human factors usability checklist
- (ii) To develop a procedure checklist for two common nursing tasks: programming a heparin infusion, and programming an insulin infusion
- (iii) To identify usability problems with our current infusion device while carrying out these nursing tasks

Project Description

We selected two common nursing tasks for evaluation: programming a heparin infusion and programming an insulin infusion. Nurses regularly carry out these tasks in any acute care ward, critical care area or emergency room. Heparin infusions are based on preprinted standard orders and protocols, whereas insulin infusions are less standardized. On the acute care wards, and in the emergency room, there is no standardized insulin infusion protocol. In the critical care units, there is a preprinted insulin infusion protocol, but the physician can still write any range of infusion parameters.

We also developed a generic usability checklist based on human factors principles (Gosbee 2004; Gosbee and Lin 2001) and advice from our human factors consultants (see acknowledgments). We used the checklist during the observation and debriefing sessions. (See Table 1 for selected features of the checklist.)

Table 2. Selected steps from heparin infusion procedure checklist*

1. Push OPTIONS.
2. Push 40.
3. Push ENTER.
4. Enter DOSE (units/hour).
5. Push ENTER.
6. Enter amount of drug in bag (units).
7. Push ENTER.
8. Enter initial volume of solution in bag (mL).
9. Push ENTER.
10. Enter the remaining volume in bag (mL).
11. Push ENTER.
12. Push RUN.
13. Confirm by observing Display.

*The entire checklist is available from the authors.

The nurse educators developed a checklist for each procedure. An excerpt from one of these checklists is found in Table 2. We focused solely on the programming steps. We did not address issues related to drug selection, intravenous admixture, labelling of infusions, or infusion line setup.

Each nurse educator recruited a convenience sample of volunteer nurse participants from their units, and each parti-

part received a briefing by the Patient Safety Service team. We emphasized that our goals were to identify and understand problems related to infusion pump use. We explained that the session was not a performance evaluation, and that all information was to be used to improve the system of care. We also emphasized that the nurses' experiences using the devices were essential to the success of the project, so that we would debrief after the session.

The volunteer nurse then entered the simulation lab (Figure 1). Two intravenous infusions were already set up on the simulated patient, and there were two infusion devices available. Two observers took notes: a patient safety specialist and a nurse educator; they both used the procedure checklist while observing the nurse. The patient safety specialists also had the usability checklist available, but they both found it more useful during the debriefing session. Each participant completed the heparin programming task, followed by the insulin programming task. After the first few volunteers, we gave participants the option of calling a “time out.” Participants said that, in usual practice, if they ran into difficulties they would take a “time out” and seek advice from a colleague.

Figure 1. The usability laboratory



After the two tasks were completed, the observers debriefed with the nurse participant, guided by the questions on the usability checklist. The biomedical engineer downloaded all of the programming steps onto a laptop for subsequent review. Later, the patient safety specialist (EE) and the biomedical engineering technician (RB) reviewed the programming steps and the field notes to identify recurrent patterns of error. The programming steps combined with the field notes were used to draw preliminary conclusions. The study team then reviewed and endorsed the conclusions.

Results

We recruited a total of 11 nurses, including eight from acute care and two from critical care or coronary care units (one was not recorded). Seven nurses reported greater than two years' experience in their current role.

We identified several usability problems (Table 3), including incorrect programming of infusion parameters, difficulty recovering from these programming errors, inability to clear previous program settings and inconsistencies between infusion rate displayed on correctly programmed device and the preprinted order sheet.

Many nurses experienced difficulty with the programming steps. First, there was an inconsistency between the order of parameters on the preprinted orders and the order of parameters requested by the machine. The machine requested in this sequence: desired rate, total dose, total volume, and remaining volume in the bag. By contrast, written orders usually listed them in this sequence: total dose, total volume, and desired rate.

In addition, the messages displayed during the programming sequence were confusing or ambiguous. For example, the machine displayed a message “CONC” twice, but each time a different parameter was needed. With the first CONC prompt, the nurse had to enter the total drug dose. With the second, the nurse had to enter the total original volume on the infusion bag. There were differences between the two prompts, but these were easily overlooked. The next prompt was for volume, but it was asking for the remaining volume in the bag, not the initial volume in the bag.

Programming errors were not visible until the final infusion rate was calculated and displayed by the device. In most cases, the nurse recognized that an error had been made somewhere, because the rate was unusually high or low. In one case, the patient would have received a significant overdose.

We observed difficulty in recovering from these programming errors. First, it was not clear where the error occurred, because there was no easy method for reviewing the programmed settings. Nurses tended to restart the entire programming sequence, because it was not possible to easily detect which step was incorrect. Some nurses attempted to clear all previous settings, but encountered difficulty. The “Clear” button did not actually clear previous settings. Similarly, turning off the device did not clear the settings. The necessary step was to choose the option code, then enter 99, but not all nurses were aware of this.

Finally, we identified problems caused by inconsistencies between the device display and the written orders. Specifically, the machine displayed the calculated rates to one decimal place, whereas the preprinted orders round up or down to the nearest unit. The nurse might expect a rate of 24 units per hour, yet see a programmed rate of 23.6 units per hour. This occasionally led to delays while the nurse decided whether the programming was correct.

Table 3. Summary of usability problems and their effects

Problem	Effects	Potential Severity	Short-Term Solution	Long-Term Design Solution
Nurse attempts to program machine after receiving a “FIX 21” message.	Slows down user. Only biomedical engineering can reset the device.	Low	Incorporate into nurse training. FIX 21 means improper unloading of tubing. Train on proper unloading of tubing, and that FIX 21 signal requires immediate abandonment of device.	Make the signal more informative, e.g., “Machine Is Disabled” instead of “FIX 21.”
Nurse attempts to clear prior settings using “Clear” button.	Slows down user. Prior settings are not cleared. Patient may receive infusion at prior settings.	High	Incorporate into nurse training. Option 99 is needed to clear all prior settings.	Simplify clear procedure. Improve user signals.
Nurse attempts to clear prior settings by turning device off then on.	Slows down user. Prior settings are not cleared. Patient may receive infusion at prior settings.	High	Incorporate into nurse training. Option 99 is needed to clear all prior settings.	Simplify clear procedure. Improve user signals.
Nurse enters wrong parameter when programming in option 40 or 42.	Slows down user. Patient may receive infusion at incorrect settings.	High	Incorporate into nurse training. Encourage use of simpler options (e.g., option 12). Incorporate into design of preprinted orders.	Improve user signals. Provide review or history function to allow recognition and recovery from errors.
Infusion rate displayed on correctly programmed device is not consistent with rate on order sheet, because of decimal point display on device.	Slows down user.	Low	Incorporate into nurse training.	Adjust display to nearest unit, instead of showing decimal places.

*The complete checklist is available from the authors

Some errors were caused by the study itself. In two cases, the participants chose an unusual programming option that calculated the rate in units per kilogram per hour. This led to additional programming steps and unusual rate displays. The participants said that they would not normally choose this option, but did so because they were being observed.

We gained additional usability problems and insights during the debriefing sessions. The major usability problem was recognition and recovery from errors. Many nurses felt that the machine did not help them recognize errors; one said “You have to rely on yourself.”

Some nurses stated that the programming options were so confusing that they never used them. Instead, they used the simplest set of steps to program the rate (displayed in millili-

tres per hour). This workaround, while it eliminated the need to program the dose of medication or the original volume in the intravenous solution bag, might lead to problems in the clinical setting. If a nurse were expecting the machine to be programmed in units per hour, the rate might be adjusted incorrectly (e.g., the rate is increased by 10 millilitres per hour instead of 10 units per hour).

Many nurses expressed particular difficulty with certain error signals (“FIX 21” and “FIX 24”). Although none of these signals arose during the study, it was clear that they were a source of great concern to the nurses. We learned that one of these signals led to immediate disabling of the machine, and only the biomedical engineering department could enable it again for clinical use. Participants described significant frustration trying to get such

machines working again, without knowing that nothing could be done to override the signal.

The participants all stated that the experience was informative and positive. The nurse educators also found the experience very instructive. They said it would change the way they carried out their orientation and training in the future.

Discussion

In this small pilot study, we identified several usability problems with our current infusion procedures. In the short term, we will use this information to modify our training procedures and the design of our preprinted orders. In the long term, we will provide feedback to the manufacturer to improve future designs, and we will use usability testing to guide procurement of new medical devices.

Prior studies have identified important usability problems with infusion devices. Lin et al. (1998) identified several usability problems with a patient-controlled analgesia device, including difficulty in viewing settings, difficulty recognizing and recovering from error, misleading and confusing displays and misleading or confusing labels. Simple redesigns of the user interface reduced errors, reduced mental workload and increased programming efficiency. Automation can paradoxically lead to new errors. For example, an automated patient identification bar coding device may create opportunities for error in patient identification and medication administration (Patterson et al. 2002). Similarly, we found that using the “advanced” programming options paradoxically increased the likelihood of programming error.

Our small pilot study has several limitations. We studied a small number of volunteers from our institution, so the generalizability of our results is limited. We have begun to address this limitation by presenting our results to local hospital nursing committees. So far, the response has generally been endorsement and enthusiasm. Another limitation is that some nurses said they changed their usual pattern of work because they were being observed, which led them to make mistakes they would not otherwise have made.

We conducted our project in a high-fidelity simulator using a simulated patient. However, the key learning was generated from observing the participants’ use of the device. We believe that any institution can conduct a similar project in a low-fidelity setting (i.e., any room); the only necessary components would be volunteer nurses, observers, an infusion device and some checklists.

Our preliminary study suggests an exciting role for human factors in the development of hospital procedures and training programs. Nursing staff and educators found the method to be instructive and constructive. The project generated recommendations and changes in infusion device training, infusion device procurement and standardized order design.

One of the new CCHSA Required Organizational Practices (Canadian Council on Health Services Accreditation 2005) is to provide ongoing, effective training for service providers on all infusion pumps. Our approach may be useful to other Canadian institutions as they address this required practice. Our results suggest that observation of simulated or actual use, and attention to human factors usability principles, will be needed to maximize the safety benefit of infusion device training.

In summary, we applied human factors usability principles to two common infusion device tasks and identified several usability problems. We have begun to modify our training programs and preprinted orders to address these problems, and we plan to provide feedback to the device manufacturer. This method can be easily adopted by any healthcare organization to enhance the safety of intravenous infusions.

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Transfer of Accountability: Transforming Shift Handover to Enhance Patient Safety

Kim Alvarado, Ruth Lee, Emily Christoffersen, Nancy Fram, Sheryl Boblin,
Nancy Poole, Janie Lucas and Shirley Forsyth

Abstract

Communication of information between healthcare providers is a fundamental component of patient care. The information shared between providers who are changing shifts, referred to as "handover," helps plan patient care, identifies safety concerns and facilitates continuity of information. Absent or inaccurate information can have deleterious effects on patient care. According to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO 2003), almost 70% of all sentinel events are caused by breakdown in communication. Issues and concerns regarding the effectiveness of handover at shift change were raised by nurses throughout Hamilton Health Sciences (HHS), leading to the approval of a hospital-wide project to implement evidenced-based Transfer of Accountability (TOA) Guidelines and a bedside patient safety checklist. This article describes the development of the guidelines, the results of the pilot study and the ongoing implementation of the project. The observed impact on patient safety within HHS is presented.

Background

Reporting mechanisms employed when providers change shifts are an integral component of the communication process used to convey information about patients between healthcare providers. A number of terms are used to describe this exchange of information, such as *patient care handover*, *transfer of accountability*, *bedside reporting*, and *shift handover*. The information

imparted during this exchange is fundamental to the professional activities that follow, and consequently to the care the patient receives (Dowding 2001; Kerr 2002; Miller 1998). Inadequate or incorrect information jeopardizes patient safety and the continuity of care (Anthony and Preuss 2002).

Many Canadian hospitals have no policy or standards for handover. Transfer of accountability (TOA) practices vary across and within healthcare organizations. Typical procedures involve spoken, written and/or taped reports (Dowding 2001; Greaves 1999; Kerr 2002; Pothier et al. 2005; Timonen and Sihvonen 2000; Williams 1998). When the process for this transfer varies between settings or healthcare providers, the risk of missed or incorrect information is elevated. The potential impact of inadequate or erroneous information on patient care is troubling. The Joint Commission International Center for Patient Safety (JCICPS) contends that effective communication is the "hallmark of health care organizations that are successful in providing safe, high-quality care" (JCAHO 2004). The JCICPS goes on to suggest that systems and processes must be established to ensure complete communication of information. The Canadian Council on Health Services Accreditation suggests patient safety can be improved by employing "effective mechanisms for transfer of information at interface points, including shift changes ..." (CCHSA 2005). The Canadian Patient Safety Institute (CPSI) has recognized the importance of this issue, designating implementation and evaluation of new

mechanisms for communication within and between caregivers as a research priority (2006).

At Hamilton Health Sciences (HHS), prior to the implementation of the TOA project, methods used for transferring patient accountability between care providers differed. Concerns related to the usefulness of the information and congruence between the report and the patient condition were raised. As a result, a team of nurses with expertise in practice, policy and research related to patient care communication was established under the auspices of the HHS Professional Affairs portfolio. Using the best available evidence supporting bedside reporting, and through a process of consensus, TOA guidelines were developed. The guidelines were pilot-tested and subsequently implemented in units with shift handovers across the organization.

Objectives

The objectives of the TOA project were to review the handover processes at HHS, develop TOA practice guidelines, provide an appropriate framework through which nurses can handover patient care, implement a standardized approach to TOA and evaluate the effect of the project on patient safety within HHS.

Setting

Hamilton Health Sciences (HHS) is a 1,000-bed regional tertiary care facility comprising five distinct hospitals and a cancer centre, serving more than 2.2 million residents of Hamilton and Central South and Central West Ontario. The facility

employs over 3,400 registered nurses (RNs) and registered practical nurses (RPNs) who are actively involved in communicating patient information between nurses at shift change, and between units and hospitals when transferring patients.

The Transfer of Accountability Project

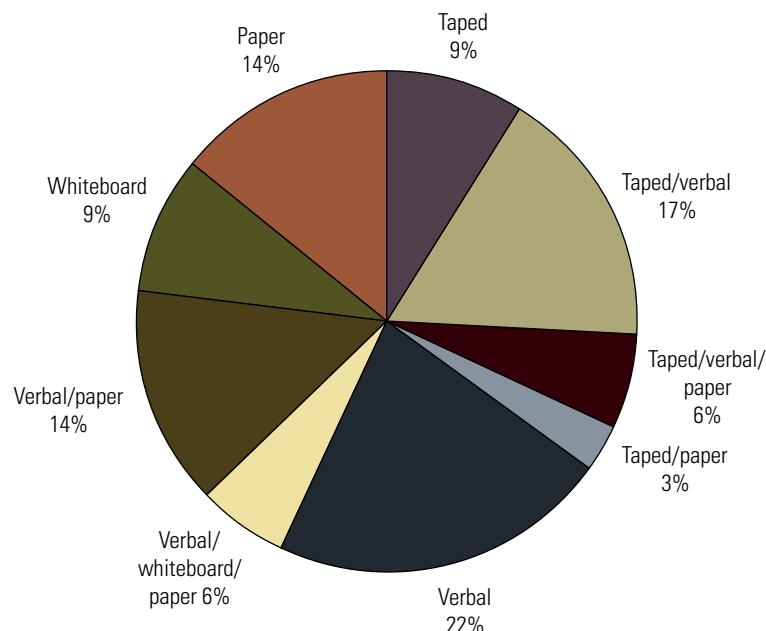
Development of TOA Guidelines

Assessment of current practice. The first phase of the project was to determine the current handover practices within the organization. In 2002, a survey was conducted, the aim of which was to determine both the handover practices of nurses and the length of time involved at shift change. The survey was distributed to the clinical educators for each of the 52 inpatient areas; responses for 36 units (69%) were received. Analysis of the responses revealed that nine different shift-reporting mechanisms were being used, including combinations of verbal, taped and written methods (see Figure 1). Length of handover ranged from as little as one or two minutes per patient on a ward to more than six minutes per patient in critical care areas (see Figure 2).

Development of TOA practice guideline. An expert panel of nurses including administrators, educators and clinicians reviewed over 25 relevant research and opinion articles related to patient handover. The literature suggested that typical transfer procedures involve spoken, written and/or taped reports, and that these reports play a pivotal role in the continuity of patient care (Dowding 2001; Kerr 2002; Miller 1998). Young et al. (1988), in a study aimed at improving the communication of patient information at change of shift, found that a hybrid approach – verbal report, coupled with a silent report when patients' notes were read – facilitates the transfer of information necessary for safe and holistic care.

On the basis of this literature, practice guidelines were drafted. The guidelines identify and expand upon the three distinct phases of TOA: pre-handover, inter-shift handover and post-handover. Within the pre-handover phase, a review of patient information is obtained from the chart, team members, patient and family; a written report capturing the key pieces of information about the patient is prepared. The format of this report, including content, can differ for patient care units, according to the information needs of care providers. During inter-shift handover, the off-going and the on-coming nurses engage in a verbal report and complete a patient safety checklist at the bedside.

Figure 1. Methods of handover, Hamilton Health Sciences, 2002



Following this, the on-coming nurse reviews the patient plan of care, medication record and summary work plan, e.g., kardex.

Pilot study. Two clinical inpatient units, a 16-bed general medicine unit and a 34-bed obstetrical unit participated in the pilot study. Orientations were held to familiarize the nurses with the TOA guidelines. Nurses were provided with an information package on each unit, and support was provided through e-mail and telephone contact. Four months following implementation of the TOA guidelines, a questionnaire was developed and

Analysis revealed that the form developed by the staff nurses was perceived as much more useful than the generic form ($p = 0.00$, 2-tailed t -test).

The conclusion of the study was that nurses were not comfortable communicating nursing information during face-to-face interaction at the bedside. Face-to-face reporting needed to be introduced, along with education to enable nurses to use this component. Nurses were more accepting of the TOA guidelines when they were involved in the development or identification of written tools for the staff nurse and charge

nurse. Needed were patient-population-specific components of the TOA standards. The importance of a bedside patient safety check needed to be communicated.

The results and conclusions were disseminated to the HHS executive team, who decided that further development and implementation was warranted. An implementation plan, including guiding principles and a staged implementation, was suggested.

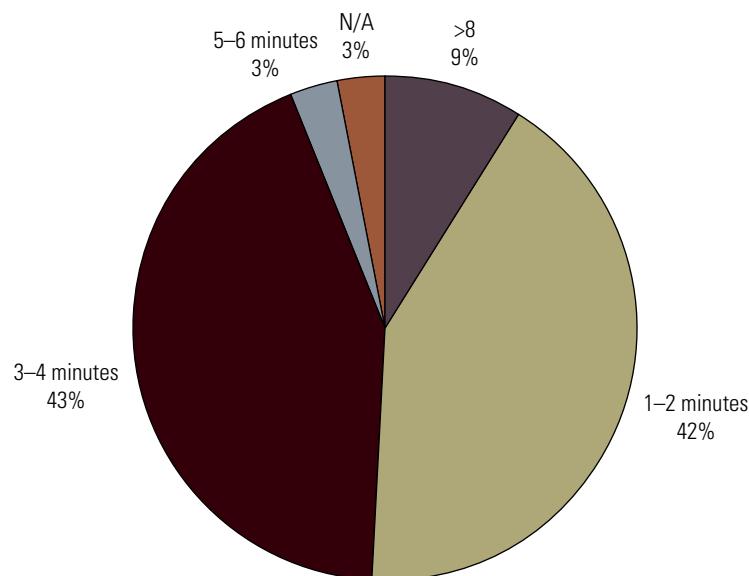
Implementation Plan

A TOA Advisory Committee convened to review the practice guidelines and the pilot study. The Advisory was made up of nurse leaders, a patient safety specialist, a clinical educator, a clinical system professional and staff nurses. They determined that the introduction of a bedside patient safety checklist, face-to-face dialogue and a written tool for both the charge nurse and the staff nurse would help nurses establish and maintain the principles of TOA. The Advisory adapted a one-page document, the “HHS Nursing Standards for Patient Safety during Transfer of Accountability” that had been

structured to determine the frequency and perceived usefulness of completing each component of handover. Responses were obtained from 57 of the 59 (97%) registered nurses and registered practical nurses working on these units. Analysis revealed that, overall, nurses were completing the written and verbal handover as per the new TOA guidelines. At times, they were choosing to conduct the face-to-face component in the hall outside the patient’s room. While each unit implemented the three phases of the TOA process, they modified the inter-shift handover. Nurses excluded the bedside safety checklist, because the process had not yet been clearly defined.

Analysis also revealed that nurses on each unit perceived the usefulness of the written tools differently. One unit used a generic computer-based form; the nurses on the other unit developed their own form. Nurses chose to modify the written tools to make them more appropriate for the particular unit.

Figure 2. Length of time of handover per patient, Hamilton Health Sciences, 2002



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Guiding principles. The TOA Advisory Committee identified four guiding principles for the transfer of accountability process:

- A mechanism (safety checklist) to review key patient safety

issues, identify errors and limit patient harm must be introduced.

- An opportunity to clarify information (face-to-face dialogue) must be included.
- Reliance on memory should be minimized through the use of a staff nurse written tool.
- One person must have a total picture of the unit through the use of a charge nurse written tool.

Figure 3. Transfer of Accountability Standards Template, 2002

(UNIT) Nursing Standards for Patient Safety During Transfer of Accountability																													
 <p>Hamilton Health Sciences</p> <ul style="list-style-type: none"> ➢ This Information must be communicated when transferring care of the patient ➢ Each nurse is responsible for documenting that the process of Transfer of Accountability and Patient Safety Checklist is complete ➢ Patient's name, age and diagnosis should be stated first 																													
Plan of Care <ul style="list-style-type: none"> ➢ Code status ➢ Past medical history relevant to current situation ➢ Complications ➢ Patient/family goals for next 12 hours 	<ul style="list-style-type: none"> ➢ Shift orders and future one-time orders ➢ Consults ➢ Infection control ➢ Medication administration issues 																												
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Approval Date: _____ Chief of Nursing Practice: _____ Director: _____ Manager: _____																													

Five-step plan for implementation. The implementation plan was divided into five steps: (1) development of a patient-population-specific component of the TOA standards; (2) development or identification of written tools for the staff nurse and charge nurse; (3) introduction and implementation of the bedside patient safety checklist; (4) introduction of face-to-face reporting; and (5) evaluation. A two-hour, facilitated workshop was prepared for each step. Implementation teams consisting of a manager, an educator and a staff nurse were identified for each

area that had shift handovers. Implementation team members attended the series of five workshops, during which they planned for implementation on their wards, developed a communication plan, drafted TOA standards and drafted written tools for the staff and charge nurses.

The TOA workshops were scheduled every two weeks, to allow members time to work with the nurses on the units to develop, review, test and revise their TOA standards, written tools and face-to-face reporting methods. This process helped to ensure the tools met the needs of the unit while remaining consistent with the guiding principles. Each workshop opened with storytelling from the members to foster collaboration and mutual problem-solving. The project coordinator followed up with members between meetings, offering to meet with staff and to assist with testing out the new tools and methods. The teams reconvened three months after the workshops to review progress and to celebrate successes.

Ongoing evaluation. A communication book was kept on the clinical units, in which nurses wrote questions and comments as TOA was implemented. One book exemplified the evolution in feelings and beliefs of the nurses as they implemented the practice change. Its first nine entries expressed frustration. A nurse stated she was "too busy" to report. Another suggested that using paper for the written report "was a waste of money." As the communication continued, the manner shifted. One nurse stated, "the checking of armbands is good, I had an incident where I was going off nights and checking an armband. The ID number did not match the patient armband and this patient was going to the OR that day." Another stated, "I feel doing TOA is helping everyone ... we can get on with our jobs. Teamwork!" And another commented, "patients have been very positive regarding armband check and face-to-face reporting."

Observational audits are currently being conducted to evaluate the handover process. Unusual findings identified by the nurse at shift change are documented. Nurses are reporting improvements in the congruency of information received in handover and their patient assessment. Patients have expressed their satisfaction with the process, particularly the bedside check. They are reassured by knowing information about their care requirements has been communicated between nurses. Incorrect patient armbands and IV solutions have been identified and rectified during the bedside patient safety check. These early "catches" help limit patient harm, identify system issues to prevent future errors and help the organization reach its patient safety goals.

Plans to extend this project to explore TOA within and between other disciplines and facilities are under way. In addition, McMaster University School of Nursing is exploring ways to introduce TOA education into the undergraduate curriculum.

Implications for Patient Safety

The intent of this project was to develop handover practices to support patient safety. Prior to the TOA project, a lack of consistency in practice about appropriate nursing change of shift handover resulted in confusion about the appropriate information to communicate. Lack of communication of significant patient information among nurses sometimes led to an inappropriate plan of care and ultimately a negative outcome. The use of TOA guidelines, a relatively standardized approach, can decrease the chance of negative outcomes, because of the limits placed on the variety of methods used to perform a task (Porto 2001). Use of a structured tool can also stimulate recall for nurses, ensuring that assessment about key issues is conducted and the reporting of significant findings enhanced.

Conclusion

The purpose of the TOA project was to provide an evidence-based framework to support nurses' handover of patient care, and to implement a standardized approach to TOA to promote patient safety. TOA guidelines were developed, pilot-tested and evaluated. Results of the pilot study were used to inform clinical practice. This was achieved by developing nursing standards for patient safety during transfer of accountability and introducing written tools, a bedside patient safety checklist and face-to-face reporting. The standardized approach to TOA improves the effectiveness and coordination of communication among nurses at shift change, and fosters complete communication of information related to patient needs during provision of care. The next step of this project is to understand and enhance handover practices within and between other care providers and facilities.

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Is Your Patient Ready for Transport? Developing an ICU Patient Transport Decision Scorecard

Rosmin Esmail, Deborah Banack, Cheryl Cummings, Judy Duffett-Martin, Dr. Karen Rimmer, Jonas Shultz,
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Abstract

Transport of patients from the intensive care unit (ICU) to another area of the hospital can pose serious risks if the patient has not been assessed prior to transport. Recently, the Department of Critical Care Medicine, Calgary Health Region, experienced two adverse events during transport. A subgroup of the Department's Patient Safety and Adverse Events team developed an ICU patient transport decision scorecard. This tool was tested through Plan-Do-Study-Act cycles and further revised using human factors principles. Staff, especially novice nurses, found the tool extremely useful in determining patient preparedness for transport.

Introduction

Many medical errors involve loss of information or lack of appreciation of significant patient problems as patients transition from one locus of care to another (Leonard et al. 2004). There are two types of patient transfers: interhospital, referring to the transportation of patients between hospitals, and intrahospital, referring to the transportation of patients within a hospital for the purpose of undergoing diagnostic or therapeutic procedures or transfer to a specialized unit (Martins and Shojania 2001). The critically ill patient being transported is at increased risk of morbidity and mortality during the process (Warren et al. 2004; Durairaj et al. 2003). Intrahospital transport exposes the patient to many of the same risks of an interhospital transport. Intrahospital transport to

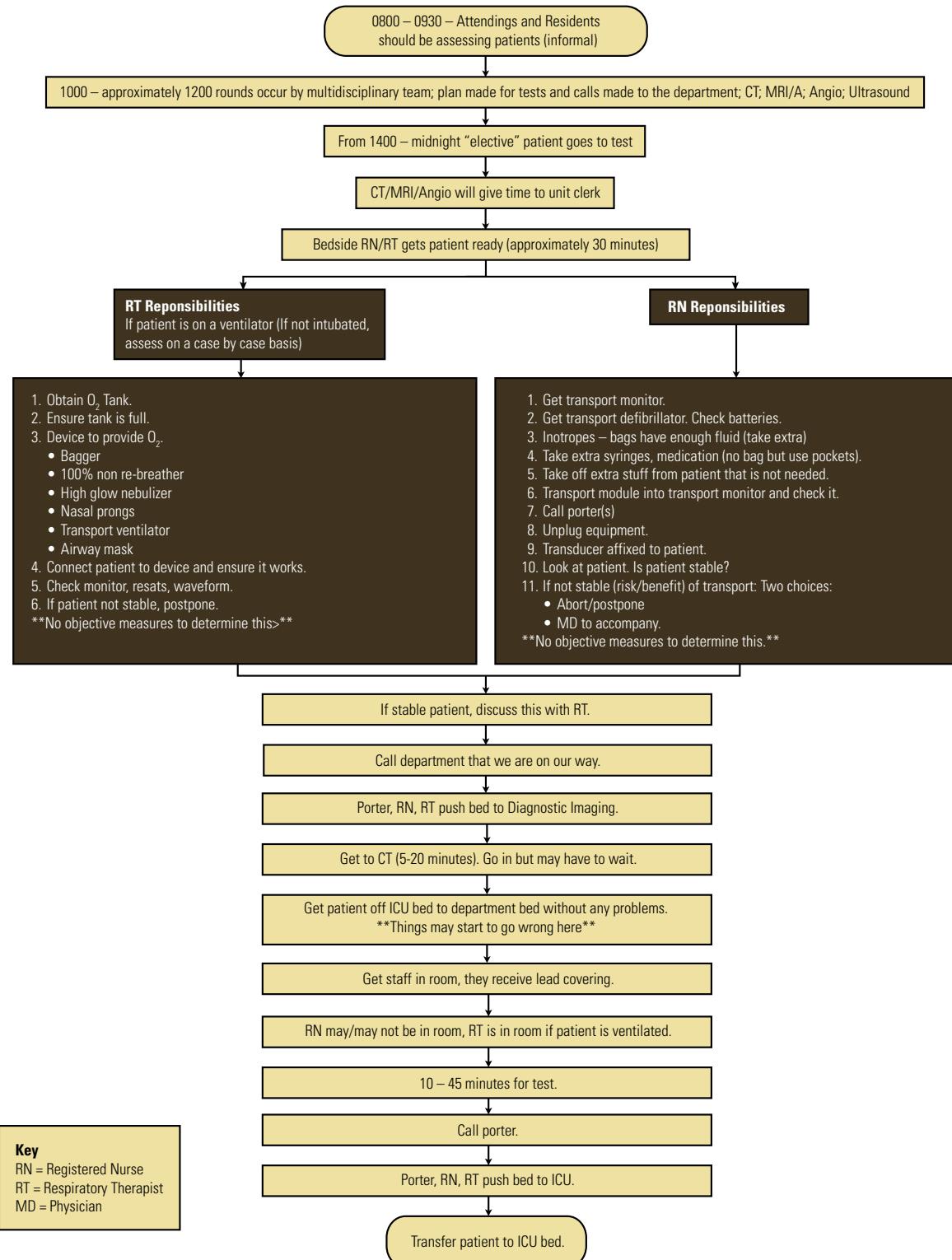
diagnostic imaging (DI) testing areas is associated with the longest duration a patient spends outside the unit (Venkataraman and Orr 1992). However, transporting critically ill patients within a hospital cannot be avoided when diagnostic tests and procedures cannot be performed in the ICU. The benefits of transporting the patient must be balanced against potential for harm (Warren et al. 2004; Shirley and Bion 2004).

In 2005, the Department of Critical Care Medicine, Calgary Health Region, experienced two critical incidents, both with a theme related to the transport of nonintubated patients to DI. The Department's Clinical Safety and Quality Assurance Council felt a process needed to be in place to improve the safety of both intubated and nonintubated patients leaving the ICU for tests. The following case study describes the development and early testing of an ICU patient transport decision scorecard.

The Two Cases

In a three-month period, two similar incidents occurred in ICU patients sent off the unit for diagnostic testing. In both cases, the patients were not intubated, but had a compromised respiratory status. They were being investigated for intra-abdominal sepsis with a CT scan of the abdomen, which required that the patients receive large volumes of oral contrast and that they lay flat during the test. In each case the patient had cardiopulmonary arrest during the scan.

Figure 1. Steps for transporting an ICU patient for diagnostic test



The two incidents raised the question of the safe transport of nonintubated, critically ill patients – in particular, best monitoring and airway protection practices. Other members of the department cited previous similar incidents and a system issue was identified, initiating a review and development of a solution.

Literature Search

A two-step process was undertaken to determine if there were existing tools that could be used for this purpose. Initially, a literature search was conducted. The review was conducted using CINAHL, MEDLINE databases and other Internet sources. Keywords included: transfer, emergency medical technicians, critical care, ambulances, transportation of patients, professional role, intrahospital, equipment and supplies, quality assurance, patient safety, mechanical ventilation, aero medical transport, flight nursing and adult. This search was updated in May 2006.

Guidelines and recommendations for the safe inter- and intrahospital transport of critically ill patients have been developed (Warren et al. 2004; Australasian College for Emergency Medicine 2003; Intensive Care Society 2002; Ferdinand 1999). Critically ill patients undergoing transport should receive the same level of monitoring and physiologic support as they would in the intensive care unit. Changes during transport should be quickly identified and managed in the same way as in an intensive care unit.

Waydhas reviewed the literature of the intrahospital transport of critically ill patients (Waydhas 1999) and identified the nature and incidence of adverse events. The reported incidence of adverse events or patient harm for intrahospital transports has ranged from 6 to 71%. The severity of these events was often not reported in detail. Life-threatening events may be as high as 8% of intrahospital transports. Waydhas noted circulatory and respiratory complications were most commonly reported and were due to inadequate ventilation during transport. Equipment-related complications occurred in up to one-third of transports. The long-term outcomes were not well studied. The diagnostic yield or benefit of the transport was highest in trauma and surgical patients, ranging from 25% to 70%.

Beckmann and colleagues, using data from the Australian Incident Monitoring study (AIMS-ICU), analyzed 191 incidents, reported anonymously, occurring during intrahospital transports to or from 37 ICUs (Beckmann et al. 2004). Equipment problems were found in 39% of cases; patient- or staff-related problems were identified in 61%. Significant adverse events occurred in 31% of the reports analyzed, including four deaths and six cardiac arrests. The cause of most of these incidents was multifactorial, with human-based factors contributing to the 191 incidents. Human factors included inadequate preparation, failure to follow protocol and errors of judgment and of problem recognition.

Staff orientation and training improved patient outcomes during transport (Wilson 1998; Boyko 1994). A transport team might include nurses, paramedics, respiratory therapists and physicians, depending on the stability of the patient.

Proper documentation and communication were vital for both referring and receiving departments to be prepared for the transport (Warren et al. 2004).

An environmental scan was conducted by asking critical care units in the United States and Canada whether there had been such a tool developed. The Barnes-Jewish Hospital has developed the transport stability scale (© R. Corcoran and M.J. Barnes, Barnes-Jewish Hospital, St. Louis, MO). The scale has three colour-coded areas and identifies the patient's appropriate level of transport accompaniment. The colours of traffic lights are used: *green* – May travel with patient transporter; *yellow* – Required higher level of oversight, must travel with nurse or physician; *red* – Unstable, must travel with nurse and physician. We used this scale as the foundation for our tool.

Intervention

A subgroup of the Department's Patient Safety and Adverse Events team (PSAT) was formed, consisting of a respiratory therapy supervisor, two registered nurses, a critical care physician and the department's quality improvement and patient safety leader. The group determined 29 steps involved in transporting an ICU patient for diagnostic tests, from the time the decision was made for testing, to when the patient returned to the ICU, making it a complicated process (Figure 1). Two options were determined if the patient was unstable: abort/postpone the test or have a physician accompany the patient. It was determined by the group that there were no objective criteria to make this decision. The group agreed to develop an ICU transport decision scorecard to assist the bedside nurse in determining the stability of the patient being transported.

The team decided that the scorecard should be considered from the point of view of the novice staff member to ensure that conditions were not missed due to lack of experience or ability to recognize potentially critical sequelae. The team walked through the process for preparing for an intrafacility transport using a "systems" approach and identified endpoints that would require reassessment by the critical care physician. The tool led the nurse to determine whether a physician should accompany the transport or suggest delaying or cancelling the test.

These items were then inserted into a draft scorecard. Initially, we used "*green-yellow-red*" columns: *green* identifying those who were safe to travel with an RN; *yellow* identifying the need for a RRT to accompany the patient; and *red* identifying the need for further assessment by a critical care physician and inclusion in the transport team. Nurses, respiratory therapists and physicians have a role in the completion of the scorecard prior to the transport (Figure 2).

Figure 2. ICU patient transport decision scorecard

System	Green Patient to be accompanied by IV direct & defibrillation certified RN	Yellow Checkmark in ANY box indicates patient to be accompanied by RN & RRT. MD/RRT to assess items as indicated below	Red Checkmark in ANY box indicates patient to be accompanied by RN & RRT and may include MD assistance. MD to assess items as indicated below
CNS	<input type="checkbox"/> Riker 1 – 4 or GCS 13-15 <input type="checkbox"/> PRN sedative orders & adequate supply <input type="checkbox"/> Cleared/stable C-spine		<input type="checkbox"/> Unexplained change in Riker &/or GCS. <input type="checkbox"/> Riker > 4 <input type="checkbox"/> Unstable/uncleared C-spine <input type="checkbox"/> Paralysed (with orders for sedative/paralytics & adequate supply of drugs) <input type="checkbox"/> Seizures <input type="checkbox"/> ICP unresponsive to ongoing therapy <input type="checkbox"/> Active warming or cooling
CVS	<input type="checkbox"/> Chest pain relieved & no new ECG changes <input type="checkbox"/> Stable or decreasing vasopressor requirements <input type="checkbox"/> Stable dysrhythmias <input type="checkbox"/> Hemodynamic goals ordered & met <input type="checkbox"/> Ensure adequate supply of IV fluids & meds to complete transport		<input type="checkbox"/> New onset or chest pain unrelieved &/or ECG changes <input type="checkbox"/> Increasing vasopressors <input type="checkbox"/> New onset or hemodynamically unstable dysrhythmias (i.e. VT/VF/Afib/PSVT) <input type="checkbox"/> Active fluid resuscitation in progress <input type="checkbox"/> Active bleeding <input type="checkbox"/> No hemodynamic goals ordered
Resp	<input type="checkbox"/> FiO ₂ ≤ 0.5 & unchanged <input type="checkbox"/> Nasal prongs ≤ 6L/min & unchanged or decreased <input type="checkbox"/> Regular nasal prongs <input type="checkbox"/> RR 10 – 24 <input type="checkbox"/> Ensure oxygen tank is full	<input type="checkbox"/> Intubated & tube position confirmed by CXR or bronchoscopy MD to confirm → <input type="checkbox"/> Suctioning ≥ Q1H required <input type="checkbox"/> FiO ₂ > 0.5 or increasing RRT to assess → <input type="checkbox"/> High flow nasal prongs RRT to assess → <input type="checkbox"/> Presence of a Tracheostomy or Cricotracheostomy tube	<input type="checkbox"/> PEEP > 10 &/or FiO ₂ >0.6 <input type="checkbox"/> Change in RR <10 or >24 <input type="checkbox"/> pH < 7.25 <input type="checkbox"/> Ventilation mode: IRV, APRV, HFV <input type="checkbox"/> Hemoptysis <input type="checkbox"/> Non-invasive ventilation (BiPAP, CPAP) <input type="checkbox"/> FiO ₂ > 0.5 or increasing (non-ventilated pt) <input type="checkbox"/> Known or suspected difficult airway, difficult intubation, or traumatic intubation
GI/GU	<input type="checkbox"/> Vomiting controlled with meds <input type="checkbox"/> Orders for anti-emetic & adequate supply <input type="checkbox"/> Quantity of contrast given per order & OG/NG clamped <input type="checkbox"/> Insulin infusion off & chemstrip > 4.0		<input type="checkbox"/> Open ABD cavity with exposed viscera <input type="checkbox"/> Insulin infusion off & Chemstrip ≤ 4.0 <input type="checkbox"/> Active treatment of life threatening electrolyte abnormalities <input type="checkbox"/> Active uncontrollable vomiting <input type="checkbox"/> Active GI bleed or bleeding from surgical wound or drain
Lines	<input type="checkbox"/> All lines dressed & secured per policy <input type="checkbox"/> Lumbar subarachnoid drain levelled & secured as per policy <input type="checkbox"/> Chest tubes that can be clamped or to straight drainage during transport <input type="checkbox"/> Transvenous pacemaker with good capture <input type="checkbox"/> ICP monitoring device secured		<input type="checkbox"/> Chest tubes that need suction during transport <input type="checkbox"/> Transvenous pacemaker with poor capture <input type="checkbox"/> Intracranial pressure monitoring device secured <input type="checkbox"/> Unsecured vascular access
MISC	<input type="checkbox"/> Isolation patient with transport precautions as per CHR infection control policy		

Methodology/Change Process/Results

The draft tool was developed (Figure 2) and tested using the Plan-Do-Study-Act (PDSA) cycle (Langley et al. 1996). Numerous PDSA cycles were undertaken at two of the three major hospitals in the city, focusing on novice bedside nurses and respiratory therapists. The bedside RN reviewed and completed the transport tool prior to leaving the unit. A delay

in departure from the unit that exceeded two hours resulted in a reassessment of the patient's status.

Results from testing the transport tool were fairly consistent despite the variety of patients from the two distinctly different participating ICUs. Anecdotally, nursing staff agreed that the tool allowed them to pause and evaluate the patient immediately prior to leaving the controlled and well-supported ICU.

Figure 3. Revised ICU patient transport decision scorecard

calgary health region
Critical Care Medicine

ICU PATIENT Transport Decision Scorecard
To be used for patient assessment prior to transport within the hospital
IF IN DOUBT, ALWAYS ASK FOR HELP

Patient addressograph:

Flowchart steps:

- Read instructions on back of page and start here
- Order received and all supplies available
- Full O₂ tank(s)
- Lines & Tubes secured & position verified by MD
- Adequate IV drip and infusions
- Assess Each System Below
- Does patient require IV contrast? If yes, consent signed?
 - Yes
 - No
- Discontinue IV insulin (if applicable) unless otherwise ordered by MD
- Emergency medication/sedation, analgesia

System	Criterion	Green	Red
CNS	Riker	<input type="checkbox"/> 3-4	<input checked="" type="checkbox"/> < 3 or > 4
	GCS	<input type="checkbox"/> 13-15	<input checked="" type="checkbox"/> < 13
	C-spine fracture	<input type="checkbox"/> Stable	<input checked="" type="checkbox"/> Unstable
	Consciousness	<input type="checkbox"/> No change	<input checked="" type="checkbox"/> Unexplained change
	ICP	<input type="checkbox"/> Controlled	<input checked="" type="checkbox"/> Uncontrolled
	Paralyzed/sedated	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes
	Seizing	<input type="checkbox"/> Controlled	<input checked="" type="checkbox"/> Uncontrolled
	Active Warming/Cooling	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes
	CVS	Goals	<input type="checkbox"/> Met
Chest pain		<input type="checkbox"/> Relieved	<input checked="" type="checkbox"/> New pain or ECG changes
Pacemaker		<input type="checkbox"/>	<input checked="" type="checkbox"/> Pacer with poor capture (exclude MRI)
Pressors		<input type="checkbox"/> Stable	<input checked="" type="checkbox"/> Increasing
Dysrhythmia		<input type="checkbox"/> Stable	<input checked="" type="checkbox"/> New or unstable
RESP	Fluid resuscitation	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Active
	RR	<input type="checkbox"/> 10-24	<input checked="" type="checkbox"/> < 10 or > 24
	Oxygen	<input type="checkbox"/> < 40% or ≤ 6 Lpm	<input checked="" type="checkbox"/> 40% or > 6Lpm or increasing
GI/GU	Artificial Airway	<input type="checkbox"/> Not present	<input checked="" type="checkbox"/> Present
	Difficult Airway	<input type="checkbox"/> Not suspected	<input checked="" type="checkbox"/> Difficult Airway anticipated or confirmed
	pH	<input type="checkbox"/> ≥ 7.30	<input checked="" type="checkbox"/> < 7.30
	Ventilator setting	<input type="checkbox"/> N/A	<input checked="" type="checkbox"/> Non-conventional mode of ventilation (IRV, APRV, HFOV)
	PEEP	<input type="checkbox"/> N/A	<input checked="" type="checkbox"/> □ ≥ 10 cm H ₂ O
	Abdomen	<input type="checkbox"/> Closed	<input checked="" type="checkbox"/> Open
OTH	Electrolyte abnormalities	<input type="checkbox"/> Not life threatening	<input checked="" type="checkbox"/> Life threatening
	Bleeding	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Active
	Vascular access	<input type="checkbox"/> Secure	<input checked="" type="checkbox"/> Unsecured
	Lines/tubes	<input type="checkbox"/> Standard	<input checked="" type="checkbox"/> Complex
	Isolation	<input type="checkbox"/> Contact	<input checked="" type="checkbox"/> Droplet/Airborne
	IF ANY CRITERIA MET IN GREEN, RN TO ACCOMPANY A PER ICU PRACTICE		IF ANY CRITERIA MET IN RED, MD AND RRT TO RV ASSESS, RN AND RRT TO ACCOMPANY AND MAY INCLUDE MD AND ANOTHER RN

RT MUST RE-ASSESS

Staff felt empowered to present their patient to the attending physician as being stable or unstable for transfer from the unit. It also helped them to identify and minimize the risks associated with removing a critically ill patient from the ICU environment. Comments arising from these PDSA cycles led to further revisions of the scorecard.

At the third site, there was resistance to using the tool. One

reason was that PSAT did not have any members from this site. DI was immediately adjacent to the ICU, and staff did not feel it necessary to go through the checklist. However, they did feel it would be useful for tests that were performed further away.

In total, 80 forms were obtained through the testing. Frequency of responses from each item on the scorecard was entered into an Excel spreadsheet. In an effort to shorten the

scorecard, the team collectively reconsidered each of these items and removed those that had not been considered in the assessment.

Further PDSA cycles revealed the tool was too complex and not user-friendly. There was resistance from senior nurses and physicians to using the tool. The tool was further modified to include items that are clear decision points or “show stoppers.” This would ensure the physician accompanied the transport or the transport was aborted (Figure 3).

Outcome measures have been added to record cancelled transports, physician presence and any problems during the transport. The ultimate goal will be to ensure that incidents such as those described in our section “The Two Cases” above will be prevented.

Application of Human Factors

Effective forms accommodate two streams of information: instructions for the person completing the form and collection of specific information from that person. When successful, the information flows in both directions between the form and the form filler. While it sounds simple, it can be particularly challenging in light of estimates suggesting that form fillers read less than 50% of relevant information such as instructions (Frohlich 1986).

A variety of formats (i.e., directed forms and checklists) have been designed to change typical behaviours to increase the likelihood that users will more effectively complete the form because they have read the instructions and the questions. Directed forms incorporate forced choices or decision points (i.e., yes/no) whereby users must read the question in order to make a decision. Data from Frohlich’s observational study confirmed the benefits of directed forms to effectively alter form completion behaviours. Checklists, on the other hand, permit users to scan through a list in search of relevant points. Critical information perceived to be irrelevant can be skipped.

As applied to the ICU patient transport decision scorecard, decision points were created for each criterion to ensure form fillers considered all points. In other words, the successful completion of this form required users to allocate (and consider) one checkmark for each criterion. The utilization of a traditional checklist would permit users to scan through the criterion list, increasing the likelihood that some points would be missed.

Although directed forms require form fillers to read the questions, the same cannot be assumed about the instructions. In an effort to reduce the reading effort and general memory requirements, attempts were made to incorporate instructions into the form where required by users. To illustrate, instructions previously located on the cover page of the tool (Figure 2) read:

Patient should score in the Green zone to be stable for transport. If there are any checkmarks in the yellow or red zone

the MD needs to reassess patient for transport (please read instructions below).

To successfully carry out these directions, users are required to read the instructions, store this information in their short-term memory, conduct the assessment and then recall (or reread) the instructions. The subsequent version of the tool has the checkboxes inside coloured columns with subsequent actions required when boxes within the column are checked. In this way, the instructions are available when required by the user.

The final version of the tool now has only two colours: green and red. Feedback from PDSA cycles suggested further simplification of the tool by having two columns only. The yellow column only had items specific to the respiratory therapist’s assessment. Incorporating human factors principles to reinforce decision points, these items were refined and moved into the red column.

Discussion/Conclusions

The transport of the ICU patient is a complicated process and can lead to patient harm. In the Department of Critical Care Medicine, Calgary Health Region, staff underestimated the risks of intrahospital transport, which led to the two adverse events mentioned above. This article has described the development of an ICU patient transport decision scorecard to support the safe transport of ICU patients for diagnostic testing.

The scorecard is a visual assessment tool. Each item on it is a decision point and a simple reminder to ensure that appropriate resources are available prior to transport. Outcome measures have been added to begin to measure the effectiveness of the tool.

Several lessons were learned from the development of this tool: the need to form a subgroup with team members from all sites and disciplines to ensure early buy-in; the involvement of a human factors expert to make the tool easier to use; and the need to continuously retest the tool using PDSA cycles.

One concern identified was the resistance to using the tool when DI is close to the ICU. Proximity may provide a false sense of safety for staff transporting the patient. As Kalisch et al. (1995) have identified, the monitoring of patients can decrease significantly during transport, and important physiologic changes may not be identified. This might lead to an adverse event regardless of where DI is located. The tool provides an initial step in training and orienting staff to the complexities of transport.

Continuous monitoring of the scorecard will be necessary to ensure it is being used to assist with the decision to transport. As one source has stated, “although standard documents and ‘pre-flight’ checklists are important in developing safe practice, they are of limited value unless the practitioner at the bedside translates them into effective action” (Shirley and Bion 2004).

The tool will be further adapted for all critically ill patients going to DI or the operating room, or patients coming from

the emergency department to the ICU. The principles used in the development of this tool will be applied in revision of the Department's ICU interfacility transfer checklist. The tool may be applicable for the transport of non-ICU patients and may be modified by other clinical departments.

Finally, to our knowledge, no such tool has been developed or is currently being used in other ICUs across Canada. We hope to share it with teams from the Canadian Collaborative to Improve Patient Care and Safety in the ICU (www.improve-mentassociates.com).

Instruction pages are available online. See Appendix at <http://www.longwoods.com/product.php?productid=18376&cat=452>

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A full-body photograph of a man from the waist up, wearing a dark suit, white shirt, and patterned tie. He is holding a large, vintage-style megaphone to his right ear, shouting into it. The megaphone has a prominent red center and a black rim.

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The Role of Typography in Differentiating Look-Alike/ Sound-Alike Drug Names

Sandra Gabriele

Abstract

Until recently, when errors occurred in the course of caring for patients, blame was assigned to the healthcare professionals closest to the incident rather than examining the larger system and the actions that led up to the event. Now, the medical profession is embracing expertise and methodologies used in other fields to improve its own systems in relation to patient safety issues. This exploratory study, part of a Master's of Design thesis project, was a response to the problem of errors that occur due to confusion between look-alike/sound-alike drug names (medication names that have orthographic and/or phonetic similarities). The study attempts to provide a visual means to help differentiate problematic names using formal typographic and graphic cues. The FDA's Name Differentiation Project recommendations and other typographic alternatives were considered to address issues of attention and cognition. Eleven acute care nurses participated in testing that consisted of word-recognition tasks and questions intended to elicit opinions regarding the visual treatment of look-alike/sound-alike names in the context of a label prototype. Though limited in sample size, testing provided insight into the kinds of typographic differentiation that might be effective in a high-risk situation.

This paper reports on a portion of a Master's of Design in visual communication design thesis project. The larger study examines how information design (an area within visual communication design concerned with the clarity of information to facilitate understanding) might lessen medication error caused by confusion of look-alike/sound-alike drug names. The purpose of this exploratory study was to develop appropriate design proposals and testing protocols for evaluation and analysis. Included was the design and testing of medicine labels in terms of content (the presence or absence of information), composition/layout (positioning, prominence and grouping of information) and typography (choices regarding the visual attributes of typographic forms) for drugs that are repackaged in acute care hospital pharmacies and sent to nursing units. The portion of the study described here demonstrates how principles of typography might help to differentiate look-alike/sound-alike drug names.

Designing for People: Human Factors and User-Centred Design

For a number of years, human factors professionals have proven to be successful at looking into complex systems to deter-

Figure 1. Contribution of packaging and labelling to medication errors

Elements of Design	Packaging and Labelling Concerns
Content	<ul style="list-style-type: none"> Inadequate warnings about proper drug use Prominence of company logos versus information that identifies the product
Composition/Layout	<ul style="list-style-type: none"> Lack of prominent placement of drug name and strength Insufficient prominence given to route of administration (e.g., nasal vs. injection, intravenous vs. intramuscular) Poorly designed or cluttered labels Similar-looking labels or packages of different products
Typography	<ul style="list-style-type: none"> Small size and poor readability of printed information Lack of differentiation between drug products that have similar names
Colour	<ul style="list-style-type: none"> Poor use or absence of colour to differentiate products
Visuals	Not Applicable

(Adapted from USP 1998)

mine root causes in aviation accidents and large-scale systems failures, such as nuclear disasters and blackouts. Healthcare providers, concerned with incidents of error, are taking measures to help reduce the occurrence of adverse events by making use of the practices of human factors engineering that have been successful in other domains (Kohn et al. 2000).

Information designers have concerns parallel to those of human factors specialists. Both are interested in how the end user interacts and behaves in relation to a designed artefact, whether it is a product, an environment or a visual communication. The information designer is concerned specifically with how his or her designs mediate communication for the user. Designers develop a “prediction” or potential solution with the intent to affect changes in a situation or user behaviour. In order to do this, the designer must become well acquainted with the problem and understand the user’s information processing in relation to the product or system and the environment in which it is used (Popovic 1999).

Psychologist and author Donald Norman (1990) recognizes that human beings routinely make errors and that designers should bear this in mind. Norman believes designing with a user-centred philosophy allows for examination of the interaction between humans and their “machines.” The success of this relationship is especially critical in any high-risk environment where errors can arise due to shortfalls on either side, contributing to accidents.

Medication Errors: Why They Occur

Professor James Reason (2000a), a leading authority on the topic of human error, believes that error in medicine can be viewed from a “person” approach or from a “system” approach. This is illustrated in a study conducted by the United States Food and Drug Administration (FDA 2002) in May 2001, in which reports of 265 cases of medication errors were reviewed and classified by cause. Human factors and communication accounted for 61% of incidents, while systems errors – labelling, packaging/design and name confusions – accounted for 39% (Thomas et al. 2001). By understanding human cognitive and physical capabilities and limitations in relation to the visual communication materials involved during the medication process, there is an opportunity for designers to intervene with visual solutions that may help minimize the occurrence of error.

Labelling and packaging concerns were cited as contributing to medication errors in an analysis of the U.S. Pharmacopeia (USP) medication errors database in a one-year period beginning June 1, 1996 (USP 1998). To help identify areas where improvements might be made from a design perspective, items listed in this report were categorized into the elements that shape visual communication design materials: content, composition/layout, typography, colour and visuals (Figure 1). One of the factors that can contribute to the administration of an incorrect medication is the confusion that can arise with look-alike/sound-alike drug names, those where the name is close to

another orthographically (in written form) or phonetically (in spoken form) (Figures 2, 3).

Figure 2. Orthographic similarity

Hydroxyzine – Hydroxyzine
Hydralazine – Hydralazine

Figure 3. Phonetic similarity

Zantac – /Zæntæk/
Zyrtec – /Zirtek/

Addressing the Problem of Look-Alike/Sound-Alike Drug Names

In recognition of reported incidents of error involving 16 specific look-alike/sound-alike drug pairs, the FDA (2002) developed the Name Differentiation Project, a recommendation to pharmaceutical manufacturers to voluntarily change the appearance of these names. They suggest cueing a part of the look-alike/sound-alike names with a change from lowercase to uppercase characters or “tallman letters” (Figure 4). Based on a series of controlled laboratory experiments, Filik et al. (2006) recently reported, “... studies suggest that tall man letters can make similar names less confusable perceptually and can increase attention to high-risk drug names.” The notion of visually differentiating names is a point of departure for this study, in which typographic variations were tested with acute care hospital nurses to see if cueing might help them to differentiate drug names.

Figure 4. Name Differentiation Project and use of “tallman letters”

Bupropion – BuPROPion
Buspirone – BusPIRone

Engaging and maintaining the attention of the nurse throughout the medication use process is crucial in ensuring

the patient receives the correct drug. James Reason (2000b) states that slips and lapses occur while performing routine tasks and are a result of automatic, unconscious processes. These types of errors take place when attention is diverted, whether by a distraction in the immediate surroundings, by preoccupation with something, or because of some type of change in the current plan of action.

By understanding that attention span is selective, has a limited capacity based on the task at hand and does not usually last very long, designers can influence a user’s behaviour. Because viewers are attracted by things that are distinctive and novel, visual strategies such as the use of contrast, making elements large, bold and clear and highlighting and isolating relevant information will help to attract attention and facilitate understanding (Pettersson 2001).

While the FDA’s recommendation is a positive step toward avoiding name confusions and error in the differentiation of the original 16 name pairs, indiscriminate use of the basic principle by applying “tallman letters” to drugs that are not on the list might lead to further confusion if the cueing is inconsistent. In addition, typographic principles and legibility research suggest that varying the visual attributes of a typeface, other than changing the case, would more effectively help to differentiate names.

We recognize words through the interactive processing at the levels of *feature*, *character* and *word*, with input from a higher level of semantic information (McClelland and Rumelhart 1981; Larson 2004). This model supports the idea that attention to features might help show differentiation within look-alike/sound-alike names and act as a comprehension cue. Observing some design characteristics of uppercase characters, one should note that their construction does not provide sufficient distinctiveness in features from character to character, because in form they are not as varied as their lowercase counterparts. Only seven characters in the uppercase set are made up of a combination of straight and curved strokes, as against fifteen in the lowercase set. Fifteen characters in the uppercase set are made up of straight lines, as opposed to eight in the lowercase set. This illustrates the lack of diversity in the design of uppercase characters – one reason why they are more difficult to discern. Some typefaces do not make a clear distinction between the lowercase “l” the uppercase “I” and the numeral “1,” which might lead to further confusion with look-alike/sound-alike drug names (Figure 5). This problem is worsened by the resolution capability of the media on which it is printed or displayed. With low-end inkjet printers (a fairly standard type of printer used in hospital pharmacies) and computer monitors, the quality of small type can be extremely poor, making drug labels difficult to read with accuracy. Most typefaces designed for print don’t automatically translate into legible text when used for screen applications. Only recently have typefaces designed specifically for this use become widely available. To compensate for technical short-

comings, the typeface designer must consider the technology that will be used for print or electronic display.

Figure 5. Lack of distinction between lowercase "l," uppercase "I" and numeral "1"

Typeface - Bodoni Book

Typeface - Gill Sans

of the designer, can serve as a guide for the development of effective visual communications. Initial designs are often based on some combination of the designer's experience – what scientists might call a “hunch” – preliminary expert and user input and existing literature. Because design is an iterative process, interim assessments, testing and final evaluation are essential.

Figure 6. Use of uppercase characters for emphasis

Pharmacy-generated medication labels often use uppercase characters to show emphasis.

Legibility and Contrast

Perhaps a reason that a better alternative has not been considered is that, from a pharmacy perspective, limitations in computers, printers and existing software have not allowed for alternatives such as boldface characters or graphics. For many years, the only method of accentuating information was the use of all-uppercase characters (Figure 6). The continued usage is based on standard practices rather than what might work more effectively if considering principles that designers draw upon to accentuate information. While this study included the recommended change between lowercase and uppercase characters to differentiate names, as a point of departure and comparison, it looks further to find alternatives that may have more visual impact while maintaining legibility.

Design researcher Ellen Lupton (2003) notes that the field of typography “remains ruled, largely, by convention and intuition.” Studies on legibility are conducted for the most part by psychologists and human factors and human-computer interaction specialists. It is important to note that although legibility studies provide valuable information in particular contexts and under specific circumstances, they cannot be generalized with certainty and used indiscriminately in all situations. In line with a user-centred approach, final designs, containing the specific content, character sizes, line lengths, etc., require testing in their intended context and with the user in their work environment, performing a specific task. Even though they are limited in their applicability, studies in legibility, combined with the experience

Contrast serves to punctuate, draw attention to and clarify elements by placing them in opposition to each other (Dair 1967; McCreight 1996). Typographic contrast is achieved by differences in the visual attributes displayed by type. These are, typestyle (serif or sans serif), typeface design or family, weight (light, medium, bold), stance (roman, italic), character width (regular, condensed, expanded) and case (uppercase, lowercase, small caps). Graphic devices (rules or lines, shapes) and spacing (character, word and line spacing) can be used in place of or in conjunction with contrasting type arrangements to highlight or cue text (Figure 7). When combined with verbal cues, meaningful or natural breaks that occur in text, they act as emphasis to capture attention and facilitate understanding. Typographic design strategies were guided by principles of typography and legibility research and by a visual exploration of variations that were assessed on their ability to create emphasis and contrast (Figure 8).

Final designs (Figure 9) selected for testing were based upon the desire to simplify the choice for participants while providing a variation in degree of contrast in terms of the “colour” of the text. In typographic terminology, *colour* refers to the grey value created in typeset text. Colour varies according to the visual attributes of a typeface and the amount of letter, word and line spacing (Ruegg 1989). For example, boldface text looks darker in colour than lightface.

Figure 7. Visual attributes and graphic devices for distinguishing text

Visual Attributes		Graphic Devices	
Typestyle	Serif Sans Serif	Rules	Rules
Typeface	Garamond Bodoni	Shapes	shapes
Weight	Light Medium Bold		
Stance	Roman <i>Italic</i>		
Character Width	Condensed Regular Expanded		
Case	UPPERCASE lowercase SMALL CAPS		

Figure 8. Exploration of typographic attributes and graphic devices to distinguish text

Hydroxyzine Hydralazine	Hydroxyzine Hydralazine	Hydr oxy zine Hydr ala zine
Hydroxyzine Hydralazine	Hydroxyzine Hydralazine	Hydro OXY zine Hydr ALAZ ine
Hydro oxy zine Hydralazine	Hydro oxy zine Hydralazine	Hydro oxy zine Hydr ala zine
Hydroxyzine Hydralazine	Hydroxyzine Hydralazine	Hydroxyzine Hydralazine
Hydroxyzine Hydralazine	Hydroxyzine Hydralazine	Hydroxyzine Hydralazine
hydrOXYzine hydrALAzine	hydr OXY zine hydr ALAZ ine	Hydroxyzine Hydralazine
hydr OXY zine hydr ALAZ ine	Hydralazine Hydralazine	Hydr oxy zine Hydr ala zine

The typographic variations consisted of

- The least extreme, a contrast in case – a change from lowercase characters to uppercase characters
- A middle ground, a contrast in weight – a change from medium-weight characters to boldface (lowercase) characters
- The most extreme, a contrast – a change from black characters to white characters on a solid black rectangle

Testing Look-Alike/Sound-Alike Drug Names for Visual Attributes (Typography)

This exploratory study made use of a mixed-method approach to testing, using both quantitative and qualitative data collection. Quantitative information was used to examine error rates for each of the variations, while qualitative information was used to compare attitudes and opinions. Participants were 11 acute care hospital nurses. Three word-recognition tests were conducted to compare how effective the contrasts might be in making

names more memorable. Participants were given a stimulus list to examine for each test. Each contained seven look-alike/sound-alike names with one of the three typographic contrasts applied. This list was taken away and participants were shown a second list of seven names typeset in a single typeface that included distractor names, replacing some of the original names with their look-alike/sound-alike counterparts. Participants were asked to identify names they remembered from the first list. In a second test (Figure 10), participants were asked their to give their opinion regarding the ease in differentiating between drug names within a label context.

It was expected that participants would be more likely to accurately identify drug names with the version containing white characters on a black rectangle to differentiate parts of the name, than those that use boldface characters or uppercase characters. Also, it was expected that the version with boldface lowercase characters would be easier to identify than the version with uppercase characters, because of the higher contrast in stroke

Figure 9. Final designs chosen for testing. Final designs for testing were selected on the basis of legibility and the capacity to create emphasis.



Figure 10. Variations in a label context



weight and the variation in design that occurs in lowercase characters. The same outcomes were expected in terms of what nurses would perceive to be the easiest to distinguish.

Results

With the word-recognition tests, contrary to the expected outcomes, participants recognized more names with the use of uppercase characters than with boldface characters. However, as expected, white characters on the black rectangle seem to be most helpful in differentiating names (Figure 11). Consistently with the expected outcomes, when participants were asked which versions were better at helping to distinguish names, comments indicated that most of them perceived that differentiating the name with uppercase characters did not make the names distinctive enough. Opinions were split evenly on the versions that used the boldface characters and those that used white characters on a black rectangle (Figure 12).

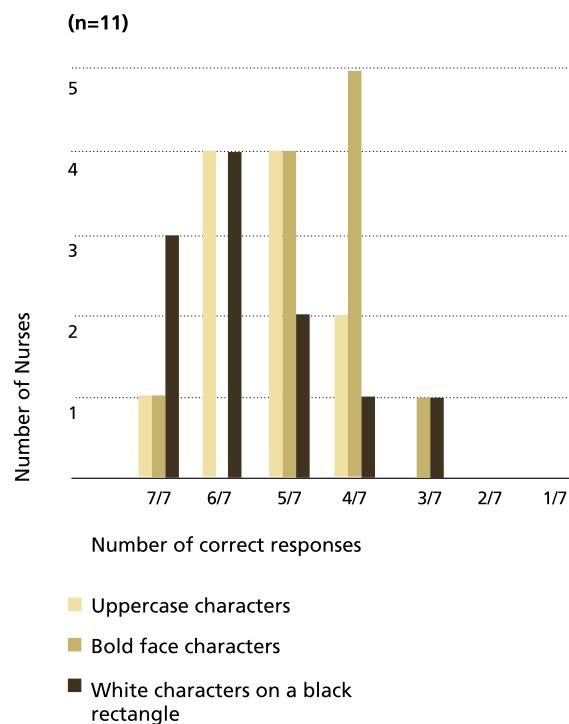
A Look to the Future

This study was concerned with the problem of errors in medicine caused by confusion with look-alike/sound-alike drug names and how the application of typographic choices might help to minimize their occurrence. Though limited in sample size, the testing conducted with the end users indicated that the methods developed could be used with success in a larger study.

In terms of effectiveness with the use of typographic contrast to help differentiate look-alike/sound-alike drug names, this study indicated that a stronger degree of contrast than that provided by "tallman letters," specifically, white text on a black rectangle, might help to make names more recognizable. Further research with a larger sample size is required to make concrete recommendations. While word-recognition tests are helpful in comparing the difference that typographic contrasts make in making names more or less memorable, further research should include task-based testing that simulates the medication process and the testing of names in their context, on label prototypes.

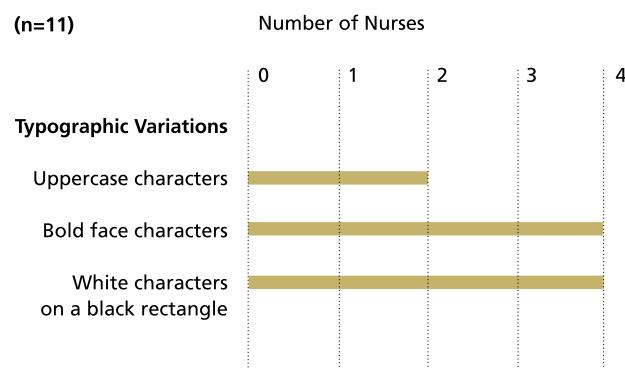
To promote safety in the healthcare environment, every effort should be made to help minimize risk to patients. A positive step toward this end would be to incorporate visual communication design practices, and specifically typographic principles and legibility studies, in the production of packaging and labelling.

Figure 11. Results of word-recognition tests



Word recognition tests, comparing the performance of typographic variations to help differentiate look-alike/sound-alike drug names.

Figure 12. Results of test of perception regarding use of typographic variations



Note: One nurse expressed the opinion that none of the choices helped to differentiate names

Test comparing the perception of nurses regarding the use of typographic variations to help differentiate look-alike/sound-alike drug names.

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Patient Safety in a Pediatric Centre: Partnering with Families

Bonnie Fleming-Carroll, Anne Matlow, Siobhan Dooley, Valerie McDonald,
Kimberley Meighan and Kim Streitenberger

Abstract

Patient Centred Care (PCC) is a recognized pillar of quality healthcare. According to the Institute of Medicine (Kohn et al. 2000), PCC respects and is responsive to individual patient preferences, needs and values, and ensures they guide all clinical decisions. In a pediatric setting, both the child and family's preferences and values are critical; as a result, the concept of PCC is broadened to include the entire family, and is termed Family Centred Care (FCC). True FCC requires transparent and ongoing collaboration between the child, family, and all members of the healthcare team.

An institution's commitment to Family Centred Care must be explicit and permeate all aspects of healthcare provisions. At Toronto's Hospital for Sick Children (SickKids), the Families as Partners in Patient Safety Committee has proven to be a successful initiative based on Family Centred Care principles. This interdisciplinary committee includes healthcare providers, parents and representatives from our hospital's Children's Council. The mandate of the group is to: (1) identify patient safety (PS) issues, (2) make recommendations to improve PS and (3) increase awareness and promote the partnership between parents and staff in PS. Key initiatives to date include developing PS information for families, a combined hand hygiene campaign and a campaign

to make the hospital 100% smoke-free. A task-oriented partnership between families and healthcare workers has proven to be a productive model for advancing pediatric patient safety.

Introduction

Enhancing patient safety in healthcare settings has been attaining much-deserved attention from both healthcare consumers and providers. Both the US report *To Err Is Human: Building a Safer Health System* (Kohn 2000) and the Canadian report *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care* (National Steering Committee on Patient Safety 2002) served as calls to action to make system-wide changes in order to improve patient safety.

In a healthcare environment focused on caring for acute and chronically ill children, ensuring safety takes on a particularly important role. Both patient factors (including developmental change, dependency on adults, different disease epidemiology and demographic characteristics) and healthcare provider factors can contribute to vulnerabilities in pediatric care. Patient complexity, clinical specialization, rapidly advancing technology and unique issues such as entanglement with equipment and accidental falls further add to the challenge. Furthermore, depending on their developmental stage or level, children may

not be capable of bringing risk to the attention of healthcare providers, therefore removing an important defence against error. These considerations make it not only intuitive to involve children and families in developing a patient safety culture in pediatrics, but essential.

From the few published studies reporting the incidence of adverse events (AE) in hospitalized children, AE rates appear lower in children than in adults. Retrospective data from chart review and administrative databases suggest that the overall rate of AEs is approximately one per 100 discharges (Woods et al. 2005; Miller et al. 2003; Miller and Zhan 2004). However, given the limitations of retrospective methodologies, the rates of AEs in hospitalized children are likely much higher. More recently, two prospective studies, focusing on adverse drug events (ADEs) alone, have reported an ADE rate of 2.3 to 6 per 100 admissions, with a potential ADE rate up to 10 per 100 admissions (Kaushal et al. 2001; Holdsworth et al. 2003). Applying trigger tool methodology to the pediatric population may further reveal the true incidence of AEs in pediatrics (Matlow et al. 2005).

In response to the need for safe care of children, SickKids developed a Blueprint for Safety (Stevens et al. 2005) made up of 10 key components: leadership and culture; management of critical occurrences; external surveillance; internal surveillance; policies, procedures and guidelines; staff education; partnering with patients and families; program coordination; proactive risk assessments and audits; and evaluation and research. This paper explores a strategic action-based initiative that highlights children and families as key stakeholders in safety. While addressing some of the above components, the Families as Partners in Patient Safety Committee emphasizes the partnership between healthcare providers and children and families in ensuring safe care.

Family Centred Care and Patient Safety

Patient Centred Care (PCC) has been identified as a key component to delivering safer care (Kohn et al. 2000). In pediatrics, the concept has been expanded to include the family, as each child exists within the family system. The importance of involving patients and families as partners in healthcare is underscored by a recent publication from the Joint Commission on Accreditation of Healthcare Organizations, entitled *Patients as Partners: How to Involve Patients and Families in Their Own Care* (JCAHO 2006). This publication and others have highlighted the positive impact Family Centred Care has on patient safety (Berntsen 2006; Uhlig et al. 2002). At SickKids, the philosophy of Family Centred Care has influenced policy, strengthened programs, aided in facility design and helped shape day-to-day interactions among children, families and healthcare providers (Cheney 2004). There is an accepted understanding of the family as the child's primary source of strength and support, and the child and family's perspectives and information are valued

in clinical decision-making (Franck and Callery 2004). Family Centred Care is threaded throughout the processes of patient care, education and research, as well as across broader hospital systems. Individual practitioners collaborate with children and families on a daily basis to share information, formulate mutual goals and partner in care. On a systems level, families are integrated into training for healthcare providers, organizational strategic planning and hospital committees. This broad application of Family Centred Care principles facilitates the integration of the child and family as collaborative partners at all levels of the healthcare team (MacKean 2005).

Integration of Family Centred Care across the organization complements our commitment to patient safety. Parents have a vested interest in helping healthcare providers make sure their children are cared for in a safe environment. Partnering with families about patient safety has highlighted the families' role in educating staff and also increased the lines of defence against error. Through this initiative, SickKids has reinforced its commitment to Family Centred Care and actively embarked on building a culture of safety through collaboration and partnership.

Families as Partners in Patient Safety Committee

Children and families have insights that are unique and are critical to successfully moving initiatives forward. SickKids has embarked on a partnership with families to ensure the safety of their children through the Families as Partners in Patient Safety Committee. The committee was established to provide leadership in supporting and promoting the partnership between families and healthcare professionals. This interprofessional committee includes healthcare professionals, parents and representatives from the hospital's Children's Council. Having family members and a Children's Council representative on the committee has enhanced the dialogue and supported a shift toward implementing a shared culture of patient safety (Berntsen 2006; Ponte et al. 2004).

The need for interprofessional representation on the committee is also essential for positively influencing patient safety culture and quality of care. Patient safety can be a sensitive topic for professionals; it is essential that the committee structure allow a safe environment in which all members feel comfortable to communicate and share safety concerns, supported by leadership that fosters openness and communication free of blame (Ponte et al. 2004).

The mandate of the committee includes: (1) identifying patient safety issues and potential contributing factors, (2) making recommendations for strategies that may include policies/procedures/frameworks to improve patient safety, (3) implementing change and evaluating the outcome in improving patient safety, (4) developing communication strategies for increasing the awareness of and for promoting the partner-

ship between families and staff in patient safety and (5) sharing leading practices locally, nationally and internationally.

Safety Initiative Highlights

The committee remains committed to action-oriented initiatives. In addition to brainstorming around the committee table, we sought the input of our Children's Council on issues they considered to be of concern from a patient perspective. Their suggestions are outlined in Table 1.

The following are four of the current priorities our committee identified and tackled (see Table 2 for details):

Patient Safety Information for Families

Recognizing the important role patients can play at each stage in their care, the Ontario Hospital Association (OHA) recently developed a provincial patient safety initiative entitled "Your

Table 1. Patient safety suggestions from the Children's Council

- Make sure playrooms are safe in both in- and outpatient areas
- Make sure kids in infectious diseases clinic follow infection control precautions
- Have a key for the closets in the patient rooms that you sign out from the front desk to use while you are here to keep your stuff safe
- Lockers for families with a padlock like you would have at a fitness gym
- Check on kids who are alone in inpatient rooms frequently to make sure they are safe
- Make sure little kids cannot strangle on I.V. tubing
- Improve the lighting in the parking garage
- Escort service with security for the parking garage
- Cars double parked/stopped on the driveway makes it unsafe
- No smoking on property and especially around the entrances to the hospital

Table 2. Families as partners in patient safety: current and future initiatives

Initiatives	Rationale	Strategies	Next Steps
OHA pamphlets Sick Kids pediatric focused information for families	To support families in becoming safety advocates for their children To utilize families as a partner in ensuring safe care To positively affect pediatric safety broadly	Market OHA brochure internally: posters throughout hospital in multiple languages Paper copies available Link on Sick Kids website to OHA website Pamphlet in multiple languages Development and production of a pediatric-specific safety pamphlet to complement OHA material Advocate for OHA to develop a pediatric version to address needs outside of Sick Kids	Distribution of new pediatric safety pamphlet with hospital family guidebook Development of risk reporting system for children and families (CCU pilot) Development of Welcome to a Sick Kids Committee pamphlet for new family members to support them in their role as committee members
Hand hygiene campaign	To identify safety concerns that broadly affect all or most clinical settings To identify safety concerns for which parents and children can partner with healthcare providers to improve care on an ongoing basis	Mobile cart developed with patient and family education materials and activities to heighten awareness of importance of hand washing	Proposed stationary handwashing booth scheduled for fall 2006 in high traffic area Evaluation-audits, satisfaction questionnaires Investigate safety concerns of "Heelies" – shoes with wheels
Smoke-free hospital	To identify organizational/system changes that support the safety of children and families	Compelling signage Letter to parents explaining reason for change Letter to staff explaining reason for change Patrolling by security staff support effective Communication for security staff	Advocate painted boundaries on sidewalk around hospital property Compliance audits Advocate regular monitoring of grounds Continued awareness campaign through hospital communication systems Looking into effect of smoke on clothing of staff – possible uniform policy change
Patient safety Sharing knowledge International conference Speakers Written materials Research	To promote knowledge transfer locally, nationally and internationally	1st Annual Safety Conference (2005) 2nd Annual Safety Conference (2006) Hospital-wide patient safety rounds held Regularly invited speakers <i>Partners in Patient Safety</i> newsletter	Education for staff acknowledging our need and expectation for families to speak up about safety – integrate a safety talk into orientation of new staff; use our communication tools, i.e., safety newsletter

Health Care – Be Involved” (OHA 2004). This initiative includes multilingual informational pamphlets, posters and multimedia presentations for patients designed to empower them to become more active in their healthcare. An implementation tool kit was distributed to hospitals throughout the province, and the posters and pamphlets were made available at key entry points to the hospital. The committee reviewed the material to ensure applicability in the pediatric setting. A patient safety section was established on our hospital’s website where patients and families and healthcare providers could easily access the pamphlets in a variety of languages as well as the multimedia presentation. During the hospital-wide implementation of the initiative, our committee identified the need to develop information and tools specifically designed to focus on the unique needs of pediatric patients and families (e.g., using simpler language, targeting substitute decision makers, advising on unique aspects of pediatric medication safety, having child-friendly graphics, etc). The group worked collaboratively with a variety of internal stakeholders including the Children’s Council, the Family Advisory Council and interdisciplinary healthcare professionals to develop a pediatric-specific safety informational pamphlet for use at SickKids that would supplement the provincial program. Through our advocacy concerning the uniqueness of child safety issues, discussion is currently under way at OHA to develop pediatric-specific resources to meet the needs of children and families throughout the province.

Hand Hygiene Campaign

The importance of hand hygiene in preventing infection has recently been underscored by the World Health Organization’s World Alliance for Patient Safety, which includes hand hygiene as one of its initiatives (Pittet and Donaldson 2006). Interest in improving hand hygiene practices at SickKids was generated following a presentation made by Infection Prevention and Control to the committee. As well, handwashing practices were identified as inconsistent by our parent representatives. An interdisciplinary task force was formed to develop a unique approach to improve hand hygiene compliance by engaging patients and families as part of a multimodal approach to improvement. The concept involves a mobile cart, the “Bug Buggy,” which is taken to areas of the hospital with high volumes of patient activity where patients and families can engage in a variety of learning activities – with printed information, DVDs, books and other products – related to hand hygiene. Trained volunteers are present to provide information and to supervise the activities. In addition to raising awareness and educating patients, families and visitors about hand hygiene, the new culture is intended to empower patients and families to articulate their expectations about it.

Once the program has been fully implemented, it will be evaluated through patient and family satisfaction surveys, by

the volume of access to the cart materials and by ongoing hand hygiene practice audits performed by the Infection Prevention and Control Program.

No Smoking on Hospital Property

In 2006, the Families as Partners in Patient Safety Committee recommended to the hospital’s executive team a change in smoking policy, and an extension of the hospital’s no-smoking zone to include the entire property. The recommendation was made after extensive discussion with parents and patients expressing concerns about second-hand smoke at hospital entrances and other areas of hospital grounds. The executive endorsed the committee’s recommendation and revised its policy, effective May 1, 2006. The committee was also instrumental in developing the policy’s marketing campaign, which involved compelling signage designed by parents that included children’s faces and written information for parents and staff. The committee felt the campaign would be effective if the focus of the smoke-free environment was the health of all vulnerable children.

We are working to integrate an education program to assist security personnel to sensitively approach staff and families and to direct them to where they can smoke. We are negotiating routine patrolling of the grounds. Our next step is to complete audits to determine rates of noncompliance, which is slated to start within the next three months.

Sharing Patient Safety Knowledge

Espousing and promoting the values of Family Centred Care has been a key determinant in designing and hosting an annual pediatric patient safety symposium. The initial symposium entitled “Partners in Pediatric Patient Safety: Taking Care of the Kids” was held in June 2005. The opening talk was delivered by a family member who had lost a child through medical error (Keatings et al. in press), setting the stage for further presentations describing strategies required and efforts currently under way to create a culture of safety for children. Workshops included those dedicated to cultural diversity and transitions in care.

This year’s symposium was entitled “Partners in Pediatric Patient Safety: Solutions and Perspectives from Around the World.” Pediatric Patient Safety experts were convened from Australia, the UK, the US and Canada, providing a global look at key patient safety issues including the nature of a culture of safety, information technology solutions, hospital-acquired infections and learning from critical occurrences. One module was devoted specifically to issues involving the family as partners, and included a talk on cultural and linguistic competence, simulation as an aid to improving provider-family communication, and a talk by a family member of the Families as Partners in Patient Safety Committee, promoting the committee as a model of working together.

Overcoming Barriers to Integrating Children and Families

One of the most difficult barriers to integrating parents and children into our safety initiatives has been scheduling issues. The majority of parents work, and children have school commitments that do not allow much flexibility for involvement. We have tried to be flexible by scheduling meetings in the middle of the day in order for parents to get their children to and from school, or in the early evening. We have supplied family members with parking passes to alleviate the cost of parking. We also utilize e-mail in order to communicate and get feedback in a timely manner. Children's voices are also heard through a representative from our Child Life, who sits on the hospital's Children's Council and the Families as Partners in Patient Safety Committee to act as a liaison representing the children's perspective.

In recruiting parent representatives, we have found that targeting parents in specific clinical areas seems to be successful. Having a relationship with the family helps when approaching a parent. We also try to prioritize the committees for which families would have the most impact. Recruiting parent members who were also members of the Family Advisory Committee is useful, since they come with an understanding of their role as parents on a committee. Future developments include an orientation pamphlet to address committee membership to help welcome and socialize parents into the group.

Another barrier to involvement has been the inability for family members to access our computerized risk reporting system. Currently, this can only be used by hospital staff for real-time risk reporting. Parent members felt strongly that there needed to be a way for parents to identify safety issues in real time. In order to address this, we are piloting a safety suggestion box in the Critical Care Unit to see if this is an effective way to capture parent feedback, which can be anonymous if desired.

We have continued to strengthen the commitment to safety by aligning the work of the committee to our strategic directions. Safety is a major priority of the hospital, and this is evident by the new reporting structure that links the committee directly to the executive.

Conclusions

The Families as Partners in Patient Safety Committee has been a model of "teamwork" around the committee table, focused on improving patient care. Our committee has become a driving force for patient safety initiatives and has contributed to building a safety culture. Discussions between staff and families have allowed risk issues to surface and proactive strategies to begin. The committee members seek and encourage participation in the development and implementation of select initiatives. This networking across the organization has facilitated organizational expectations and attitudes regarding patient safety.

Collaborating with families as partners has helped build trusting relationships. Not only are the family members on the committee a part of the system of safety, but the goal is to welcome all families at the hospital as safety advocates. Future directions include encouraging families to identify safety issues in real time through "Safety Cards" they can fill out and deposit in boxes on each unit, involving children and families in actively reminding staff to kindly wash their hands before engaging in patient care, and focusing on educating staff on how to communicate and collaborate with children and families who identify safety issues directly. The Families as Partners in Patient Safety Committee is an innovative approach to creating a system of safety in a high-risk pediatric environment. One parent committee member states, "This exceptionally productive committee is a stellar example of effective family, staff and patient collaboration. ... the combined perspective of the different members provides a very comprehensive approach to improving patient safety."

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"Your Health Care – Be Involved": The Evaluation of a Provincial Patient Safety Tips Initiative

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Abstract

When patients take an active role in their healthcare, the results may be better, safer care. That is the premise behind the Ontario Hospital Association's (OHA) "Your Health Care – Be Involved" campaign. Launched in September 2005 by the OHA's Patient Safety Support Service, the campaign encourages active two-way communication between patients and providers and highlights the important role of patient involvement in the form of five patient safety tips. This article discusses the development, implementation and evaluation of Ontario's first-ever patient safety tips program, and what its future might hold.

Introduction

Patient safety consumer advocates in the United States have stressed the importance of consumer participation in the patient safety movement (Hatlie 2004). In October 2004, the World Health Organization launched the World Alliance for Patient Safety. One of the six action areas of the World Alliance is "Patients for Patient Safety" (PPS), a group designed to ensure that the perspective of patients and families helps shape the Alliance's work. PPS works from the premise that patients and their families have a meaningful role to play in patient safety, and that safety can be improved if they are included as full partners in reform (World Health Organization 2004).

Several jurisdictions have attempted to more fully involve patients in patient safety through the use of patient safety "tips" programs. The United States, the United Kingdom and Australia, as well as the provinces of British Columbia, Nova Scotia and Quebec, have used patient safety tips campaigns to convey safety messages to patients.

However, a recent article in the *Joint Commission Journal on Quality and Patient Safety* (Entwistle et al. 2005) has cautioned against the use of "consumer advisories" such as tips campaigns. The authors analyzed the development and content of five leading safety advisories and conducted 40 interviews with individuals from federal agencies and national organizations, researchers and consumer advocate groups. Concerns highlighted include the limited involvement of patients during development, missed opportunities to inform patients about patient safety practices and an uncertainty over how the advisory messages would be reinforced by providers. Another important concern was that advisories might be perceived as a shift of responsibility for safe care from providers to patient. Therefore, there is a need for campaigns to include better process development and evaluation components.

Campaign Development

The Ontario Hospital Association (OHA) is the voice of

Ontario's hospitals. Since 1924, it has been a leader in shaping the future of the healthcare system, fostering excellence, building linkages with the community and advocating on behalf of its members for a sustainable system that meets patient care needs.

In June 2004, the OHA's Patient Safety Support Service (PSSS) was approached by Ontario's Ministry of Health and Long-Term Care (MOHLTC) to develop and implement a patient safety tips campaign that would increase Ontario healthcare consumers' knowledge of the role they can play in improving their health outcomes and their safety. The campaign, which would be the first of its kind in Ontario, would focus on patient empowerment and involvement through active, two-way communication between patients and providers. The campaign was to be province-wide, ongoing and accessible to the average Ontarian.

Despite the existence of materials and campaigns in other jurisdictions, both the concept and the specific messaging needed to be developed and tested for an Ontario patient and provider population. A list of 31 tips used in other jurisdictions was gathered and clustered under the following six topic areas: general patient safety tips, treatment, infection control, medication, falls avoidance and surgery.

Provider and patient focus groups were conducted in Toronto and North Bay. The purpose of the focus groups was to gauge reaction to the idea of a list of patient safety tips, and to isolate the top five tips that resonated most strongly with patients and would be accepted by the healthcare team.

These groups settled on the five tips that were most meaningful from their perspective. The specific wording of the tips was refined through a series of consultations with OHA members and provider associations such as the Ontario Medical Association, the Registered Nurses Association of Ontario and the Ontario Pharmacists Association. The final list of five tips was converted to a Grade 6 literacy level and translated into 13 languages.

Branding

"Branding" is a term used by advertisers to describe the process of packaging the essence of a product or concept in a few brief, memorable words. The branding strategy developed for the campaign was based on the findings of the focus groups and on

Figure 1. Campaign poster



the following principles:

- The desire not to brand the campaign as "patient safety," as this did not have much meaning for patients
- The desire to focus on patient involvement rather than on patients as guardians of safer care
- The desire to stress patient involvement as a member of a team rather than giving patients the impression that the onus for their care was being shifted to them
- The desire for the messaging to be applicable to hospitals as well as to the community sector

The campaign was branded "Your Health Care – Be Involved." A list of the tips is contained in Figure 1.

Campaign Elements and Media Strategy

The OHA developed a detailed, multipronged strategy to launch the "Your Health Care – Be Involved" campaign. The

first prong, aimed at hospitals, consisted of several communiqués addressed to hospital administrators and communicators that shared campaign details and timelines. A slide deck was developed to assist hospitals with internal and external campaign messaging and promotion, and was included in a hospital tool kit designed to inform stakeholders about the internal rollout strategy.

The elements of the campaign included a brochure (containing information on all five tips, a tips wallet card and a patient information summary form), a large plaque-mounted poster (Figure 1), acrylic brochure holders and a four-minute DVD campaign "infomercial" for use during in-hospital television programming. All bilingual hospitals were sent materials in both English and French. Materials were sent to hospitals in advance of the campaign to give them the time to prepare, and to ensure the campaign was simultaneously launched in all Ontario hospitals.

The second prong of the campaign was to use the electronic and print media, as well as limited paid advertising, to promote the campaign to the general public. The campaign was launched at a press conference at the Toronto East General Hospital on September 13, 2005. Notices and materials were distributed to media outlets across Ontario, materials were made publicly accessible through the OHA website and articles about the campaign appeared in local media and health trade magazines. Paid transit-system advertisements were also used in 16 cities throughout Ontario.

The final prong of the campaign, which is ongoing, focuses on community outreach. As such, the OHA is actively working at spreading the campaign and reach by partnering with groups such as the Ontario Seniors' Secretariat and the Association of Ontario Health Centres. The OHA is also working with the Ontario College of Pharmacists and the Canadian MedicAlert Foundation to inform their members about the campaign.

Evaluation

The "Your Health Care – Be Involved" campaign was evaluated as part of an overall evaluation of the OHA's Patient Safety Support Service.

Methodology

The evaluation of OHA's Patient Safety Support Service was conducted over a three-month period by PricewaterhouseCoopers LLP (PwC). Data collection included a variety of qualitative and quantitative methods. Three focus groups (one for providers and two for patients), a Stakeholder Satisfaction Survey and a Patient Survey were designed to address the campaign.

All focus groups were conducted by PwC. The patient groups were designed to assess the awareness and impact of the tips initiative from the patient's perspective and to identify areas for improvement. Discussion questions included "Have you heard

of the 'Your Health Care – Be Involved' campaign?," "Where have you heard about it?" and "Did you use any of the information and why?"

The provider focus group was tasked with assessing the impact of the campaign from the provider's perspective and identifying areas for improvement. Participants were recruited by telephone from a variety of locations across the province. Questions centred on the use and effectiveness of specific campaign elements and the overall successes and challenges.

The Stakeholder Satisfaction Survey was e-mailed to a group of stakeholders, the majority of whom are Directors of Patient Safety, Risk Management, Quality and Patient Relations. Participants were asked about their hospitals' tips dissemination strategy, the use and effectiveness of specific campaign elements and the overall effectiveness of the campaign.

The Patient Survey was an anonymous two-page self-report questionnaire designed to assess patient awareness and potential impact of the campaign. Research ethics approval was obtained from the Toronto Academic Health Sciences Network (TAHSN) Research Ethics Board. The six participating hospitals were recruited by telephone, and were sent English and French copies of the survey. Hospitals were asked to obtain a minimum of 20 completed surveys over a two-day period in June. Facilities were instructed to distribute the survey to patients in ambulatory clinic waiting rooms and to patients awaiting discharge on the day of survey administration. A total of 108 surveys were completed.

Patients were asked about campaign awareness and its impact on their communication with their healthcare team.

Results

Providers

Hospitals distributed the brochures in several locations including clinics (47%), patient resource centres/libraries (23%), admitting packages (28%), waiting rooms, lobbies, nursing units and common patient areas. Hospitals used a number of methods to promote the campaign internally and externally, as follows:

- Discussion at staff meeting (54%)
- Inclusion in hospital newsletter (44%)
- Posting on hospital website (21%)
- Article in local newspaper (14%)
- Advertisement in local newspaper (2%)
- Other methods (18%)

Although the campaign has only been in place for 10 months, two-thirds (66%) of stakeholders rated it "very effective" or "somewhat effective." Providers noted several positive outcomes as a result of implementing the campaign. They felt that the initiative was very helpful in reminding staff that patient care and safety is the hospital's core business. Many believe that the

campaign provided the opportunity for patient safety discussions at the senior management and board level; that it supported the hospital's patient safety and patient satisfaction programs; and that it was a simple, focused way to encourage hospital staff to focus on patient safety. Providers also felt that the initiative was well received by staff, particularly the concept of patient empowerment, and that new staff were impressed that the hospital "really cared" about patient safety. These benefits were viewed as positive and unexpected wins.

The concern most commonly cited by providers and patients was what they saw as the excessive length of the brochure. Respondents indicated that this, and the brochure's layout, limited cost-efficient hospital reproduction.

Patients

Findings from the patient focus groups suggest that while awareness of the campaign was low, patients were supportive of the five Patient Safety Tips.

The findings from the survey provide interesting insight into campaign awareness and impact. As reported in Table 1, patients were asked a series of questions about their communication with the healthcare team during their last visit to hospital. The results suggest that the majority of patients are communicating with their healthcare team in a manner consistent with the Patient Safety Tips. However, there is room for improvement in communicating information about medications (27% of patients did not bring their medications, or a list, to the hospital) and discharge instructions (16% did not know what to do once they left the hospital).

The survey also found that awareness of the "Your Health Care – Be Involved" program was not very high (Table 2). The results below indicate that only 17% of patients surveyed had heard about the program. The remaining survey questions were only asked of patients who were aware of the campaign and consequently the sample size is substantially smaller and is a limitation of this survey.

Table 2. Patient awareness of campaign

	n	Yes	No
Have you heard about the "Your Health Care – Be Involved" program?	124	17%	83%

Table 1. Patient communication during recent hospital stay/visit

Based on your current or most recent hospital stay or outpatient visit:	n	Yes	No	N/A	Yes with N/A Removed
Did you bring all of your medications, or a list of all your medications, with you to the hospital?	126	56%	27%	17%	67%
Did you tell the health team about any allergies that you have?	126	67%	9%	24%	88%
Did you tell the health team about any past illnesses that you have had?	127	77%	10%	13%	89%
Did you tell the health team about any current health conditions?	127	82%	7%	11%	92%
Did you ask your health team all the questions you wanted to?	124	90%	10%	0%	90%
Do you know what to do once you leave the hospital? (i.e., when to return to work, physical activities you should avoid, follow-up appointments, etc.)	115	84%	16%	0%	84%

The best method of informing patients about this campaign was through the hospital rather than through the limited media campaign (Table 3). Nearly one-half of patients who were aware of the campaign saw the brochures or posters in hospitals.

Table 3. Source of information

How did you hear about the "Your Health Care – Be Involved" program? (Check all that apply)	n	%
Booklet	21	48%
Posters in hospitals	21	48%
Public transit/bus shelters	21	14%
Hospital TV	21	14%
Ontario Hospital Association (OHA) website	21	10%
Hospital website	21	5%

In terms of usage of the elements of the campaign, one-third of respondents reported using the brochure and 14% used the summary form (Table 4).

Of the patients who were aware of the campaign, the majority felt the brochure was easy to understand (77%), relevant (59%), helpful (63%), practical (75%) and available in their preferred language (75%).

Table 4. Use of materials

Have you used any of the following "Your Health Care – Be Involved" program materials? (Check all that apply)	n	%
Booklet	21	33%
Wallet card	21	5%
Summary form (instructions for going home after discharge)	21	14%
Watched the DVD on hospital TV	21	5%
Ontario Hospital Association (OHA) website link	21	5%

To gauge the impact of the Patient Safety Tips on patients, patients were asked whether they had changed the way they communicated with their health team as a result of the Tips. There were only 15 responses to the question. Of those, almost half (47%) of the respondents indicated that they had changed the way they communicated with their health team as a result of having the "Your Health Care – Be Involved" information (Table 5).

Table 5. Impact on behaviour

	n	Yes	No
Have you changed the way you communicate to your health team as a result of having the "Your Health Care – Be Involved" information?	15	47%	53%

Discussion

Evidence of Success

From the OHA's perspective, the campaign has been highly successful. The OHA continues to receive requests for campaign materials from hospitals and community agencies across the province and across Canada, with a recent request for materials from the Yukon. To date, over 60 hospitals have requested additional supplies and 10 community organizations have requested their first shipment of materials. As community agencies were not involved in the original campaign, their interest and requests for materials speaks to the value and spread of the campaign.

Other, anecdotal evidence of campaign success includes the numbers of "hits" and downloads on the website and the requests for conference presentations and posters. The Patient Safety Support Service section of the OHA website and the patient safety tips subcategory continue to be some of the most active program areas. The campaign has been recognized nationally by the Canadian Patient Safety Institute (2006) as being

"one of the most comprehensive collections of patient safety tips, available in 14 languages." Recently, the OHA has received a request from a US publisher to reprint campaign materials in a guidelines manual to highlight "wonderful patient safety tools" from around the world.

The results from the PSSS evaluation indicate that both patients and providers are interested and enthusiastic about this type of campaign. Hospitals used and promoted the materials provided. Two-thirds of providers feel the campaign was effective or at least somewhat effective. Of particular interest are the "side benefits" providers report, such as the campaign fostering internal organizational discussions about patient safety and reinforcing existing patient safety programs. As with many patient safety initiatives, these "side benefits" are equally important in fostering a culture of safety.

Among patients, awareness of the campaign was low, which may be a result of a number of factors such as hospital dissemination strategy, the small media campaign and other competing hospital initiatives. However, patients seemed genuinely interested in and supportive of the initiative.

The results indicate that, while a large majority of patients surveyed already follow some of the behaviour suggested by the tips, there is still room for improvement in the areas of medication communication and discharge instructions. Of the patients who were aware of the campaign, the majority reported that they found the information useful and relevant.

Changing behaviour is challenging. Awareness of the Patient Safety Tips campaign was modest, and in light of the limited sample size, it is difficult to come to any conclusion about campaign impact on patient behaviour.

Key Learnings

Many key learnings have emerged from both the development and evaluation of the Patient Safety Tips initiative. One of the most important is that patients are ready to accept and use this type of information.

Other lessons learned include the importance of seeking upfront commitment from hospitals and healthcare providers. As the campaign focused on information-sharing and asking questions of healthcare providers, and relied on these individuals to promote and disseminate the information, it was essential to educate providers on this initiative prior to the launch. Leadership was also required within hospitals so staff and patients could see this as a priority.

Consultation and partnerships aid in project development. Messages should be tested with the target audience and stakeholders to ensure the validity of the messages used in the campaign. Partnerships help to find creative ways of distributing materials to patients.

Rigorous evaluation of a community awareness campaign can be difficult. As patient safety has become a priority for

Canadian hospitals, it has become increasingly challenging to parse out the impact of any one initiative. It is also challenging to evaluate an awareness and education campaign in a quantitative way, especially given that so little time has elapsed since its inception.

Conclusion

The OHA's experience in launching the "Your Health Care – Be Involved" campaign demonstrates the interest among patients for easily understandable information about their role in their healthcare. The

OHA is considering further refinement of selected campaign tools on the basis of information received through the evaluation. Although the five tips can be applied in some form to most healthcare sectors, they were developed with specific reference to the acute care sector. The OHA has recently received requests for sector-specific campaigns – since different patient populations have different needs – and the OHA is also exploring the need, interest and feasibility of a pediatric tips initiative.

Patient safety efforts in Canada have to a large extent focused on the system and system improvements, while very little attention has been paid to patients' roles. Patients do have the potential to influence their own health outcomes if they are actively involved in their healthcare. They also have the desire to be more active participants in their care. As Canada moves forward in our patient safety journey, it will be essential to make a more concerted effort to involve patients.

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Cancer Care Ontario's Computerized Physician Order Entry System: A Province-wide Patient Safety Innovation

Anna Greenberg, Sarah Kramer, Vickie Welch, Emily O'Sullivan and Stephen Hall

Abstract

More than one-third of all women and men in Canada will develop cancer during their lifetimes. Cancer patients typically require complex chemotherapy regimens, specific to their type and stage of disease, to slow or stop cancer cells from growing, multiplying, or spreading to other parts of the body. Despite the complexity of managing medication regimens for cancer patients and the associated risks to patient safety, current medical oncology practice throughout most of Canada is still to use paper-based tools, policies and procedures.

To increase patient safety by reducing prescription errors and to offer clinical decision support to medical oncologists across the province, Cancer Care Ontario (CCO) developed and implemented Canada's first, cancer-specific computerized physician order entry (CPOE) system. This e-health innovation is currently in use in 11 cancer centres, and represents the largest ambulatory oncology CPOE implementation in Canada, with a 100% implementation success rate, and greater than 90% physician adoption.

This paper describes the critical success factors in the design and implementation of CCO's CPOE system, including Web-based training and ease of administration to maximize physician adoption, incorporating point-of-care access to clinical practice guidelines into the tool, and the use of CPOE data to monitor and increase access to anti-cancer drugs and patient safety.

Cancer Treatment: Prime Candidate for a CPOE Solution

When it comes to medication safety, few diseases pose as big a challenge as cancer. Cancer encompasses over one hundred distinct diseases, and roughly half of all cancer patients will require chemotherapy in the course of treatment. A regimen of chemotherapy may be prescribed to destroy cancer cells, slow or control the growth and spread of a tumour, or relieve symptoms and improve a patient's quality of life. Chemotherapy is inherently toxic to cells and can cause a host of moderate to severe side effects. Since much of chemotherapy is infused intravenously, where the impact on the body is rapid and direct, there is little room for error, particularly in dosing. This is all the more important as cancer patients are likely to receive repeated infusions over time. To be both safe and effective, these regimens must be carefully tailored to the patient. If a dose is too low, it will not be strong enough to attack cancer cells; if too high, it could prove intolerable or even fatal.

Determining a safe and effective chemotherapy regimen is dependent on a patient's type of cancer; the size, spread and genetic expression of the tumour; the patient's age, body surface area (calculated from their height and weight), medication allergies and general health status; and other factors. Factors affecting the appropriateness of a given regimen include the intent of treatment (curative or palliative); the right medications; dosing schedule, and timing of treatment relative to surgery and radia-

Table 1. Ontario Chemotherapy Facts

- 63,000 new patients will be diagnosed with cancer in 2006.
- 25,000 patients will die from cancer in 2006.
- Depending on the type of cancer, between 30 and 60% of Ontario cancer patients receive some form of intravenous chemotherapy.
- Five-year relative cancer survival is high and growing for common cancers such as prostate (92%), breast (86%) and colorectal (60%) owing to advances in treatment, including new drug therapies.
- 60% of the clinical practice guidelines and evidence summaries produced by Cancer Care Ontario's Program in Evidence-Based Care are specific to chemotherapy.
- Over 50% of all chemotherapy drug orders across Ontario are placed using Cancer Care Ontario's computerized physician order entry system – OPIS 2000 and 2005

Source: Cancer Care Ontario, "Cancer System Quality Index, 2006," CCO site, retrieved August 7, 2006 <<http://www.cancercare.on.ca/qualityindex2006>>.

tion treatment; and the need for supporting medications to combat side effects.

At the same time, the number of established and emerging drug therapies available to treat cancer is staggering. In 2005, 400 anti-cancer medications were under development (in clinical trials or awaiting FDA approval) in the US alone (Pharmaceutical Research and Manufacturers of America 2005). This is two times the number of drugs that were under development in the US for mental illness, three times the number for heart and stroke, and five times the number for AIDS (*ibid.*). Worldwide, over 2,000 clinical trials specific to chemotherapy are currently recruiting patients (National Institutes of Health 2006). Over 200 of these are for breast cancer alone (*ibid.*). For approved chemotherapy medications, over 300 clinical practice guidelines are available internationally specifying indication, dose, timing and other aspects of optimal treatment (Agency for Healthcare Research and Quality 2006). For providers, staying on top of all of the available and emerging therapies, their precise indications and recommended dosing in the absence of clinical decision support is extremely challenging at best.

Despite the complexity of prescribing and managing medication regimens for cancer patients, current medical oncology practice throughout most of Canada is still to use paper-based tools, policies and procedures. Chemotherapy delivery occurs in outpatient settings by a multidisciplinary team of physicians, pharmacists and nurses. From the time a physician handwrites an order, the order gets interpreted, transcribed and dispensed by a pharmacist, and a nurse administers the chemotherapy at bedside, there is the potential for minor to severe adverse drug events to occur.

It is well known that over 20% of adverse events in Canada are drug- or fluid-related (Baker et al. 2004). There are no Canadian data to date on cancer-specific adverse events. However, in the

US, it is estimated that 4% of all newly diagnosed cancer patients will experience some type of adverse event in the course of treatment, and that at least 2/3 of these are preventable (Dinning et al. 2005). In a recent study in the ambulatory chemotherapy setting at Dana-Farber Cancer Institute, Gandhi et al. (2005) found medication errors in 4% of adult chemotherapy orders. The most common of these were in drug ordering, followed by administering and dispensing errors. In the same study, it was shown that chemotherapy-related errors were significantly more likely to be serious than non-chemotherapy-related medication errors (48% compared to 12%).

The ability of computerized physician order entry (CPOE) systems to prevent medication errors has been shown in primary care (Tamblyn et al. 2003), and in several adult inpatient settings both in randomized controlled trials and prospective studies (Kaushal et al. 2003). As with patient safety in general, there is little data specific to cancer on the benefits of CPOE systems. However, a recent study evaluating the impact of a Web-based dose calculator on reducing errors in pediatric intravenous infusions found an 84% reduction in orders containing one or more errors (Lehmann et al. 2006). Researchers at the same children's hospital found that CPOE implementation in the pediatric chemotherapy department resulted in a 74% drop in improper dosing and a 91% drop in incorrect dosing calculations, among other benefits (Kim et al. 2006).

From a technical perspective, chemotherapy ordering is a very difficult process to automate. It involves a multitude of inputs, including the drugs themselves, drug-to-drug interactions, disease-to-drug interactions, dosing and scheduling, and the interface of these inputs with all the variables within a particular patient's profile. This unusual set of circumstances makes a cancer-specific approach to CPOE technology essential. More generic CPOE systems would simply not support the degree of functionality required.

Cancer Care Ontario's CPOE strategy uniquely meets the challenges of cancer care. In 2003, CCO surveyed 18 hospital sites in order to identify the factors that would influence the implementation of the initiative, to make recommendations to increase the probability of success and to start the process to gaining buy-in and support for the systems approach.

The key findings were as follows:

- Currently available versions of more generic hospital information systems cannot support the specific needs of computerized physician order entry for systemic therapy.
- It is not feasible for individual hospitals to maintain common chemotherapy drug formulary and clinical decision support rules.
- Physicians and pharmacists will support a well-managed provincial system, tied to Cancer Care Ontario and its mandate to improve quality of cancer services.

CCO has reconfirmed these findings on a regular basis over the past three years.

Cancer Care Ontario's CPOE System: OPIS 2005

In 1996, Cancer Care Ontario (CCO), the Ontario government's principal advisor on cancer care, began the design and implementation of the first jurisdiction-wide, cancer-specific CPOE system. CCO's OPIS (Oncology Patient Information System) 2005 was designed for use by physicians, pharmacists and nurses to increase patient safety and offer clinical decision support to medical oncologists province-wide. To date, versions of the system have been implemented in 11 institutions delivering chemotherapy, representing over 50% of all chemotherapy orders in the province, almost 500 prescribing physicians, and over 600,000 medications ordered every year. This e-health innovation, with greater than 90% physician adoption, represents the largest ambulatory oncology implementation in Canada.

In addition to its role in improving patient safety, CCO's CPOE system is a critical component of the organization's clinical knowledge transfer and brokerage functions. As new clinical guidelines are developed and integrated within the clinical decision support components of OPIS 2005, the system provides a vehicle to ensure broad uptake of best clinical practice across the province.

On the basis of 10 years' experience in the implementation, use and continuous enhancement of this system, we describe below the critical success factors in the design and implementation of a cancer-specific CPOE system.

Figure 1 shows the current use of OPIS/OPIS 2005 across Ontario.

On the basis of a 2003 Cancer Care Ontario survey of OPIS physician users, the vast majority of respondents said the system improved efficiency and safety and that they would be unwilling to practise without it:

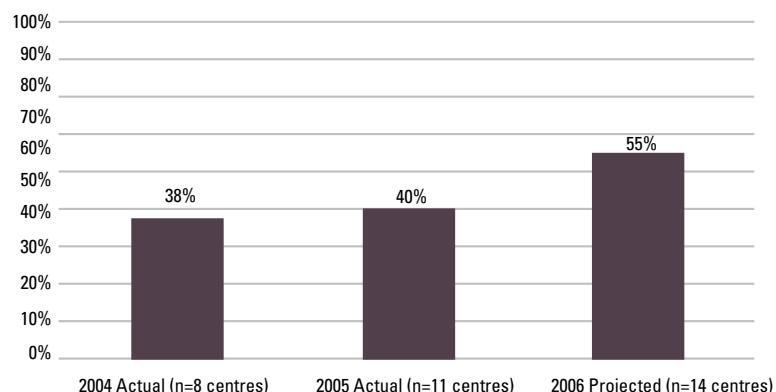
If you remove OPIS 2000, we will have to reduce our patient load. (Medical oncologist, Ottawa Hospital Regional Cancer Centre)

The system is easy to use, and it has everything we need. (Medical oncologist, Kingston Regional Cancer Centre)

Figure 1. Current use of OPIS across Ontario

Use of Best Practice Drug Ordering Technology

Percent of Systemic Therapy Treatments Ordered Using Computerized Physician Order Entry (CPOE/OPIS)



Source: Cancer Care Ontario, New Drug Funding Program

Table 2. CPOE system functions and primary users

Function	Primary User(s)
1. Systemic therapy drug order entry	Physician
2. Non-systemic therapy drug order entry	Physician
3. Verbal order authorization	Physician
4. Drug funding program eligibility registration	Physician
5. Patient clinical information: • Disease registration and cancer staging • Patient cumulative drug dosage • Patient allergy alerts • Medication profile • Patient toxicity • Lab results entry	Physician, Nurse, Pharmacist
6. Electronic medication administration and chart review	Nurse
7. First Data Bank Drug Formulary management	Pharmacist
8. Chemotherapy regimen formulary management	Pharmacist

We have been trying to get our hospital administration to let us use OPIS 2000 on the inpatient floors. (Medical oncologist, Kingston Regional Cancer Centre)

How do I get Grand River to be one of the first sites to implement OPIS 2005? (Glen Kearns, CIO, Grand River Regional Hospital)

Of course, as with any clinical system, there are areas that require additional development, identification of issues and concerns by users and an upgrade of the technical infrastructure and platform. Building on its business model of stakeholder and expert input into improving the quality and accountability of cancer services in Ontario and its tight ties to the community of users, Cancer Care Ontario's CPOE strategy includes regular and active involvement of clinical and technology leaders in identifying, and prioritizing system improvements to meet evolving needs.

Integrated Clinical Decision Support (CDS)

Not only is the system tailored to medical oncology practice; it is also built to integrate with a facility's existing information management system. OPIS 2005 is designed to interface with any facility's hospital information system (HIS) so that complete information in a patient's profile, including demographics, disease, allergies and medication history, is pulled up as the order is being placed, dispensed and administered. This being the case, the real-time clinical decision support features include:

- *Cumulative dosing.* This feature keeps track of chemotherapy medications that have a maximum cumulative dose that can be given to a patient in his or her lifetime and alerts the ordering clinician when this maximum is reached.
- *Calculating creatinine clearance.* A creatinine clearance calculator is available (two formulas) for drugs such as Cisplatin and Carboplatin that require dosing based on the patient's creatinine clearance. The dosage of these medications is automatically calculated according to this value.
- *BSA calculations.* There are two formulas available in OPIS 2005 to calculate a patient's body surface area in order to automatically calculate the patient's ideal dose.
- *Maximum dose and minimum dose alerts.* Drugs can be set up so that alerts appear if a dose reaches the maximum or minimum value set.
- *Dose capping.* Drugs can be set up so that if the dose exceeds the allowed maximum, the dose will be capped at the specified value.
- *Allergy alerts.* Colour coding alerts for allergies and potential allergies. Allergy override reasons must be entered for drugs that are ordered where the patient may have an allergy or potential allergy to that drug.
- *Height and weight tolerance.* A tolerance can be set up, so that if a weight has changed by, say, 10%, the clinician ordering will receive an alert that a 10% change has occurred and will be asked whether he or she would like to recalculate the body surface area and change the ideal doses calculated on the basis of the previous body surface area.

The system comes with a menu of hundreds of pre-built

chemotherapy regimens based on the latest available evidence.

The system allows the prescribing physician to override any of the automatic alerts on the basis of clinical judgment. In addition, physicians can determine eligibility, and enrol patients in the province's cancer drug funding program at the point of care.

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Robust Scalable Technology

As the implementation in 11 facilities across the province has shown, OPIS is easily disseminated in a variety of clinical environments. It is an Oracle development platform with interface capability enabling the system to be integrated into the hospital's existing clinical information system. In addition, facilities tailor the implementation of the tool to their clinicians' specific practice patterns. For example, in some facilities nurses access the system through a wireless mobile flat-screen device so that a patient's regimen and care information is available at the point of care.

In 2004, an informal market survey compared Cancer Care Ontario's CPOE system to commercially available systems and revealed that CCO's system had more in-depth functionality, including the seamless incorporation of clinical practice guidelines, and greater support for clinical workflow. Moreover, no commercially available system had achieved the physician adoption rate achieved by CCO. Importantly, in the rollout of OPIS 2005 to date, the system has generally proven to be easy for physicians, pharmacists and nurses to use.

Central Coordination of System Dissemination

One of the goals of Cancer Care Ontario's CPOE initiative is to implement the system wherever chemotherapy is delivered in Ontario. While established OPIS/OPIS 2005 users may find it difficult to imagine practising without it, the initial implementation represents an enormous change to current clinical practice. A recent and emerging body of literature (Koppel et al. 2005; Wears and Berg 2005) has identified new risks in the implementation of CPOE that can exacerbate patient safety and cause barriers to optimal physician workflow. The case studies in question highlight CPOE installations that have been poorly managed; do not adequately engage and tailor the system to end-users; and underestimate or fail to acknowledge the signifi-

cant change management and adoption support required to ensure successful implementation.

Mindful of these risks, Cancer Care Ontario has continued to adapt and improve its approach to CPOE implementation. The project has a well-developed methodology involving a six-month, rigorous implementation process to manage this change as effectively as possible. Key components include:

- Ensuring that a fully staffed project team exists at the target facility
- Gaining support from executive leadership, both clinical and administrative, at the facility
- Involving stakeholders (end-users and leadership) in decision-making processes to ensure a sense of ownership of the system and empowerment with the change
- Providing in-depth, on-site training, including "train the trainer" sessions, and instructor-led and independent Web-based training
- Ensuring extensive set-up of the system by on-site pharmacists prior to "go live" date to ensure systems are carefully tailored to the facility
- Extensive testing of the system at each facility
- Customized post-launch support and maintenance

CCO managed and continues to manage implementation of OPIS 2005 over multiple sites using Project Management

Institute (PMI) methodology and a well-seasoned implementation staff with clinical, technology and project management experience and credentials. One of the critical success factors in site implementation is ensuring that there are clinician leaders within the CCO project team who not only understand the software, but also understand clinical workflow. This deep understanding of the clinical environment and of the change management challenges facing clinicians in the field – particularly physicians – has served to increase the credibility of the project, and ensured a solid change management approach.

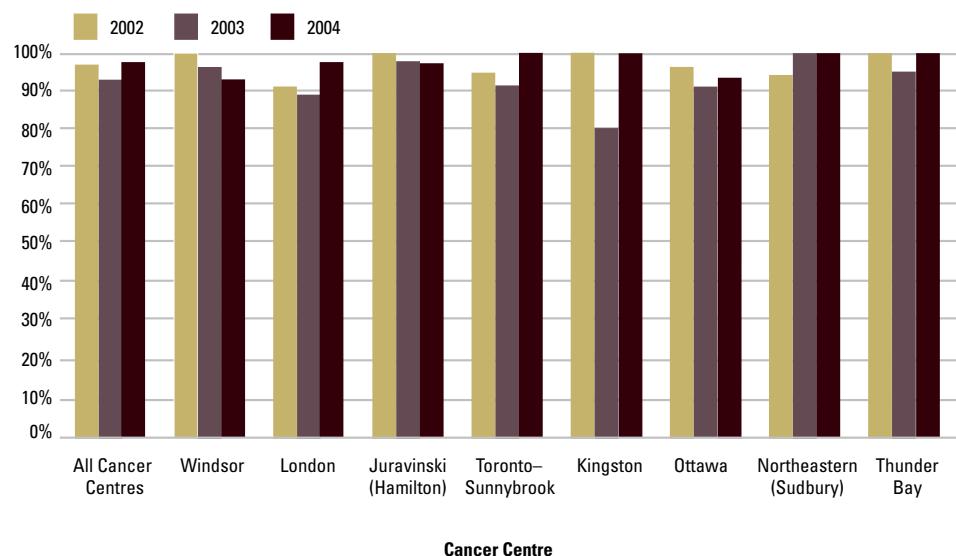
One of the critical success factors in site implementation is ensuring that there are clinician leaders within the CCO project team who not only understand the software, but also understand clinical workflow.

Demonstrated Utility beyond Medication Safety

In addition to the use of OPIS to manage cancer patients' chemotherapy regimens in the clinical setting, Cancer Care Ontario centrally monitors activity and system quality using data from participating sites. One of the core functions of Cancer Care Ontario is to manage the performance of the cancer system. Data from OPIS 2000 and 2005 have proved highly effective

Figure 2.

Use of Clinical Practice Guidelines – Colon Cancer
Percent of newly staged stage 3 colon cancer patients treated with adjuvant systemic therapy according to the clinical practice guideline, Ontario, 2002-2004



Source: Cancer Care Ontario, Activity Level Reporting

on this front. For example, data from the system are used to monitor and report publicly in the Cancer System Quality Index (Cancer Care Ontario 2006) on adherence to evidence-based clinical practice guidelines based on patients' type and stage of cancer (see Figure 2). Providing this type of report to clinical leadership assists in quality improvement efforts while demonstrating the broader benefits of the system.

Conclusion

The complexity of prescribing and managing cancer chemotherapy regimens makes it a prime candidate for a CPOE solution. Recognizing this, Ontario became the first jurisdiction to roll out a CPOE system in multiple institutions delivering chemotherapy. While most cancer-specific CPOE systems in use today have been implemented within a single institution, Ontario's system has been successfully implemented in 11 distinct institutions across the province. With support from Canada Health Infoway, next steps for the initiative are to implement OPIS 2005 at an additional five facilities across the province over the next two years. This has major implications for cancer patient safety across the province, since over 50% of all chemotherapy orders are already being ordered in Ontario using CCO's OPIS 2000 and 2005. The increased adoption and implementation of OPIS 2005 will enable the first-ever province-wide assessment of the impact of CPOE on cancer patient safety.

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Predicting Changes in Workflow Resulting from Healthcare Information Systems: Ensuring the Safety of Healthcare

Andre Kushniruk, Elizabeth Borycki, Shige Kuwata and Joseph Kannry

Abstract

This paper describes an approach to studying medical error and workflow that can be applied to help ensure the safety of new healthcare information systems. The approach focuses on identification of usability problems resulting from implementation of new information technology, as well as identification of problems related to changes in workflow. The paper illustrates how the approach can be applied in the simulation-based analyses of emerging healthcare information systems. The paper includes discussion of the application of an approach to identifying inadvertent changes in healthcare workflow that may result from design issues in a range of information technologies including medication order entry systems. General implications for the design, development and evaluation of safer healthcare information systems are discussed. It is argued that there is a need for thorough simulation-based testing of systems under a variety of conditions before they are released in order to ensure the safety of healthcare.

Introduction

The need to reduce medical error has become a driving force and motivation for the widespread deployment of healthcare information systems. Indeed, a number of highly influential publications have supported the notion that introduction

of information technology, such as computerized patient records, will lead to decreased medical error (Bates et al. 1998). However, recent work by the authors (Kushniruk et al. 2004; Kushniruk et al. 2005) and others (Koppel et al. 2005) has indicated that poorly designed user interfaces and systems may actually increase the likelihood of occurrence of certain types of errors. On the basis of such work, the necessity of ensuring that new information systems not only reduce medical error but also that they do not inadvertently add new types of errors (or inadvertently change healthcare workflow) is becoming recognized as being a critical issue in healthcare. This paper extends the authors' previous work in developing novel methodologies based on usability testing and simulations for the identification and prediction of technology-induced errors prior to release of new healthcare information systems. In addition, in this paper we will demonstrate how the approach can be used to identify how implementation of healthcare information systems may inadvertently affect workflow, and how this can be detected prior to release of the system. The paper describes a recent case study in order to illustrate how the approach can be used to accurately pinpoint potential issues and changes in workflow that may arise in the implementation of a new medication order entry system.

Application of Simulations in Detecting and Predicting Technology-Induced Error

In life-critical industries such as aviation and nuclear power, a range of simulation approaches have been used in order to deliver effective and safe information systems, with an extremely low tolerance for error introduced by technology. This has included use of computer-based simulations to model complex physical and mechanical interactions in the design and testing of applications. Such simulations can be considered to be completely "in the box," since they use a computer program that simulates real-life activities. A second category of simulations includes more realistic testing of software applications under conditions that approximate real-life conditions. Such simulations incorporate both physical and cognitive stimuli that are representative of real-life situations "outside the box" in order to test how software will behave under different conditions. In this paper we describe how simulations of realistic work activities, inspired by methods used in domains such as the aviation industry, can be applied in studying health information systems.

The overall approach to testing health information systems extends a method used in medical education, known as the "standardized patient" (Kushniruk et al. 1996). In this case a physician or other healthcare professional interacts with an information system (e.g., enters patient data into a computerized patient record system) while interacting with someone playing the role of a patient (who may be answering questions posed by the healthcare professional on the basis of a "patient script"). This approach builds on related work in usability testing, where representative users of a system (e.g., physicians or nurses) are observed while they carry out representative tasks (e.g., entering a medication) using a system under study (Kushniruk and Patel 2004).

An example of this approach is work by Kushniruk and colleagues (Kushniruk et al. 1996) using videorecordings of doctors interacting with an information system while they carried out a data retrieval task (e.g., obtaining data about patients from the system). Subjects in such studies may be asked to "think aloud" while carrying out the task (which is audiorecorded), or in the case of interaction with a simulated patient they may be asked to carry out a doctor–patient interview while using the system under study (with the dialogue between the doctor and patient audiorecorded, while the computer screens are videorecorded). A number of evaluations have been conducted that have been able to identify problems with health information systems and user interfaces under relatively realistic conditions prior to

their release. For example, work based on simulation testing by Kushniruk et al. (2005) identified a range of usability problems with the interface to a commonly used handheld personal digital assistant (PDA) application for prescription writing.

Methodological Approach

Our methodological approach has emerged from recent advances in usability engineering and the study of human–computer interaction in patient safety. This research uses low-cost software for recording computer screens of a system under study in conjunction with low-cost videorecording equipment and computer systems used by a physician or healthcare worker (see Kushniruk and Patel 2004 for details of recording methods used). Our early work in the study of healthcare applications allowed us to isolate the cognitive effects of technology (e.g., interface design and content) and their potential for inadvertently inducing or facilitating medical errors. In the case study described in this paper, the focus is on extending this approach to analyzing the impact of a new information technology upon both cognitive and physical interactions (i.e., clinician workflow) in a realistic clinical setting, including consideration of both the computer system and the work environment.

Case Study: Evaluating the Impact of a Medication Order Entry System

A simulation approach was used to study a new medication order entry system to be deployed in a teaching hospital. The system was designed to allow users (i.e., doctors and nurses) to

Figure 1.

A nurse subject interacting with a medication order entry system while being video-recorded.



obtain information about what medications to give patients and to record the administration of the medication in a computer system. This system is similar to many systems currently being deployed in hospitals around the world. The computer component of the medication order entry system was also integrated with bar-coding technology that allows the doctor or nurse to scan the wristband of the patient to identify the patient and to also scan labels on medication bags. Figure 1 illustrates the set-up, with a nurse working with a medication order entry system while being videorecorded (physical activities are recorded using a camcorder on a tripod; in addition, all computer screens are automatically recorded using Hypercam® screen recording software).

Sixteen subjects, consisting of doctors and nurses, were given written instructions for entering medications for a list of simulated patients. The subjects interacted with both the computer system (via a keyboard as shown in Figure 1), to obtain instructions for administering medication, and the "patient," actually a mannequin with a bar-coded wristband. In the simulation, subjects were specifically instructed to interact with the computer system and the dummy patient (e.g., to hang intravenous medication bags) just as in a real situation. In order to record the use of the system in the simulation, we employed a digital video camera on a tripod to record the interactions of the subject with both the computer system and the patient.

Subjects were asked to use the computer application to enter the patient's name, obtain the list of medications to give the patient, administer the medication (to the dummy patient) and then record the administration in the computer application. All computer screens were recorded, while subjects' interactions with a dummy patient were recorded using the camcorder. At the end of the session the subjects were also interviewed (and the interviews audiorecorded).

In order to analyze the data collected, first the audio portion of the recorded sessions was transcribed in its entirety (including the interviews at the end of each session – see Figure 2 for the transcripts from one nurse subject), and then annotated by the experimenters by reviewing the videorecordings of the computer screens and subjects' physical activities (e.g., actually hanging medication bags). In Figure 2 the numbers on the left-hand side refer to the video counter corresponding to the actual actions of the subject. The latter portion of Figure 2 also contains the transcript of the interview with the subject (a nurse) conducted immediately following completion of the simulation task.

From analysis of the recordings of the subjects carrying out the study tasks, it was observed that the system imposed a very sequential order of activities in order to document the medication administration. Also, from the interview portion, ergonomic issues related to difficulty in subjects actually scanning the information on labels on medication bags were noted by subjects. In addition, a number of computer-related issues were brought up

Figure 2. Annotated transcript of subject (nurse) administering medication, and post-task interview

Medication order information obtained by nurse

00:14 Nurse searches for patient on the computer
00:45 Nurse views order list on the screen
00:51 Nurse selects medication order from list
00:55 Verification screen appears

Nurse walks over to patient to check identification

01:09 Nurse talks to patient – "Nice to meet you. I will now give you an IV drip."
01:09 Nurse scans patient identification (from patient's wristband)
01:10 Verification screen automatically updates

Nurse walks back to computer

01:25 Nurse views execution information on the computer

Nurse walks over to patient and sets medication bag

Nurse walks back to computer

03:15 Nurse confirms administration of medication on the computer

Post-task Interview:

Experimenter: Did you find any difficulty with the task?

Subject: I'm used to this operation, but sometimes it is hard to use the bar-code reader when the bar code is not clearly printed.

Experimenter: What difficulties did you have with the bar-code reader?

Subject: There are no problems when we have both a printed order and a label on the bottle (we can use either of them, because there are the same bar codes on both). But if the bar code is only on the bottle with its rough surface, I have often pushed its surface to flatten it, and scan it many times until I can read the bar code correctly.

Experimenter: Do you find any difficulty during the workflow process?

Subject: Sometimes I could not open the record of the patient whom I was giving a medication to, because another nurse or doctor was opening the record at the same time.

by subjects in such interviews, such as the inability to record medication administration when the patient's record is "locked out" by other users of the system who are accessing the system at the same time as the nurse or doctor is attempting to administer medication.

In addition to identifying potential sources of specific problems that would arise from implementation of the new system, from the analysis of all the subjects it was observed that introduction of the computer actually led to a major change in the process of medication administration. This was characterized by a serialization of the workflow process that could not be deviated from – for example, as shown in the annotated transcript in Figure 2, the physician or nurse would have to administer one

medication at a time, first accessing the computer, moving to the patient, scanning the identification band on the patient's wrist, moving back to the computer for details, then back to the patient to administer that drug and finally back to the computer to record the administration prior to administering the next medication (which is repeated each time for each medication). Thus, compared to the previous workflow, the new system imposed a rigid order of activities for medication entry.

Results: Impact of the System on Healthcare Workflow

Analysis of the data collected indicated that use of the system would have the impact of changing the workflow of the physicians and nurses considerably, compared to the manual paper-based procedures they used before the system was introduced. For example, in hanging intravenous (IV) medications, prior to introduction of the system physicians and nurses could hang the drugs in a parallel manner (e.g., checking the paper medication administration record, verifying and arranging all the medication bags and equipment, checking the client's identification band, explaining the medications to the client, hanging and administering the medications and documenting them) (Kozier et al. 2002). In cases in which only one or two medications needed to be administered, it appeared that the system was not problematic. However, when we adjusted our simulations to include medication lists with many medications, the serial process of administering medications became not only tedious for users but under time constraints led to perceived stress by users. Under normal conditions, this might lead to increased safety in medication entry by providing a structured and standardized procedure for medication entry; however, from our simulations it was also clear that under certain conditions (e.g., when there is a need to administer a number of medications under time pressure) the new system might also result in cognitive overload, necessitating complete bypass of the system by users under emergency or stressful situations. It should be noted that such consequences were not anticipated by the designers of the system.

Lessons Learned

Using the approach described above, we are examining the impact of a range of healthcare information systems, including decision support tools, Web-based health-related information resources and computerized patient record systems. In these studies we have worked with system designers and implementers (using simulation approaches) to identify and rectify usability problems. On the basis of our current work described here, we have also found that a close relationship exists between specific usability problems and the potential for occurrence of specific types of medical error. Furthermore, introduction of a new healthcare information system may result in unexpected changes

in workflow that may also be related to medical error under certain circumstances. It is therefore essential that methods such as those based on simulation testing be developed and refined for assessing the potential impact of a range of healthcare systems prior to their release in real clinical environments.

As illustrated in the case study, in order to provide accurate and predictive information about the impact of healthcare information systems, simulation studies need to consider not only the interaction of the user of the system with the computer, but also the complex interplay between use of the computer application, the patient and other technologies involved in the workflow. This can be observed in the real-world environment (e.g., a hospital room) by employing portable, low-cost video- and audiorecording equipment. It is essential that we observe interactions of typical users with new information technologies in realistic settings prior to release of these systems, particularly as healthcare workers may be unaware of the impact of systems on workflow. Understanding how the system may impact the interaction of the healthcare worker with the patients, co-workers and other individuals in the actual clinical environments where systems will be implemented is key. In the case of complex systems, such as medication order entry systems, this also includes consideration of other technologies (e.g., bar-coding scanning devices, IV pumps, etc.) that may be integrated into the new process and not just the computer system in isolation. This includes consideration of the physical placement of different components (e.g., computer, patient bed, bar-code scanner, etc.) and how they integrate into the overall process of healthcare.

Predicting potential impact of systems requires simulations that represent a wide range of cases or scenarios. This includes not only routine, non-urgent conditions, but also urgent or time-constrained ones. For example, one of the main findings in our case study was that use of the system serialized the process of order entry, which under certain conditions might result in increased cognitive load. Thus, under some conditions advantages can be outweighed by disadvantages. Such feedback leads to corrective action early in the implementation process, and has an impact on cost savings as well as increasing the likelihood of user acceptance of systems. More studies similar to that described here are needed to see emerging information technologies in healthcare, including use of portable tablet devices, mobile handheld devices, mobile carts and workstations at the bedside.

Discussion/Conclusions

Many types of simulations have been employed in life-critical industries to assess the potential for new systems to inadvertently induce error. In this paper we have described an approach to analyze and detect potential technology-induced error and to identify inadvertent changes to workflow that may impact

safety. We are currently working on refining the methodological approach and creating an empirically based classification of problems encountered by subjects based on the results of our ongoing simulation studies. Usability-based approaches involving simulations of clinical contexts allow for considerable power in predicting potential problems with systems prior to their release. This approach to in-depth study of the interaction of healthcare workers with information systems and devices prior to their release in healthcare settings will be essential to ensure that the systems we introduce are safe, and that we reap the full benefits of technological innovation.

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Frequency and Type of Medication Discrepancies in One Tertiary Care Hospital

Jennifer Turple, Neil J. MacKinnon and Bryan Davis

Abstract

Background/Objective: Discrepancies in records used within the medication use system have been identified as a contributing factor of medication errors. The objective of this study was to determine the frequency and type of discrepancies in the medication use system in one tertiary care hospital.

Methods: Using a sample of patients (convenience sampling technique), the physician's orders, the nursing medication administration record and the pharmacy profile were compared in an attempt to identify discrepancies among them. A discrepancy was defined as a deviation from the physician's order as written in the chart. Each discrepancy was categorized according to seven components of the medication order, its location in the medication use process and its mode of delivery.

Results: One thousand, four hundred twenty-four orders representing 197 patients from 13 nursing units were sampled for this study. Thirteen percent of the orders were discrepant and 61% of patients had at least one discrepancy. The most frequent types of discrepancies were drug omissions and unordered drugs.

Discussion: The discrepancies identified in this study suggest that either orders are not reaching pharmacy or orders are not being processed appropriately in pharmacy. The location of discrepancies also suggests that there are deficiencies in communication between healthcare professionals.

Background/Objective

The safety of the medication use system (MUS) is an issue which is a concern in many healthcare organizations today. This problem was clearly identified in the Institute of Medicine's report *To Err Is Human* (Kohn et al. 1999). The Canadian Adverse Events Study (Baker et al. 2004) helped to quantify the magnitude of this problem in the Canadian inpatient environment. In that study, almost one-quarter of all the adverse events identified were drug- or fluid-related. The annual cost of preventable drug-related morbidity and mortality in Canada has been estimated to be \$11 billion per year in older adults alone (Kidney and MacKinnon 2001).

Problems related to documentation and communication in the MUS are commonly cited in studies. Of 134 patients in the intervention arm of a study (Nickerson et al. 2005) at the Moncton Hospital, NB, 96.3% (129) patients had at least one drug-therapy problem for monitoring, while 39.6% (53) patients had a drug-therapy inconsistency or omission. All of these problems were identified just prior to discharge from hospital. In another study that focused on unintended discrepancies on admission, 53.6% of patients had at least one such discrepancy (Cornish et al. 2005). Current efforts by the Canadian Council on Health Services Accreditation (2006) and the Safer Healthcare Now! (2006) campaign directed toward

the documentation and communication of the patient's prescription profile through medication reconciliation will hopefully improve the situation.

Given the importance of identifying potential flaws in the MUS, the goal of this study was to identify discrepancies in the documentation throughout the MUS in the Queen Elizabeth II Health Sciences Centre (QEII HSC) in Halifax, and to assess whether these discrepancies could be contributing to medication error.

Methods

This study was approved by the Capital Health Research Ethics Board. The MUS at the QEII HSC relies heavily on three documents, which are independently maintained by physicians, nurses and pharmacists. These documents include: (1) the physician's handwritten order located in the patient's chart, (2) the medication administration record (MAR), which is transcribed by nurses and guides subsequent medication administration and (3) the pharmacist-maintained electronic medication profile, which guides the dispensing of medications. In this study, these key documents were compared to identify and evaluate discrepancies. A discrepancy was defined as a deviation (spelling excluded) from the physician's order as it was written in the chart.

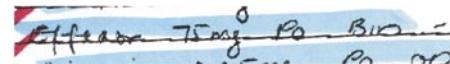
A sample of patients was selected using a convenience sampling technique. These patients were admitted to acute care beds on a nursing unit that utilized the unit-dose system at the Halifax Infirmary Site of the QEII HSC between April and May 2003. Patients were excluded if no scheduled medications were ordered.

For each patient selected, photocopies of all physician's orders, the current "scheduled" MAR (as opposed to the "prn" MAR), and the current (RxTFC TM [BDM Information Systems Ltd., Saskatoon]) electronic pharmacy profile were obtained. For simplicity, the following orders were excluded from analysis: (1) newly written orders that had not been processed throughout the entire MUS (i.e., transcribed and dispensed), (2) "as needed" orders and (3) "one time only" orders.

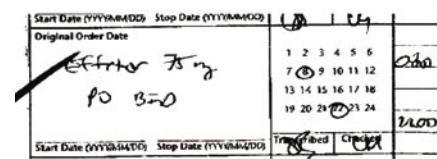
At the end of the two-month data collection period, the orders were reviewed to identify all medications the patient was to be actively receiving at the time of document collection. Once all active orders had been identified, each one was cross-referenced to the other MUS documentation (see Figure 1).

Discrepancies between the original physician's order from the chart, the nurse's transcription in the MAR and the pharmacist's order entry in RxTFC were noted. Specifically, seven components of the order were examined for discrepancies. These components (or types) included: dosage, route of administration, frequency or duration, unordered drugs, omission of drugs,

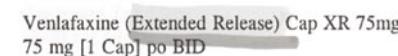
Figure 1. Example of documentation sources for a medication order



Physician's Order from Chart



Entry in Nursing Medication Administration Record



Entry in Pharmacy Profile

dosage form and improper administration. Each discrepancy was then categorized according to the type and the location of the discrepancy (e.g., between the physician's order and pharmacy profile). For each discrepancy, the drug involved was categorized according to the mode of delivery (e.g., unit dose, floor stock) to the patient.

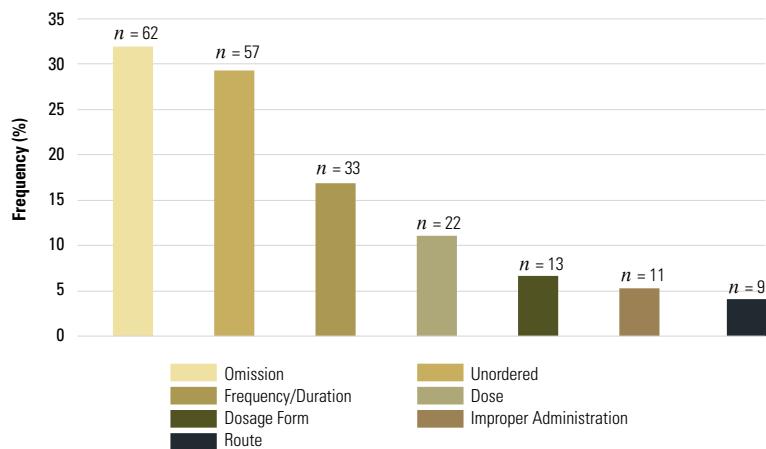
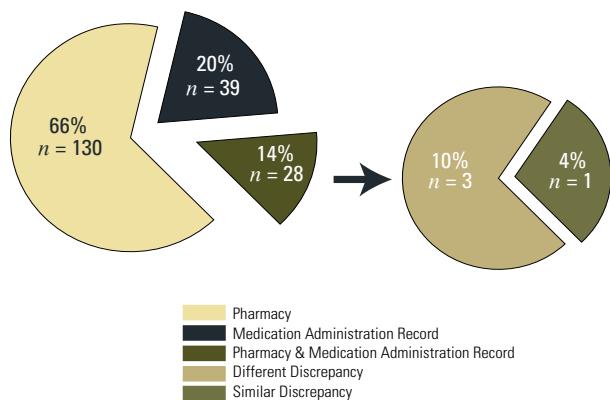
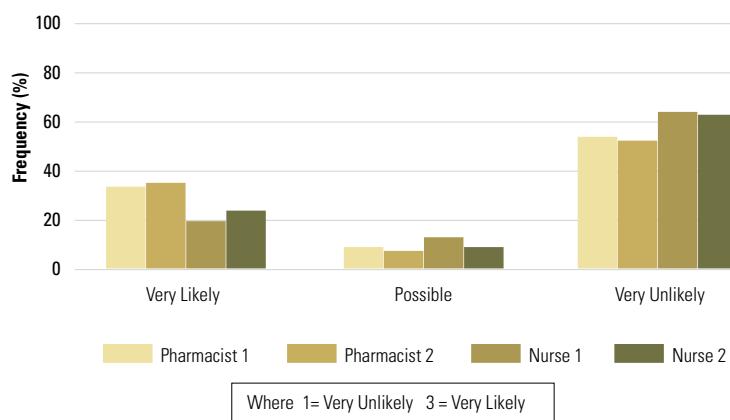
A panel of two pharmacists and two nurses, who work within the MUS at the QEII HSC, assisted in assessment of discrepancies. The investigator prepared the documents for review, which included the discrepant transcription and/or pharmacy entry, the category of discrepancy and the delivery method. Using their professional judgment, each panel member independently assessed the likelihood that each discrepancy, as described, led to an actual error in drug administration. The likelihood was documented using a 3-point Likert scale (1=Very Unlikely, 2=Possible and 3=Very Likely).

Statistical analysis was completed using SPlus 6.0 software. Descriptive statistics were used to qualify patient characteristics, discrepancy characteristics and rates. Linear regression and proportion testing were also used in the data analysis.

Results

The previously specified documentation for 197 patients was included in the study over the two-month data collection period. There were 100 (51%) male and 97 (49%) female patients, with an average age (\pm SD) of 69.3 (\pm 16.1) years old. There were approximately 15 patients from each of the 13 nursing units included in the study.

Active orders were reviewed for the 197 patients, and 197 discrepant orders were identified from a total of 1,424 active orders. The discrepant order rate was 13% (197/1,424), yielding an average of one discrepant order per patient. Furthermore, 61% (120/197) of patients had at least one discrepancy identified. Figure 2 represents the discrepancies by type. There were a total of 207 discrepancies by type, as there were several orders

Figure 2. Frequency of medication discrepancies, by type (n = 207)**Figure 3. Frequency of medication discrepancies, by documentation source****Figure 4. Frequency of assessment of likelihood of error by assessor (n = 197)**

that contained more than one type of discrepancy. The documents in which the discrepancies were identified are shown in Figure 3. The methods of delivery of the medications involved in a discrepancy were (as frequencies): floor stock 54.3%, unit dose 52.7%, multidose format 19.2%, infusions 11.0%, and intravenous admixtures (IVAD) 4.0%, respectively. (The sum of frequency is greater than 100%, as some items can be obtained via more than one delivery method.)

Age and gender of the patient did not influence the frequency of discrepancy ($p = 0.3469$ and 0.6762 , respectively). Linear regression revealed no statistically significant differences in discrepancy rate by nursing unit ($p = 0.1812$). There was no difference in the frequency of discrepancies among nursing units, when grouped according to service (i.e., cardiology, orthopedics) ($n = 6$, $p = 0.2178$). Furthermore, correlation coefficients indicated that neither individual nursing unit nor groups of units were predictive of the frequency of discrepancy ($r = 0.0823$ and 0.0359 , respectively).

Figure 4 represents the judged likelihood of actual error per discrepancy by individual assessor. Assessor agreement was calculated for all pairings using the Cohen kappa coefficient test. For all pairings of assessors, a high level of agreement among them was confirmed through statistical testing (the Z values for all pairings represent p -values < 0.001 , indicating agreement between all pairings of assessors).

Linear regression showed a strong relationship between assessments of likelihood and documentation source of discrepancies ($p = 0$). Discrepancies were more frequently assessed as likely to lead to error when both the pharmacy profile and MAR were discrepant (average likelihood rating = 2.73) (where 1=Very Unlikely ... 3=Very Likely), followed by a discrepant MAR (average likelihood rating = 2.36). When all three documents were noted to be discrepant the average likelihood rating fell to 2, and finally when pharmacy profile was noted to be discrepant the average likelihood ratings were 1.28.

Relationships between assessments of likelihood and discrepancy types were analyzed and showed that discrepancies of “dosage form” were more frequently assessed as “very likely” to have led to an error ($p = 0.0081$). Discrepancies of

“dose, route and omissions” were less frequently assessed as “very likely” to have led to an error ($p = 0.0041$). All other types of discrepancies did not contribute in any way to a “very likely” assessment of likelihood of error.

Discussion

This study indicates that there are deficiencies in documentation and communication in the MUS in this institution. Fortunately, the majority (87%) of orders processed within this MUS were processed without discrepancy. Yet, in 13% of orders – roughly one in eight orders reviewed – there was a discrepancy noted in documentation. These discrepancies represent chances for medication error, as demonstrated in previously published studies (Wilson et al. 1997; Manley et al. 2004).

Discrepancies in documentation in this facility may be explained, in part, by the independent nature of document maintenance by physicians, nurses and pharmacists. The QEII HSC does not currently utilize a joint nursing–pharmacy MAR, nor does it have computerized physician order entry (CPOE). These technologies could lead to improved sharing of medication-related information among MUS users (Ackroyd-Stolarz et al. 2005). An example of a discrepancy that may have been avoided with such technology is an order written by a physician for a topical product to be applied “qd” (an unapproved abbreviation in our facility). The order was subsequently transcribed by nursing as “once daily” and entered by pharmacy as “four times daily.” Currently, neither are there processes in place to ensure accuracy of order processing throughout the documentation system (i.e., from ordering to administration).

There were no associations between age, gender, or nursing unit and discrepancy rate. In determining factors most likely to contribute to a discrepancy, the statistical analysis revealed a random spread of error across all the variables studied. This is an important finding, because this indicates that no particular characteristics or areas should be the target for MUS improvement, but rather an overall system enhancement.

The two most common types of discrepancies were omissions ($\approx 31\%$) and unordered drugs ($\approx 29\%$). The frequency of these discrepancy types suggests that there are system breakdowns occurring at both the transcription and the order entry stage. Specifically, orders written to both initiate and discontinue medications are not being processed through the MUS in the proper manner. This is further supported by the fact that, of the discrepant orders, the pharmacy profile was the documentation source of the discrepancies 66% of the time. A possible explanation for this high frequency is that orders that do not require pharmacy involvement for drug availability (i.e., floor-stocked drugs) are not being sent to the pharmacy for entry on a profile, or the orders are not being processed properly once they reach the pharmacy. Furthermore, more than half of the orders involved in a discrepancy were noted to be floor-stock items.

Although discrepancies were identified, the results from the assessment of the likelihood of actual medication error were promising in that, on average, the assessors felt that these discrepancies would not have led to erroneous drug administration to the patient. In one example the pharmacy profile noted a heparin drip as “active,” yet both the physician’s order and MAR noted the order as “discontinued.” In this scenario, the patient was not likely to still be receiving the heparin despite the discrepancy on the pharmacy profile alone. An interesting result in the assessment was that when the pharmacy profile was found to be the documentation source of a discrepancy, this was deemed “least likely to lead to error” by the assessors. This is an important finding in view of the fact that the majority of discrepancies were noted in the pharmacy profile.

Of greater concern, however, were the discrepancies assessed as “possible” and “very likely.” In this study, the assessors deemed discrepancies identified in both the MAR and the pharmacy profile as most likely to lead to actual error. These discrepancies represent an area of priority in implementing process and policy change.

Any discrepancies located at the time of data collection may have been rectified at another point during the hospital stay. Unfortunately, it was only possible to make inferences about the likelihood that a discrepancy led to an actual error, because actual drug administration was not witnessed. The panel members’ own professional judgment was the gold standard in this study to determine the likelihood of an actual error occurring. The scale used to document this assessment of likelihood of error has not been validated. Also, it is important to note the bias that exists in the interpretation of the original order. The determination of a discrepancy is based on a pharmacist’s own view of what the order reads.

Conclusion

This study has provided insight into the nature of discrepancies that occur in the documentation used in one facility’s MUS. The discrepancies identified suggest that either orders are not reaching pharmacy or orders are not being processed appropriately in pharmacy. Approximately one in eight medication orders were discrepant; however, only a small percentage of these were deemed to have the potential to lead to a medication error. Discrepancies in documentation in this facility may be explained, in part, by the independent nature of document maintenance by physicians, nurses and pharmacists. The location of discrepancies suggests that there are deficiencies in communication between healthcare professionals, so future efforts should be directed toward improving interprofessional communication.

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Broadening the Patient Safety Agenda to Include Home Care Services

Ariella Lang, Nancy Edwards, Carolyn Hoffman, Judith Shamian, Kathleen Benjamin and Marguerite Rowe

Abstract

Caring for an individual in the home is inherently complex. The physical environment, family dynamics and the cognitive abilities of the client and family members are only a few of the factors to be considered in delivering services. Although targeted initiatives have been established to reduce preventable injuries and deaths in the hospital sector, there has not been a corresponding level of research or patient safety initiatives in other healthcare delivery sectors. A coordinated and collaborative approach to generate new knowledge pertaining to safety in home care in Canada has therefore been undertaken by the Canadian Patient Safety Institute (CPSI), VON Canada, and Capital Health (Edmonton). Actions included the development of a background paper (Lang and Edwards 2006) that informed an invitational roundtable discussion, where key safety issues in home care were identified and priority actions discussed. Over 40 individuals from across Canada participated, reflecting various disciplinary and organizational affiliations in the delivery of home care services. This paper describes key findings from the background paper, outcomes from the ensuing roundtable discussions and implications for practice, research and policy.

Background

There is a growing demand for home care services in Canada (Canadian Institute for Health Information 2003), and the level of patient acuity at transition to this setting is also increasing

(Canadian Institute for Health Information 2006). Caring for an individual in the home is inherently complex. The physical environment, family dynamics and the cognitive abilities of the client and family members are only a few of the factors to be considered in delivering services. Although targeted initiatives have been established to reduce preventable injuries and deaths in the hospital sector (Safer Healthcare Now 2005), there has not been a corresponding level of research or patient safety initiatives in other healthcare delivery sectors. A coordinated and collaborative approach to generate new knowledge pertaining to safety in home care in Canada has therefore been undertaken.

The Canadian Patient Safety Institute (CPSI) and VON Canada jointly identified a commitment to focus on safety in home care. Capital Health (Edmonton) was approached to collaborate, and an invitational roundtable discussion was held in conjunction with the first Patient Safety in Home, Community and Long Term Care Conference. Actions included the development of a background paper (Lang and Edwards 2006) that informed the roundtable discussion, where key safety issues in home care were identified and priority actions discussed.

Over 40 individuals, reflecting various disciplinary and organizational affiliations in the delivery of home care services, received the background paper and participated in the round-table. This paper describes key findings from the background paper, outcomes from the ensuing roundtable discussions and implications for practice, research and policy.

Results

The literature suggests that there has been a shift toward recognizing the complexity of the healthcare system and how it affects patient safety, while moving away from the culture of blame (Lang and Edwards 2006). Overwhelmingly, research on patient safety is focused on institutions such as hospitals. These are regulated systems designed for providing healthcare with credentialled professionals, and support staff guided by supervisors and administrators. The environment for home care is less controlled, with much of the care being provided by unregulated workers, family and caregivers in settings that were designed for daily living and not for providing healthcare (Coyte, Baranek and Daly 2000). Thus, the care and safety of patients in home care settings cannot be attended to without including the family members, the unpaid caregivers and the paid providers in the equation (Harrison and Verhoef 2002; Lehoux 2004).

Key informants from seven Canadian provinces and one American state were interviewed for the background paper. Their insightful views about issues, concerns, gaps and priorities related to safety in home care were more concordant than discordant. They shared a socioecological perspective and acknowledged that the traditional institutional patient safety perspective does not fit, but rather that a “different set of glasses” are needed to view the complexity of issues in the home setting. They discussed physical, emotional, social and functional safety. Informants recognized the importance of considering the family as the unit of care and propounded that safety for the patient is inextricably linked to the safety of family members, caregivers and providers. The implications of safety in home care need to be addressed in relationship to: service provision for vulnerable patients such as the frail elderly; ethical considerations underlying the myriad daily decisions in home care; the critical role of patients, family members and unpaid caregivers as part of the healthcare delivery team; human factors principles for technology within the built home care environment; and the cost of doing nothing, both economic and human (Lang and Edwards 2006).

Key safety issues identified at the roundtable were: the conventional institutional focus on the physical safety of the patient rather than considering the client, family, caregiver and provider as an interlinked unit; problematic communication and coordination among service sectors, providers, caregivers, family and clients; and challenges of a fit between technology and the built environment in an uncontrolled and unregulated setting such as homes.

Other important safety issues identified were medication reconciliation, wound care, fall prevention and workplace issues (e.g., regulated versus unregulated providers, casual versus part time, lack of standards). Although research on safety in home care is limited, participants agreed that there is evidence for at least some of the safety issues identified.

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Discussion and Implications

Providers of home care services are guests in people’s homes where the clients, family members and caregivers are active partners in their health and safety. Ignoring or minimizing the value of family members and caregivers and their respective safety is problematic. It is clear that attention to safety in the home care sector is essential. The partners in this initiative (CPSI, VON Canada and Capital Health [Edmonton]) have created the platform for further explorations of this agenda. It is important to note that by undertaking this agenda, Canada would be providing international leadership. Although there are similarities between patient safety in institutional and home care sectors, framing the research within a socioecological perspective (Edwards, Mill and Kothari 2004; Marck et al. 2006) will help us to better understand the complex interplay among determinants of safety in home care.

The roundtable is a call to action, and research is needed to support decision-making. Budget allocation to hospitals obscures the fact that most healthcare actually takes place at home and in the community. Tackling the issue of safety in the home care research agenda will require a different approach from that in institutional settings. With concentrated and collaborative efforts, a solid path may be forged.

We've learned that there are many areas that are pertinent to home care that we do have evidence for. ... [A] strong issue came out today about the importance of family caregivers, the family as a unit. There is tons of literature on systems and intervening with the families. ... [C]ertainly, there is also enough evidence around prevention of falls, wound care and medication reconciliation that could be implemented across the country right now.

— Roundtable participant

About the Authors

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Adverse Events among Winnipeg Home Care Clients

Keir G. Johnson

Abstract

Patient safety research has focused almost exclusively on hospitals, with few studies investigating the safety of other healthcare sectors, including home care. Before measuring patient safety in home care, this study first sought to translate hospital-focused patient safety definitions and concepts to home care. A context-appropriate approach to measuring adverse events (AEs) in home care was developed using chart reviews prompted by a mixed screening process. These methods were then applied to measure the incidence, type, severity, cause, preventability and ameliorability of AEs among Winnipeg Home Care clients.

Patient safety has recently received considerable attention, with prominent studies in Canada (Baker et al. 2004), the United States (Brennan et al. 2001; Thomas et al. 2000) and other countries examining this critical healthcare issue. Baker et al. (2004) found that 7.5% of hospital admissions in Canada resulted in an adverse events (AE) – defined as unintended injuries or complications resulting in death, disability or prolonged hospital stay that arise from healthcare management and not the patient's underlying condition. These studies capture only part of the picture, however, as patient safety research has been limited almost exclusively to the hospital sector, with little research in other care settings, including home care.

Home care is an integral and growing component of Manitoba's healthcare system. Approximately 16% of seniors in Winnipeg use these services (Roos et al. 1999). The limited patient safety research in home care is focused primarily on adverse drug events (Ellenbeker et al. 2004; Gray et al. 1999) and potentially inappropriate medication use (Fialová et al. 2005; Golden et al. 1999; Meredith et al. 2001), with a lesser focus on other areas such as rehospitalization (Madigan et al. 2001) and operational failures (Bruno and Ahrens 2005). The last study examined errors rather than AEs and found that errors are caused not only by home care providers, but also by other healthcare providers, clients themselves and their informal caregivers. One study that examined AEs broadly in home care reported *potential* events, and might be more accurately interpreted as quality indicators (Madigan and Tullai-McGuinness 2004).

This study sought to fill this gap in research about AEs experienced by home care clients by translating hospital-centred patient safety concepts to the home care context, developing a method to measure AEs in home care and applying this method to measure the annual incidence, type, harm, cause, preventability and ameliorability of AEs among home care clients of the Winnipeg Regional Health Authority (WRHA). Ameliorability is a relatively new concept to AE research, accounting for events that could not have been prevented, but where the harm or impact could have been reduced if a different approach had been taken (Forster et al. 2003; Forster et al. 2004).

Study Setting

The WRHA is responsible for healthcare service delivery to more than 700,000 people living in Winnipeg and elsewhere in Manitoba. As part of the WRHA portfolio, the Home Care program is provincially mandated and seeks to ensure safe community living and promote independence while avoiding or delaying institutionalization. The program facilitates earlier hospital discharges for patients with short-term post-acute-care needs; however, the large majority of clients have long-term needs, and the program helps them remain at home for as long as possible.

Development of Definitions

Common patient safety concepts were developed in the hospital environment. Their transferability to home care needs to be reexamined, because care provision is quite different than institutionalized care. Delivering care in the home is less controlled than in hospitals, delivered in varying unfamiliar environments and relies heavily on client choice, family action and health and social services delivered by other professionals.

Two consultation sessions were conducted with case managers, supervisors of direct service staff, team managers, specialists, quality managers and directors, to translate the concepts of harm and cause and to generate a home-care-specific definition of "adverse event." For this study, an *adverse event* is defined as "any harm to the client that negatively affects their overall health and/or functioning and is the result of care actions and/or inactions rather than the client's underlying condition." *Harm* can include physical and mental injuries, emotional distress, unneeded or unplanned hospitalizations, premature or inappropriate nursing home placement, and death. *Result of care*, or cause, includes a number of different providers, including the WRHA Home Care program (coordinators, direct service staff, "systems"), other healthcare providers, clients (self-care) and informal caregivers. Because clients' care is fragmented among several providers, this study considered AEs caused by any provider, not only home care providers.

Methods

Patient safety studies have used a variety of retrospective and prospective methods. This study used retrospective chart reviews prompted by a mixed screening process.

In retrospective studies, the availability of comprehensive clinical and functional data is critical. The WRHA Home Care program uses a comprehensive electronic record that includes client demographic information, case manager progress notes, assessments and care plans. The program uses the internationally developed Minimum Data Set for Home Care (MDS-HC) assessment tool (Landi et al. 2000; Morris et al. 1997). The care plan component includes home care services and the contributions of other healthcare providers, clients and informal caregivers. While

the home care client file is not a system-wide electronic health record, it contains comprehensive information about clients' health and functioning that was used to identify AEs.

Study Sample

The study focus was on long-term clients, who account for the majority of clients in the Home Care program. There were 14,624 such clients in WRHA Home Care during 2004 (based on program statistics provided by WRHA). A random sample of 400 client files opened in February and March of 2004 was extracted from the electronic client file database. Clients were excluded if they were discharged within 30 days of intake, did not have a completed assessment, or were identified as palliative.

Table 1. Summary of screening protocol

Screening Protocols	Sample Search Criteria
Fall	MDS-HC: At least 1 fall in last 90 days Keyword: "fall" or "fell" Occurrence Report: 4.2 Falls
Injuries/breaks/fractures	MDS-HC: Presence of fractures or other injuries Keyword: "injure"
Skin problems or ulcers	MDS-HC: Presence of pressure ulcer Keyword: "ulcer" or "sore"
Infections	MDS-HC: Urinary tract infection and use of indwelling catheter Keyword: "infection"
Medication-related events	Keyword: "reaction" or "overdose" Potentially inappropriate medication search Occurrence Report: 4.1 Medications
Hospitalization	MDS-HC: At least 1 overnight hospital stay, visit to the ER or emergent care in last 90 days Discharge: Hospitalized Keyword: "hospital" or names of hospitals in Winnipeg
Nursing Home Placement	Discharge: Placed in nursing home Keyword: "panel" or "nursing home" or "personal care home"
Death	Discharge: Deceased Keyword: "death" or "died"
Screening Types:	
<i>MDS-HC (Minimum Data Set for Home Care):</i> Standardized assessment tool used by WRHA Home Care.	
<i>Discharge:</i> Discharge records including reason for discharge.	
<i>Keyword:</i> Search for list of keywords in clients' progress notes.	
<i>Potentially Inappropriate Medication Search:</i> Medications identified as potentially inappropriate for seniors, as defined by expert panels.	
<i>Occurrence Report:</i> Voluntarily reported incident report.	

Screening

Screening protocols were developed to identify a variety of types of AEs clients might experience or the harm AEs could cause (Table 1). Screening was limited to the year following intake, as this study sought to measure the annual incidence of AEs.

The screening process had four components. First, clients' MDS-HC assessments and their discharge records were searched for items identifying possible AEs. Second, clients' progress notes were searched for keywords or phrases, developed by adapting lists from other studies (Forster et al. 2005; Murff et al. 2003) and findings from the consultation sessions. The search was case-insensitive and looked for matches that contained roots of keywords to ensure both singular and plural forms were included (e.g. a search for "fall" could yield matches for "falls" and "fallen") as well as common synonyms (e.g., "pressure ulcer" and "bed sore").

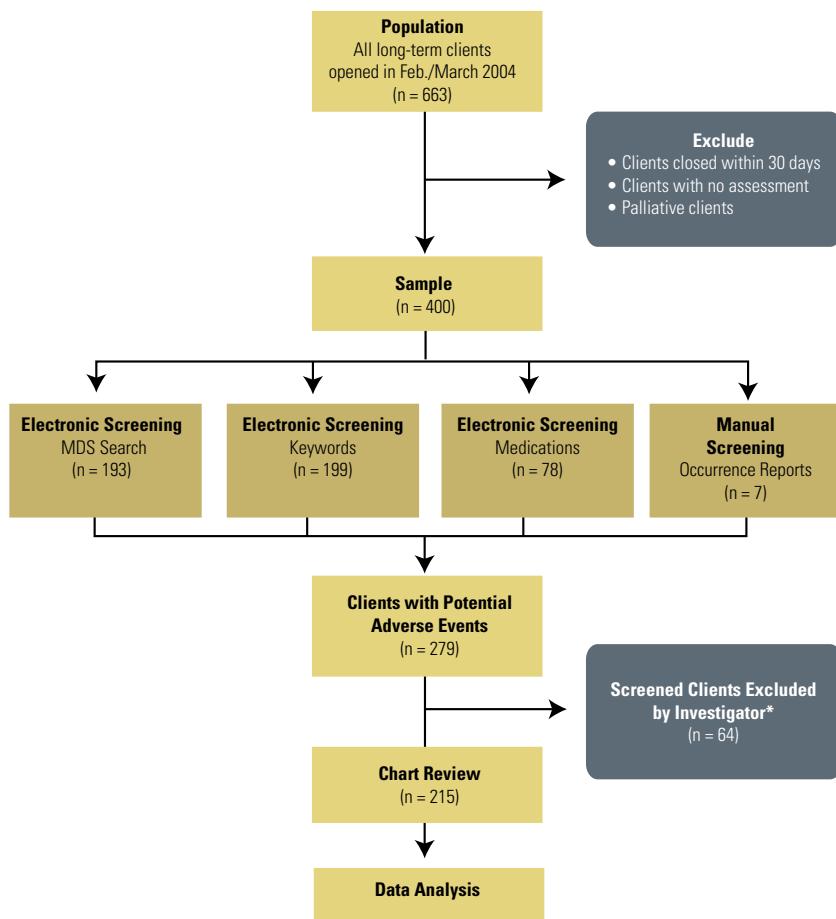
The third screening process involved searching assessment records and medication notepads for any potentially inappropriate medications, as defined by expert panels (Beers 1997; Fick et al. 2003; McLeod et al. 1997) using Fialová et al.'s (2005) search criteria. While the names of medications, dosage, route and frequency are noted in client files, Drug Identification Numbers are not consistently recorded. Consequently, this screen was limited to searching for the full names and key name fragments of potentially inappropriate medications, which could exclude some matches due to incorrect spelling. This search was limited to clients aged 65 and older, expected to account for most of the sample.

Table 2. Rating scales for judging adverse event and preventability/ameliorability

Adverse Event Rating Scale	Preventability/Ameliorability Rating Scale
0 No event occurred	
1 Virtually no evidence event caused by care	1 Virtually no evidence of preventability/ameliorability
2 Slight to modest evidence event caused by care	2 Slight to modest evidence of preventability/ameliorability
3 Not likely event caused by care (less than 50-50, but close call)	3 Not likely event could have been prevented/ameliorated (less than 50-50, but close call)
4 More likely event caused by care (more than 50-50, but close call)	4 More likely event could have been prevented/ameliorated (more than 50-50, but close call)
5 Moderate to strong evidence event caused by care	5 Strong evidence of preventability/ameliorability
6 Virtually certain evidence event caused by care	6 Virtually certain evidence of preventability/ameliorability

Rating scales based on those used in existing hospital and post-discharge studies (Baker et al. 2004; Forster et al. 2003; Forster et al. 2004).

Figure 1. Data collection and review methods with client counts



*Some screened-in clients were excluded because they clearly hadn't had an adverse event (i.e., the word "fall" screened the client in, but the word was used as "will follow-up in the fall") or potential event happened before client was open to home care.

The Micromedex database was cross-referenced for all Canadian and American listings for noted medications.

The final screening approach searched WRHA occurrence (incident) reports. Occurrences are reported voluntarily by staff and filed centrally. An administrative assistant manually searched for occurrence reports on file for the study sample.

Chart Reviewing

Four trained chart reviewers reviewed charts for all clients who screened positive. Three of the reviewers were Home Care Specialists and one was a Team Manager; each had worked in home care for at least 15 years. Three of the reviewers were social workers and one a nurse. Chart reviewers attended a half-day training session to ensure they were familiar with the concepts used in this study, the screening process and chart reviews.

For all clients flagged during the screening stage, chart reviewers judged whether an AE had occurred. If an AE occurred, chart reviewers indicated the date, type of AE, level of harm or impact to the client, and cause, and rated whether the AE could have been prevented or ameliorated. Scales for judging the likelihood an AE occurred and preventability/ameliorability were adapted from other studies (Table 2 provides sample rating scales). For clients judged to have had a preventable or ameliorable AE, reviewers explained how the event could have been prevented or ameliorated. Reviewers also rated the adequacy of client records using an existing scale (Woloshynowych et al. 2003).

Chart review data were entered into an anonymized electronic database twice for accuracy. Scores for judging whether an AE had occurred and for preventability and ameliorability were dichotomized, with scores of four or more (at least 50% certainty) indicating the presence of an AE or that the AE was preventable or ameliorable. Steps in the study methods are illustrated in Figure 1, along with the results for each step.

Approval was obtained from the University of Manitoba Joint-Faculty Research Ethics Board and the WRHA Research Review Committee.

Results

Characteristics of the study sample were compared with those of the home care population (Winnipeg Regional Health Authority 2005). The sample and population were similar in age and gender distributions, functional impairment and medication usage (Table 3), though the sample is slightly younger and less impaired, and took fewer medications.

From the sample, 279 clients (69.8%) were flagged during the screening process (Figure 1). Several clients were identified by more than one method (Figure 2). Sixty-four of the screened-in clients were excluded during a brief manual review of the screens. Clients were only excluded if the context of a keyword match was clearly inappropriate (e.g., searching for the word

Table 3. Demographic and functional characteristics of sample and population

	Study Sample (n = 400)	Home Care Population* (n = 10,991)
Age		
Mean (SD, range)	75.4 (12.8, 26–96)	77.5 (13.8, 15–104)
≥ 65 years	81.5%	87.8%
≥ 85 years	23.8%	33.5%
Gender		
Female	65.7%	70.9%
Functional Characteristics† (n=9026)		
Cognitive impairment (CPS ≥ 2)	26.5%	27.3%
Depression (DRS ≥ 3)	7.3%	8.6%
ADL dependency (ADL hierarchy ≥ 2)	17.0%	22.0%
IADL dependency (IADL involvement ≥ 2)	81.5%	87.7%
Medication Usage in Prior 7 Days‡		
≥ 1 medication	91.8%	96.5%
≥ 6 medications	53.8%	61.0%
≥ 9 medications	26.0%	32.9%
Psychotropic drug use	30.3%	39.6%

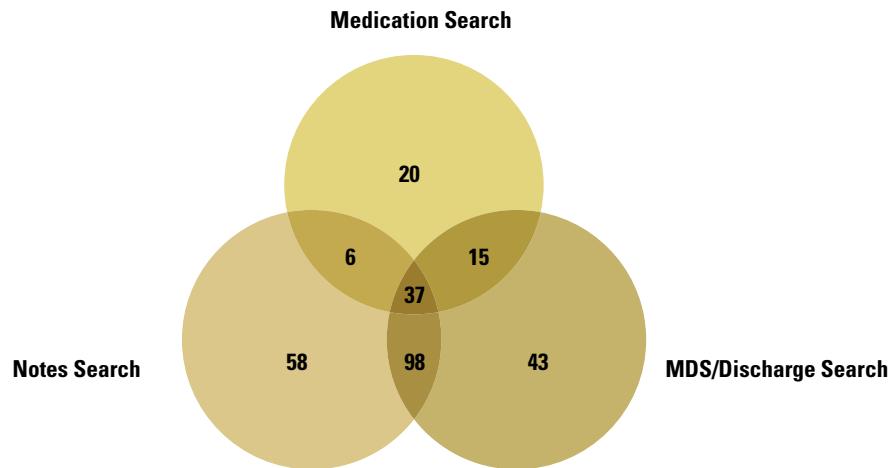
*The description of the home care population is drawn from a report based on all long-term clients opened as of December 31, 2004. For age, gender and geographic distribution, all clients were included (n = 10,991). For functional and medication use characteristics, only clients with Minimum Data Set for Home Care (MDS-HC) assessments completed in the previous year were included (n = 9026).

†Functional characteristics, based on MDS-HC, include: CPS (Cognitive Performance Scale), in which a score of 2 or more indicates some level of impairment (Morris et al. 1994); DRS (Depression Rating Scale), in which a score of 3 or more indicates potential depression (Burrows et al. 2000); ADL Hierarchy, in which a score of 2 or more indicates assistance in any of eating, toilet use, locomotion and eating (Morris et al. 1999); and IADL involvement, in which a score of 2 or more indicates that at least one of ordinary housework, meal preparation and/or phone use was performed by someone else (Landi et al. 2000).

‡Medications in past 7 days include both prescription and over-the-counter drugs; psychotropic drug use includes any of antipsychotics/neuroleptics, anxiolytics, antidepressants, hypnotics.

“fall” and finding “will call client in the fall”) or if the potential event clearly occurred before or after the study period (e.g., client had a fall before intake).

The remaining 215 clients (53.8% of sample) were forwarded for a full chart review to determine if an AE had actually

Figure 2. Results of electronic screening methods

*Total of 277 clients identified in Venn diagram. The additional two clients that make up the total 279 identified by screening were identified exclusively by an occurrence report; of the seven clients identified by occurrence reports, five were also identified by an electronic screening technique.

occurred. Of these clients, 22 were found to have experienced at least one AE, indicating a 5.5% annual incidence of AEs among the sample (95% CI 3.3%–7.7%). Twenty-six AEs were found among these 22 clients, with three clients having had multiple events.

Injurious falls accounted for nearly half (46.2%) of the 26 AEs, followed by medication-related events (23.1%), non-injurious falls (15.4%), pressure ulcers (3.8%), mental harm/injury (3.8%) and other (7.7%). Most of the AEs (69.3%) resulted in temporary harm or injury to the client. One of the 26 events caused permanent harm. For the remaining events, the level of harm was listed as otherwise unneeded hospitalization (15.4%), premature nursing home placement (3.8%) and other (7.7%). No events were found that resulted in a death.

Chart reviewers also identified providers that were associated with the AE. Reviewers identified multiple contributing providers in 46.2% of events. Fifty percent of AEs were associated with home care, and all but one of these were related to case management issues rather than to direct service delivery. Informal caregivers were identified as contributing to 42.3% of AEs, and clients themselves in 30.8% of events. Other healthcare providers, identified by chart reviewers as family physicians and hospitals, were associated with 42.3% of the AEs.

Chart reviewers also judged whether the AE could have been prevented or ameliorated. Of the 26 events identified, 42.6% were rated as ameliorable and 26.9% as preventable. Among the 22 clients who experienced at least one AE, 45.5% had an AE

that was ameliorable and 27.3% had an AE that was preventable. This means that 4.0% of the sample experienced an AE that was either preventable or ameliorable (95% CI 2.1%–5.9%).

Many of the reviewers' comments about preventability and ameliorability reflect "system" issues, such as practice and communication. Most comments related to the absence of or delay in referrals for occupational or physical therapy that might have prevented or ameliorated falls. The involvement, or noninvolvement, of other providers (e.g., physicians, hospitals) was also noted as a contributing cause, with specific examples related to communication challenges between providers, premature hospital discharge and delays in referrals.

Further analysis by contributing providers found that nearly all of the events associated with home care were rated as preventable or ameliorable (94.5%). For AEs for which other providers were responsible, reviewers rated only 36.4% as ameliorable or preventable. Nearly all (92.6%) of the home care AEs were falls while adverse drug events (ADEs) accounted for just over half (54.3%) of the AEs for which other providers were responsible. Table 4 provides a description of the types, preventability and ameliorability of AEs by responsible providers.

One final aspect of the study, which applies only to clients 65 years and older ($n = 326$ or 81.5% of sample), identified clients taking potentially inappropriate medications. A total of 78 clients, or 23.9% of seniors in the sample (95% CI 19.4%–28.5%), had taken potentially inappropriate medication. While many of these medications are listed as high-risk by the Beers

expert panel (Beers 1997; Fick et al. 2003), very few AEs were found among clients taking these medications. Eight of these 78 clients had an AE, and two of these were classified as a drug-related event.

Discussion

Extrapolating the results from this sample of Winnipeg home care clients suggests that 478 to 1,131 WRHA long-term home care clients likely experienced an AE in 2004. Of these events 304 to 866 were potentially preventable or ameliorable.

The annual incidence of home care AEs is lower than the rate of 7.5% found in Canadian hospitals (Baker et al. 2004), but higher than the rates of 2.9% and 3.7% found in American hospitals (Brennan et al. 1991; Thomas et al. 2000). It is considerably lower than rates of 19% and 23.2% found among hospital patients following discharge (Forster et al. 2003; Forster et al. 2004). The preventability and ameliorability ratings for this study, 26.9% and 42.3% respectively, are slightly higher than those found in post-discharge studies by Forster et al. (2003; 2004).

Home care was judged to be a contributing provider in half of all AEs, while other providers (family physicians and hospitals), informal caregivers and clients themselves were identified as contributing to many events. This confirms findings from both the literature and consultation sessions about the fragmentation of care provision for home care clients. Client choices and family care can create difficult situations that escalate client risk and possibly result in an AE. Clearly, the quality of care for

clients relies not only on quality home care services, but also on quality care from other healthcare providers and informal caregivers, as well as educated client and family choices about risk and care.

As this was one of the first studies to examine AEs in home care, it provides an important starting point for understanding safety issues in this setting. The approach used to adapt hospital-centred patient safety concepts and methods could prove useful not only to other home care programs, but also in other care settings (e.g., mental health, public health, primary care and long-term care), which have also been largely overlooked in patient safety research.

These findings offer important information about "client safety" and have direct implications for home care quality improvement that might help to reduce the incidence of AEs. Results suggest that client safety may be improved if two broad issues were addressed. First, nearly all of the home care associated AEs were falls, and the most common method suggested by reviewers to prevent or ameliorate falls was a referral for occupational or physical therapy. A falls prevention program and a review of the use of therapy services might be effective strategies and have the largest impact on client safety.

The second issue relates to the fragmentation of care provision for clients. Stronger communication and collaboration between home care and other providers might help to reduce the number of events attributed to these providers. Furthermore, additional client and family education might help to prevent or ameliorate AEs.

Table 4. Adverse events by contributing provider

	All Adverse Events (%) (n = 26)	Home Care Providers		Non-Home Care Providers		
		Direct Service Staff (%) (n = 1)	Coordinators (%) (n = 12)	Clients (%) (n = 7)	Caregivers (%) (n = 11)	Other Providers (%) (n = 11)
Type of Adverse Event						
Fall, injurious	46.2	0.0	66.7	14.3	54.5	27.3
Fall, non-injurious	15.4	100.0	25.0	28.6	18.2	9.1
Pressure ulcer	3.8	0.0	0.0	0.0	0.0	9.1
Adverse drug event	23.1	0.0	0.0	28.6	9.1	54.6
Mental harm/injury	3.8	0.0	8.1	14.3	9.1	0.0
Other	7.7	0.0	0.0	14.3	9.1	0.0
Preventability and Ameliorability						
Ameliorable	42.3	0.0	83.3	42.9	45.5	18.2
Preventable	26.9	100.0	8.3	0.0	36.4	18.2
Neither	30.8	0.0	8.3	57.1	18.2	63.6
Note: Some adverse events (AEs) might be listed in more than one column, because multiple providers might be identified for a single event.						

✓ Practice Improves Safety

Study Limitations

Retrospective chart review can have several limitations, including interrater reliability (agreement between chart reviewers), incomplete documentation and loss of context, and reviewer bias (Anderson 1996; Baker 2004; Birnbaum and Scheckler 2002; Localio et al. 1996; Thomas et al. 2002; Thomas and Peterson 2003). To address interrater reliability, a subsample of 18.1% ($n = 39$) of screened-in clients received two independent reviews. Reviewers agreed 87.2% of the time that an AE had occurred; the Kappa statistic for judging this variable was 0.65, described as substantial (Landis and Koch 1977). Only those units in the subsample identified as having an AE were included for comparing ratings of preventability and ameliorability. For this small number of clients ($n = 7$), reviewers agreed on all cases, a Kappa score of 1.00, or perfect agreement. Incomplete documentation and loss of context are difficult to assess in a retrospective setting. In this study, reviewers rated the adequacy of each reviewed record and deemed nearly all charts (96.8%) as adequate or having only slight deficiencies.

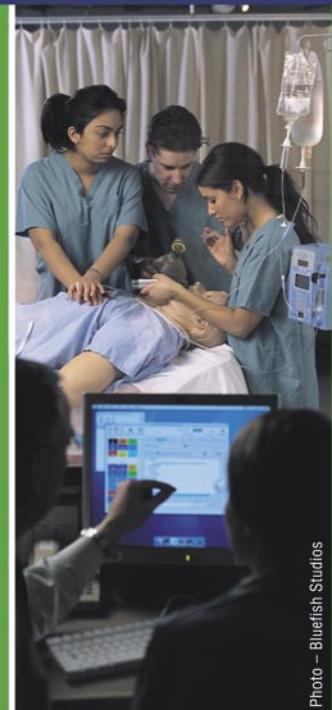
It remains possible that additional AEs occurred but were not documented in the home care file. Specifically, events caused by other healthcare providers, informal caregivers and clients may not have been recorded and, consequently, may have been missed in this study. The rate of ADEs found in the sample (1.0%) was lower than the 20.1% incidence of ADEs found among home care clients post-hospital discharge (Gray et al. 1999). This difference raises concerns that additional ADEs may have been missed.

Additional research may help to address these limitations. A more comprehensive approach for identifying ADEs is needed – perhaps linking client data with other healthcare databases, such as hospital abstracts and physician billing information. Also, this study was limited to Winnipeg clients; research in other jurisdictions would allow for a broader understanding of client safety in home care.

To view Appendix see <http://www.longwoods.com/product.php?productid=18377&cat=452>

About the Author

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Exploration of Patient Safety Phenomena in Rehabilitation and Complex Continuing Care

Carol Fancott, Karima Velji, Elaine Aimone and Lynne Sinclair

Abstract

Patient safety has been relatively unexplored in rehabilitation and complex continuing care (CCC) settings. From the perspectives of staff members, this qualitative study aimed to explore patient safety phenomena that exist within rehabilitation/CCC and to identify the characteristics of the current workplace culture that act as enablers of or barriers to patient safety. Sixty-six staff members in a large, multisite, academic rehabilitation/CCC health centre volunteered to participate in one of six interprofessional focus groups, designed to model patient care teams that exist within the clinical programs; one focus group was also conducted with support services staff. Thematic analysis revealed that rehabilitation/CCC settings present with distinct patient safety issues due to the unique and increasingly complex populations that are served, and the place of rehabilitation/CCC along the continuum of care. Enablers and barriers identified related to teamwork, culture, resources and organizational and individual responsibility. Results of this study have helped form the foundation for future patient safety initiatives within our settings, with clear emphasis on enhancing an open and just culture in which to discuss safety issues through development of improved leadership-staff relations, teamwork and communication and clearer processes and structures for accountability. The approach to addressing these issues must fit within our rehabilitation models of care.

Introduction and Background

While patient safety concerns have existed for decades, the sentinel report issued by the Institute of Medicine in 1999 entitled *To Err Is Human: Building a Safer Health System* (Kohn et al. 1999) catalyzed much of the current momentum in the area of patient safety. Much of the literature to date has focused on detecting, reporting and managing adverse events within acute care settings, as these are sites of a variety of risky medical procedures and extensive drug treatment with a high potential for errors and accidents. The literature has highlighted the issue of underreporting adverse events in acute care settings (Cullen et al. 1995) and the need for improved measurement and reporting (Baker and Norton 2001; Wong and Beglaryan 2004). However, for different settings such as rehabilitation and complex continuing care (CCC), reporting safety events may be compounded by the lack of knowledge of unique patient safety phenomena that exist within these settings, where there are differences in clinical issues, patient populations, team composition, reduced availability of physicians, higher involvement of non-nurse practitioners (e.g. rehabilitation therapists) and greater participation of patients and family members within a client-centred model of care.

The rehabilitation patient safety literature has focused more on particular processes and outcomes, for example, falls prevention (Simpson et al. 2003; Theodos 2003) and the use of physical

restraints and bedrails (Gallinagh et al. 2001). Equipment used in the rehabilitation setting (e.g., wheelchairs, bathing equipment and other modalities) has also been examined (Kirby and Lugar 2000; Malassigne et al. 2002; Travis et al. 2001). Specific rehabilitation populations have been studied (e.g., acquired brain injury), along with issues unique to these populations (e.g., physical aggression, establishing risk and harm) (Willis and LaVigna 2003). Discharge planning and home assessment have also figured prominently in the literature (Durgin 2000; Gitlin et al. 2002). However, these studies focus on one specific aspect of patient safety, and do not consider the broader context or environment in which safety occurs within these different settings.

As one of Canada's largest rehabilitation and CCC facilities, the Toronto Rehabilitation Institute (Toronto Rehab) has responded to the need to enhance patient safety specifically through a rehabilitation lens. Currently, we know from the approximately 1,100 incidents reported electronically every year in our hospital that the majority of incidents fall into one of three categories: patient falls, medication errors and incidents involving aggressive patients. To help us consider these patient safety issues and to explore others within our settings, we have proposed a new framework, the Toronto Rehab Patient Safety SAFE Framework (Velji and Aimone 2004), that broadens our notions of patient safety beyond adverse events to creating best outcomes for patient care. This framework consists of four pillars that contribute to the overarching beam of a safety culture, one that is open and safe to allow for honest discussions of patient safety issues and concerns. The four pillars required to support such a culture include: a systems approach; apply lessons learned; find solutions that minimize human error; and evaluate and monitor systems and processes appropriately (see Figure 1).

Purpose of the Study

Using the SAFE Framework as a theoretical basis, the purpose of this qualitative study was to explore patient safety issues within rehabilitation and CCC, and the environment in which patient safety occurs. Specifically, this study had the following research questions:

From the perspective of staff members:

1. What are the phenomena of patient safety within rehabilitation and complex continuing care?
2. What are the characteristics of the current workplace culture that act as enablers of or barriers to patient safety?

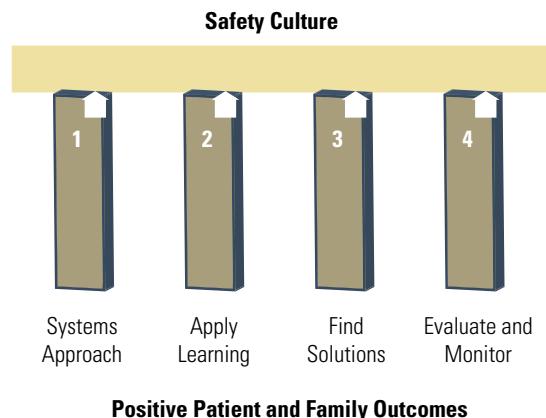
Study Design

Guided by the research questions above, a qualitative methodology was employed using focus groups as the method for data collection. A key feature of these focus groups was to model not only the interprofessional teams that exist within our settings, but also to model an open and safe environment in which to discuss safety issues. A total of seven focus groups were conducted; one

focus group was done in each of the six programs of Toronto Rehab and one was conducted with support services staff who have direct patient contact. A semistructured interview guide with open-ended questions was used to allow for consistency of core questions, but probes differed depending on the opinions expressed by group members.

A constant comparative approach to data analysis was conducted, as outlined by Strauss and Corbin (1998). Interview transcripts were coded line by line, allowing for the identification of emerging categories and trends. Similarities and differences were constantly compared across groups to derive themes. These themes and concepts were examined by the investigative team, to determine their meaning and how they may or may not be related to each other and the questions under study (Creswell 1998; Strauss and Corbin 1998). As a method of triangulation, two focus group transcripts were coded by the investigative team to ensure consistency in meanings and derivation of the themes. The research coordinator coded all of the interview transcripts

Figure 1. Toronto Rehab Patient Safety SAFE Framework



Positive Patient and Family Outcomes

The 4 pillars of the SAFE Framework include:

Systems Approach Evaluating sentinel events and preventing their recurrence – appropriate use of tools such as root cause analysis and failure mode effect analysis; creates a practice environment that produces safe outcomes.

Apply Learning Have clear formal mechanisms for transferring lessons learned from one area to another or one committee to another, and with other healthcare organizations.

Finding Solutions Improved systems to counteract human error (simplifying, reducing handoffs, limiting options, scheduling, decision aids and verification steps), electronic triggers (flag for wrong dose), standardizing processes of care (assessment of pain, skin care protocols).

Evaluation/Monitoring Method for measuring trends in incidents, establishing tolerance limits, sustaining improvement – adding “near misses” to data capture, implementing a standardized follow-up process to prevent recurrence of incidents.

and completed the thematic analysis in consultation with the investigative team.

Study Findings

Description of Participant Group

Sixty-six staff members participated in one of seven scheduled focus groups. Participants included managers, leaders and educators, service coordinators, physicians, registered nurses and registered practical nurses, physical and occupational therapists and assistants, speech language pathologists, social workers, pharmacists and pharmacy technicians, chaplains, psychologists, kinesiologists and cardiovascular technologists. Support services staff included representatives from housekeeping, maintenance, portering services, occupational health and safety, infection control and administrative services. Almost one-third of participants have been in the organization for 1 to 5 years, and almost another third had over 16 years of experience within Toronto Rehab. Over 60% of the participants had a minimum of a bachelor's degree; over 80% of the participants worked full time and were female staff members, which mirrors the workforce within our organization.

Thematic Analysis

A number of interrelated themes emerged from the focus groups, which will be presented in line with the research questions posed. As highlighted in the quote below, this group of participants perceived and experienced patient safety broadly in our settings, articulating patient safety beyond notions of adverse events and medical errors:

"It [patient safety] is multi-level. It is physical, it is spiritual, it is emotional – safety is multi-layered. ... I sort of see it as a sense of comfort, trust, and a sense of ease, a sense of community, something to do with regularity of communication and familiarity. It is more than just the absence of critical incidents ... we all work for the best possible outcomes for our patients. ... It makes me think about dignity and how to protect the client as much as possible while still not compromising their feelings of autonomy."

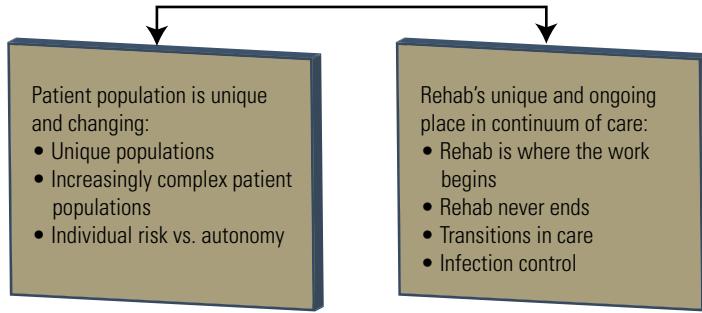
Patient Safety Phenomena in Rehabilitation and CCC

In research question one, we wanted to explore the phenomena of patient safety within rehabilitation and CCC settings. Two main themes emerged from the focus groups: first, that our

Figure 2. Exploration of patient safety in rehabilitation and complex continuing care settings

RQ 1: What are the phenomena of patient safety within rehabilitation and complex continuing care?

Two main themes emerged:



patient population is unique and is rapidly changing; and second, that unique challenges and phenomena related to patient safety exist due to where rehabilitation and CCC are situated in the continuum of care (see Figure 2).

Participants consistently talked about their patient populations as unique – distinct from acute care, but also distinct from program to program. While some commonalities existed, such as vulnerable and/or frail populations, staff also discussed dealing with patients with cognitive impairments, or those with aggressive or violent behaviour who may pose a threat to themselves, to staff, or to other patients and their families. The issue of individual risk vs. the autonomy of patients figured prominently in the discussions, particularly as it pertained to informed decision-making, discharge planning and dealing with a third-party decision-maker. Patients may make informed choices and may engage in behaviours we consider "risky." For those patients for whom the institution is their home, compounding factors include consideration of the safety of other patients and staff sharing similar space.

Staff also discussed dealing with an increasingly complex patient population. Patients are admitted sooner to rehabilitation from acute care, and often with increasing complexity and comorbidities. Staff expressed concern as to the appropriateness of some patients admitted, who may not be ready to truly engage in the rehabilitation process. They also expressed concern as to their own skill level and experience in dealing with these "new" populations, and how staff development and ongoing learning was managed within their programs.

The second major theme to emerge was the view of rehabilitation and CCC's unique and ongoing place in the continuum of care. Many staff felt that this is where the "real work begins," as we are pushing patients to their limit physically, mentally and

emotionally, throughout the rehabilitation process. Due to the permanency of many of our patients' disabilities, rehabilitation "never really ends" when they are discharged from the institution, as the patient may require ongoing care and rehabilitation in the community.

When looking at rehabilitation and CCC's place in the continuum of care, numerous transitions in care occur – from acute care to rehabilitation to another facility or to home, all of which require effective communication, timely discussions about discharge, and ensuring that the appropriate supports are in place to allow seamless transitions to occur. There are also numerous internal transitions – from shift to shift, from caregiver to caregiver – again all requiring appropriate and timely communications. The internal struggle that many staff deal with related to discharge planning and transitions is highlighted in this quote:

"I mean I don't think any of us around the table have a vested interest in keeping patients here longer. We all recognize that living in an institution isn't a great thing. ... But if we could be confident that we had really good services in the community, there would be appropriate places for people to live and receive care – then that wouldn't be a problem."

Enablers of and Barriers to Patient Safety

The second research question examined the enablers of and barriers to a culture of patient safety. Four main themes emerged that were consistent across all of the focus groups, some which were discussed as enablers or, alternatively, as barriers to patient safety culture depending on the unit, program or site across the organization. The emerging themes are interrelated and included teamwork, culture, resources and organizational and individual responsibility for safety (see Figure 3).

Teamwork was a consistent message that emerged in all of the focus groups, that is, the development of teamwork, which ultimately was built on relationships of trust and respect for peers and colleagues, and the development of communication patterns in an open and honest manner. Staff pointed to strong leadership that would foster team collegiality and cohesiveness, and to set the tone for how communication and respect are developed and how both clinical and nonclinical staff are included as part of the team.

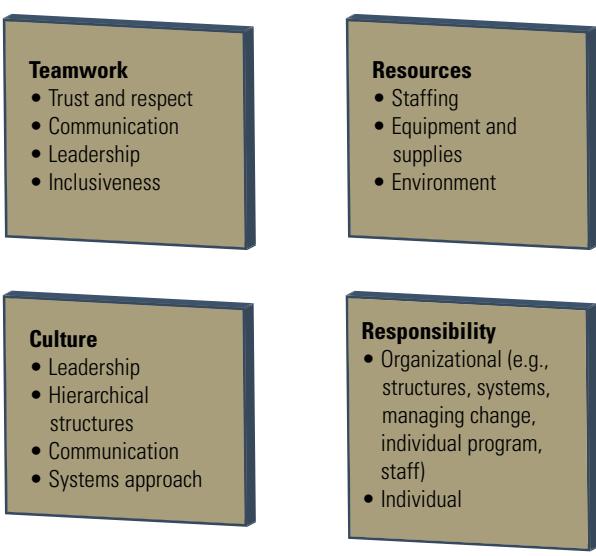
Organizational culture, deemed in the literature to be one of the most important elements for patient safety, emerged as another key theme. Staff participants again discussed the need for strong leadership, both to model the appropriate behaviours regarding safety and to set the tone for patient safety as a priority. Frontline workers desired a culture that fostered mechanisms to provide feedback, suggestions or ideas. Staff participants articulated a safety culture as one of learning rather than one of reprisal. The issue of hierarchy was raised by one staff member as a barrier to patient safety and communication:

"There is still a big hierarchy in this facility and there is still a lot of not feeling safe about being honest and advocating for your patients because people have had consequences as a result of advocating for their patients, so it makes you think twice about what you are going to say and how you are going to say it. ... I think that is a safety issue because if I'm afraid to say what I think needs to be said, then I can't do my job properly and that sort of strangles me. ... We have to feel supported, like it's not risky to tell the truth."

Appropriate staff and equipment resources were also deemed essential for patient safety culture. Staff resources included manageable staff–patient ratios, appropriate discipline and skill mix and the required experience or professional development opportunities to ensure staff

Figure 3. Enablers of and barriers to patient safety

RQ 2: What are the characteristics of the current workplace culture that act as enablers of or barriers to patient safety?



were well prepared to deal with changing patient populations. Participants pointed out that equipment and supplies need to be readily available, functional and well maintained. The physical environment needs to be conducive to safety and security – one that does not exacerbate patients' symptoms or anxiety and that provides adequate space for team members to do their jobs appropriately (e.g., gym space for therapy, private space for counselling).

Lastly, focus group participants drew attention to both the organizational responsibility and their individual responsibility for patient safety. They felt that appropriate and accountable systems and structures are required to support a safe environment. Organizational and program change need to be managed in a structured, coherent, inclusive manner. Staff also felt that they had a right to safety at work, and that if their work environment was safe, patient safety would emerge naturally. At the same time, they all recognized that they had individual responsibility and accountability. One participant felt that all staff needed to take on a "this is my house" mentality, and not "pass the buck" to others to assure responsibility.

Implications for Practice

Knowledge gained from this study has highlighted the distinct populations and type of care delivered in rehabilitation and CCC that contribute to the patient safety phenomena experienced within our hospital. The findings also reaffirmed that enablers of and barriers to a patient safety culture as described in other literature (Wong and Beglaryan 2004) are relevant to rehabilitation and CCC settings. The focus group method in this initial research project allowed us to operationalize a key feature of the SAFE Framework by providing an open, transparent and safe environment in which interprofessional staff could discuss safety issues. Grounded in evidence from these internal stakeholders, we have embarked on a patient safety agenda that includes a number of initiatives:

1. **Building an open and accountable culture of safety.** The results of our study support other literature that points to a safety culture as a key element for patient safety. A number of concurrent initiatives have been developed to support and enhance an open, transparent and accountable culture within our organization.

(a) **Leadership development and engagement:** As a first step to enable a safety culture, we are currently engaging and energizing all clinical leaders and managers within the organization through a series of workshops and discussions about patient safety culture, what it means and how it may be operationalized. These discussions also include the development and implementation plans of a number of policies, procedures and process mechanisms

to support patient safety initiatives, such as a disclosure policy and transforming incident reporting to be reflective learning experiences. Key to this process has been the engagement and focus of senior leaders to model supportive behaviours of openness and accountability. In step with this leadership engagement, we will launch Patient Safety Leadership Walkabouts where members of our senior management team will engage staff in open and meaningful discussions about patient safety concerns and ensure timely response to concerns raised.

- (b) **Incident reporting and debriefing:** Staff who participated in this study articulated broad notions of patient safety to move beyond adverse events and to encompass best patient outcomes. Our challenge is to have staff act on these views by reporting both near misses and incidents that reflect this broad notion of safety within our organization. We also know from our study that intrinsic to reporting safety incidents is the ability of staff to do so in a safe and trusting environment, and to know how processes are standardized to manage reported events. Our efforts to engage leaders and staff in a culture shift, along with discussions with external healthcare leaders, have helped to guide the development of clear and transparent mechanisms ensuring that incident reports are consistently managed and debriefed as a learning opportunity rather than an exercise of blame.
- (c) **Evaluation of safety culture:** The qualitative description of the current organizational culture for safety gained in this study will be augmented by results of the recently administered "Hospital Survey on Patient Safety" (Westat et al. 2004). Results of this survey will provide another baseline indicator of our safety culture and will be conducted on a regular basis (i.e., yearly) to assess any changes in culture and assist with the development of future patient safety initiatives.

2. **Teamwork and communication.** Clearly, staff have highlighted the necessity of strong teamwork and communication for patient safety. To build upon the findings of this study and other literature, we have been funded by the Canadian Patient Safety Institute to conduct a study aimed to enhance team communication for patient safety by adapting, implementing and evaluating the use of the SBAR (Situation-Background-Assessment-Recommendation) (Leonard et al. 2004) communication tool within one of our clinical teams. Positive learnings and outcomes from this new study will be transferred to other clinical areas within our organization.

3. **Staff resources.** Findings from this study have highlighted the need for consistent and experienced staff in order to develop strong teams that have clear communication channels. These results support the recently implemented "Nursing Staffing

for Quality of Care Project" as a strategy to reduce the use of agency staff and increase full-time nurse staffing ratios to build effective and stable teams for quality patient care.

Conclusion

We have learned that adverse events and factors that impact on quality of care and patient safety are unique in a rehabilitation and CCC setting; however, the enablers of and barriers to safety, including teamwork and communication, organizational culture and resources, are similar to safety issues raised in other settings. We have applied this learning in our next steps to focus safety efforts on developing and implementing a formal leadership engagement plan to enhance a culture of openness, improvement and accountability, break down hierarchical communication barriers, improve incident reporting and debriefing mechanisms and examine resource issues related to patient care. Our patient safety agenda is a work-in-progress. Through the unique lens of rehabilitation and CCC, we look to build upon this foundation and continue to progress our work in this area. As articulated by our staff:

"Number 1 priority is patient safety. I think everything that we do revolves around their safety and progressing them or however we interact with them. I think in the back of our mind even though we are not conscious of it, it is constantly the #1 priority."

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