volume eight • 2005 • www.patientsafetypapers.com

Healthcare Quarterly

SPECIAL ISSUE

Papers

PATIENT SAFETY

IHQ Fonds cpsi icsp Canadian Patient Safety Institute Institut canadien pour la sécurité des patients OHA ONTARIO HOSPITAL ASSOCIATION

"Safer Healthcare Now!"

National Campaign Inspires Hospitals to Utilize IT to Improve Patient Care

In Canada, studies show that 7.5 percent of patients admitted to acute-care settings experience adverse events. Now, through a grassroots campaign called "Safer Healthcare Now!," more than 80 healthcare organizations have enrolled to help reduce the incidence of injury and death due to these events. Taking its inspiration from the "100K Lives" campaign in the United States and adapted to the Canadian healthcare system perspective and data collection process, the "Safer Healthcare Now!" campaign consists of six main strategies:

1. Deploy rapid response teams
2. Consistently deliver reliable, evidence-based care for acute myocardial infarction
3. Prevent adverse drug events
4. Prevent central line infections
5. Prevent surgical site infections
6. Prevent ventilator-associated pneumonia

Cerner Corp. is the only healthcare IT company with the tools to make the content executable and actionable to successfully meet the strategies of "Safer Healthcare Now!"

Deploy Rapid Response Teams

Cerner's *Executable Knowledge*®, APACHE® and *CareNet*® solutions can notify the rapid response team at the first sign of an impending crisis such as heart attack, stroke or allergic reaction that could be life threatening.

Prevent Adverse Drug Events

Cerner's medication-utilization and error-prevention modules are the only patient safety content offering on the market supported by peer-reviewed research. Through alerts that support each step of the medication process, this system of automated checks and balances saves time and provides added insurance against life-threatening ADEs.

Prevent Acquired Infections and Provide Evidence-Based Care

Cerner's *PowerPlan*™ provides centralized plan and order management, clinical pathways, protocols, variance and outcome documentation and *Executable Knowledge* embedded at the point of care. The results of planned activities are measured against expectations, the variance is captured and the care team is notified.

Through Cerner's structured, enterprise-wide data warehouse, *PowerInsight*®, real-time access to clinical, financial and operational data is available in one location. Using this information, physicians and nursing leaders can track process outcomes and trends and identify best practices.

Cerner has a passion for transforming healthcare through the use of technology and applauds the "Safer Healthcare Now!" campaign for its efforts. For more information on how Cerner supports patient safety, please contact us at **www.cerner.ca**.

"The Cerner Millennium® clinical applications are fully integrated applications that provide clinicians immediate access to test results, alerts for adverse drug events and the patient's medical history for the previous visits to the institution. These applications are the foundation for building the electronic medical record, thus providing the conduit for reducing medical errors and increasing patient safety."

— Judith C. Preuitt, Deputy Chief Information Officer, St. Joseph, Sisters of Mercy Health System

Editorial

Lessons learned and challenges ahead: Canadian experiences in improving patient safety

"Medicine used to be simple and ineffective and relatively safe, but now it is complex, effective, and potentially dangerous." (Chantler 2001).

This special issue of *Healthcare Quarterly* reports Canadian experiences in identifying and improving patient safety. The commitment to quality in Canadian healthcare is not new; but the identification of patient safety as a strategic goal is still emerging, and the recognition of the need to master and apply new skills and knowledge has just begun. The papers in this issue bear witness to a growing awareness and accelerating efforts to enhance the reliability of healthcare in our country.

Several events were critical in stimulating this engagement with patient safety. The National Steering Committee on Patient Safety, ably chaired by Dr. John Wade, alerted policy-makers and national organizations to the overlooked burden of injury resulting from poorly designed systems and inadequate communication and teamwork in our healthcare organizations. Their 2002 report, *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care,* led to the creation of the Canadian Patient Safety Institute in late 2003. CPSI, together with a set of provincial quality and safety councils in Alberta, British Columbia and Saskatchewan and important initiatives in Quebec, Manitoba, Ontario and elsewhere, provide a growing infrastructure for the development of the skills and knowledge to improve patient safety. Yet policy recommendations and quality councils are not enough to convince those who are skeptical that current patterns of delivery and professional education need to be redesigned to create safer healthcare. The Canadian Adverse Events Study, which reported in May 2004, offered the first national data on the incidence of adverse events in acute care. While the study addresses only one component, it offers a model for understanding the burden of injury across the healthcare system. Just as important as the study was the parallel knowledge linkage and exchange effort designed to engage decision-makers from government and professional organizations. As early as June 2002, the researchers and decision-makers worked to build a receptive environment for the release of the results of the adverse events study two years later.

The reports in this issue bear witness to the achievements of people and organizations across Canada in improving patient safety. They are organized by key themes. First there is a series of articles addressing the critical but elusive task of crafting organizational and professional cultures that enhance patient safety. Such cultures are essential for engaging staff and creating an effective environment for improving care. In the section *Nurturing a Patient Safety Culture,* the authors provide guidance on measure and shifting cultures to support safety.

One critical aspect of an effective patient safety culture is the acknowledgment and reduction of risk. Improving patient safety requires the surfacing of current risks in all critical processes and the use of structured techniques for analyzing and reducing such risks. In the section *Identifying and Reducing Risk*, several papers provide insights into the experiences of organizations in identifying and ameliorating such risks.

The Canadian Adverse Events Study and other research have pointed up the importance of improving medication safety. New tools have been developed to identify issues in medication ordering, dispensing and administration, and to improve practices in these areas. Canadian practitioners and researchers are world leaders in this area; the results of several key medication initiatives are reported in this issue in the *Medication Safety* section.

The reports in this issue bear witness to the achievements of people and organizations across Canada in improving patient safety.

Despite the enormous volumes of data generated by the daily work of the hundreds of thousands of encounters, tests and decisions in healthcare, remarkably little useful information is available for those who wish to reduce risk and design more effective systems. Our fourth group of papers, in the section *Developing Information for Improving Safety*, address some of the challenges of collecting and transforming data to inform busy clinicians and managers responsible for safety.

Provincial and healthcare organizations have had varied approaches to patient safety. The lessons learned from these different efforts offer a rich array of experience for those facing choices in the design of their own safety initiatives. In the section *Designing an Agenda for Change*, authors provide accounts of experiences from leading organizations across the country to advance patient safety.

A critical challenge for those working on patient safety has been the fear of litigation and discipline that limits discussion of the actions and conditions leading to adverse events. In the final section of this issue, *Disclosure and Accountability*, we highlight the nature of the legal environment that influences and sometimes steers our efforts to improve safety, and provide important accounts of organizational strategies for improving disclosure and balancing the needs for accountability and safety.

While risk can never be totally eliminated, we know safer healthcare is possible.

Together, the more than two dozen papers in this special issue offer an important resource for those just beginning to grapple with these complex issues. Clearly the achievement of more reliable healthcare will require substantial efforts to build new competencies and change the existing attitude that the risk of injury is the inevitable accompaniment of complex care. While risk can never be totally eliminated, we know safer healthcare is possible. The wisdom derived from the experiences reported in this issue highlight the successes achieved and some of the challenges that remain.

– 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.

References

Chantler, Sir Cyril (former Dean, Guy's, King's and St. Thomas's Medical and Dental School, England). 2001 July. *Learning from Bristol.* Bristol Royal Infirmary Inquiry Final Report: The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984–1995. Presented to Parliament by the Secretary of State for Health (England).

BD.id™

Patient Identification System for Specimen Management

BD

Helping all people live healthy lives

A notch above…

- Protect patients by reducing mislabeling mistakes.
- Protect your bottom line by incorporating the cost of the BD.id™ System into your BD Vacutainer® Plus Plastic Tubes, with the patented alignment notch.
- Contact us at **1.800.268.5430** or visit our Web site at **www.bd.com/bdid** to learn more.

Mislabeling may result in costly mistakes

BD Diagnostics
Preanalytical Systems
2771 Bristol Circle
Oakville, ON L6H 6R5

HQ In This Issue

Safety Starts with the Label

Bolder, Clearer IV Bag Labels

Committed to a Safer Healthcare Environment

Baxter

DESIGNING AN AGENDA FOR CHANGE

DISCLOSURE AND ACCOUNTABILITY

Patient Safety and the Contribution of Canada Health Infoway

Canada Health Infoway / Inforoute Santé du Canada

Patient safety is one of the most important healthcare issues of our time. Public concern continues to revolve around getting access to the care we need, the quality and safety of the care we receive, and the productivity of our healthcare system. In 2004, the Canadian Institute for Health Information co-sponsored the Canadian Adverse Events Study. It estimated that between 9,250 and 23,750 hospital patients die each year from a preventable adverse event.

The persistence of a paper-based information management system presents an almost insurmountable challenge to healthcare providers given the volume of information they must manage, and the inadequacy of the tools currently available. Enhanced information technology (IT) is recognized as a key component necessary to improving healthcare access, quality and productivity, and to reducing the number of adverse events.

IT systems have successfully modernized and enhanced performance in many sectors that affect our daily interactions. It is widely recognized that interoperable electronic health records (EHRs) can fill information gaps that currently compromise the accessibility, quality, safety and productivity of Canada's healthcare system. Canada Health Infoway invests in information infrastructure solutions that will make a difference.

In the last 12 months in Canada, 322 million visits to physicians' offices were recorded, 382 million prescriptions were filled, and 60,000 Canadian physicians were faced with 1.8 million new medical papers in 20,000 journals and 300,000 clinical trails worldwide.

The sustained commitment from *Infoway* and the federal, provincial and territorial governments, working together on strategy and investing in joint projects, benefits Canadians by providing a safer, more efficient and more productive healthcare system. The challenge is great, but *Infoway*, in close collaboration with all three levels of government, continues to make progress.

In fact, *Infoway*'s investment strategy is on track towards its goal of having an interoperable EHR in place across 50 per cent of Canada (by population) by the end of 2009. In 2004–05, *Infoway* approved $195 million in new investments for a cumulative total of $321 million. Projects are now underway in every province and territory.

Infoway will continue to accelerate the pace of investment for 2005–06 with new investment approvals of between $275 and $375 million. This will result in a total of $646 million in approved investments, or 54 per cent of the $1.2 billion capital provided to *Infoway* by the Government of Canada.

Infoway is committed to providing healthcare professionals with the tools and information they need to make our healthcare system safer.

Electronic Drug Information Systems Improve Patient Safety

Adverse events are often drug-related. Efficient dissemination of drug knowledge, immediate availability of accurate patient information — current and historic — and the appropriate exchange of information between healthcare providers and pharmacists are all imperative to avoiding drug-related errors and ensuring patient safety.

Infoway's Drug Information Systems program will implement solutions that will significantly reduce the number of adverse drug events.

Using electronic drug information systems, a physician is able to access all data concerning a patient's medication history and no longer needs to rely on oral information given at the time of examination. Drug and drug interaction checks are performed quickly, alerting the physician to any potential dangers. The prescription can be sent electronically to a pharmacist.

By receiving a patient's prescription on-line, the pharmacist can avoid transcription errors and unnecessary delays due to having to verify hand-written scripts. The prescription can be filled and an electronic confirmation returned to the patient's physician. The dispensed drug information is automatically added to the patient's drug profile in the EHR.

Interoperable electronic drug information systems improve patient safety, as well as provide quality advancement in effectiveness and appropriateness of care. They increase productivity and efficiency, support the coordination of care and improve patient compliance with drug therapy.

Infoway's strategy is to invest in a single commercial drug repository solution for each jurisdiction and commercial solutions that enable e-prescribing and drug-profile viewing. Our goal is for all jurisdictions to fully implement drug information systems by December 31, 2009.

Healthcare Quarterly
SPECIAL ISSUE

PATIENT SAFETY *Papers*

Volume 8 Special Issue • 2005

How to Reach Us
Phone 416-864-9667
Fax 416-368-4443

Our addresses are:
Longwoods Publishing Corporation
260 Adelaide Street East, No. 8
Toronto, ON M5A 1N1, Canada

For deliveries to our studio:
18 Eastern Avenue
Toronto, ON M5A 1H5, Canada

Quarterly Online
For back issues, JobSite, JobSheet and Conference Calendar go to: www.healthcarequarterly.com

Subscriptions
Healthcare Quarterly is designed to serve healthcare executives, administrators and providers. Subscription rate for one year: $80 in Canada, US $80 elsewhere, (Individual), $240 in Canada, US $240 elsewhere (institutional). Subscriptions are payable in advance.

An additional 7% Goods and Services Tax (GST) is payable on all Canadian transactions. Our GST # is R138513668.

For subscription information call Barbara Marshall at 416-864-9667 or fax 416-368-4443, or e-mail to bmarshall@longwoods.com.

Subscriptions Online
Go to www.healthcarequarterly.com and click on "Subscriptions."

Reprints/Single Issue
Single issues are available at $30. Includes shipping and handling. Reprints can be ordered in lots of 100 or more.

For reprint information call Barbara Marshall at 416-864-9667 or fax 416-368-4443, or e-mail to bmarshall@longwoods.com.

An additional 7% Goods and Services Tax (GST) is payable on all Canadian transactions. Our GST # is R138513668.

Editorial
To discuss an article idea, submit an abstract or obtain general information please contact Dianne Foster-Kent, Managing Editor at 416-864-9667 or e-mail dkent@longwoods.com.

Advertisers
For advertising rates and inquires, please contact Susan Hale at 416-864-9667 or e-mail shale@longwoods.com, or Anton Hart at 416-864-9667 or e-mail ahart@longwoods.com.

Return Undeliverable Canadian addresses to Circulation Department, 260 Adelaide Street East, No. 8, Toronto ON M5A 1N1 Canada

Healthcare Quarterly is published quarterly and issued in Fall, Winter, Spring and Summer by Longwoods Publishing Corp., 260 Adelaide St. East, No. 8, Toronto, ON M5A 1N1, Canada. Tel: 416-864-9667, Fax: 416-368-4443. This is a special issue.

ISSN #1710-2774 Canada Post Publications Agreement No. 40069375

Perspective

Canadian Patient Safety Institute

As a senior healthcare executive, I experienced several incidents in which patients were adversely affected, though no one had intended to harm or compromise anyone. While these were all difficult and painful, I remember one in particular, in which a patient died on a procedure table due to medication overdose. I remember the emotions of the parents and everyone involved as if it were yesterday. All knew this was an unnecessary loss.

Anyone who has worked in a hospital any length of time has seen patients grievously affected by an adverse event. No one goes to work in healthcare anywhere wanting to make an error. Canada's health professionals and our many other staff are committed to providing care to anyone in need. But occasionally something does go wrong. We know that somewhere between 9,000 and 24,000 people die annually (Baker et al. 2004) from an adverse event in hospitals. And how many more have been adversely affected in home care, long-term care or community care? The research mostly has yet to be done in those areas.

So who is responsible? And who is going to "fix" the now-well-known problem documented by Baker et al.? We are not going to fix the problems by focusing on individual(s) caregivers; instead we need to focus on the system. I have travelled across the country and heard from professional caregivers – doctors, nurses, pharmacists and many others – and they yearn to give *safer care*. That aim resonates with Canadian CEOs who recently attended a session with Dr. Donald Berwick, CEO of the U.S. Institute for Healthcare Improvement.

To get at the issue, boards and CEOs of hospitals must make patient safety a priority, and a few have begun this journey. So too must community and other healthcare organizations. Researchers must help us better understand the problems and the underlying causes – be they processes, human factors, design of equipment or supplies, systems, etc. We must learn from the work of the airline industry and other high-risk ventures that make safety a priority. We must learn and apply all of this to our complex system of healthcare. It will not be easy and it will take time.

I believe that part of what has created compromises in patient safety is the fact that we are asking our staff to master new technologies, processes, drugs, equipment, knowledge, etc. at an alarming rate, and asking them to be increasingly efficient and effective.

The culture of our organizations must change. Being able to report adverse events without blame or retribution, to participate in addressing the causes and to disseminate the

Ontario Hospital Association

The Ontario Hospital Association (OHA) is pleased to co-sponsor this special edition of *Healthcare Quarterly* dedicated to patient safety.

The OHA is a voluntary organization representing Ontario's public hospitals. The OHA, founded in 1924, is the voice of Ontario's hospitals and a leader in shaping the future of the healthcare system, fostering excellence, building linkages with the community and advocating for quality healthcare.

One of the things we are proudest of is our ability to identify patient needs within the healthcare system and then use our expertise to create and implement programs and strategies to address those needs. For example, in the days before universal, publicly funded healthcare and the Canada Health Act, the OHA recognized the need for affordable healthcare coverage and, in response, created the highly successful Ontario Blue Cross program. And in 1957, when the Government of Ontario created the Ontario Hospitals Services Commission to administer a provincial health insurance plan, they relied on staff from the OHA to make this initiative a success. (History buffs will note that the Ontario Hospital Services Commission initiative became the Ontario Hospital Insurance Plan [OHIP], and led to the creation of the present-day Ministry of Health and Long-Term Care.)

Today, we believe that improving patient safety and increasing patient involvement in the management of their own healthcare are among the most pressing challenges that healthcare providers face. We also believe that the solutions to these challenges are interwoven – that successfully increasing our patients' involvement in managing their healthcare will lead to improved patient safety.

That is why, with funding from Ontario's Ministry of Health and Long-term Care, the OHA established the *Patient Safety Support Service* (PSSS), the first service of its kind in Canada.

The mandate of the PSSS is to: raise awareness among hospital management and frontline staff about patient safety; foster the development of local expertise in patient safety; promote effective leadership strategies that enhance patient safety; and provide leadership and be a resource to hospitals in their efforts to effect system change for improved patient safety, with assistance that is both focused and practical.

Since its creation in March 2004, the PSSS has developed key resources, including discussion papers, tool kits, newsletters, and an interactive website to help raise the awareness of patient safety and promote effective strategies that enhance patient safety. The PSSS staff have also worked with the Institute for Safe Medication Practices Canada (ISMP-

lessons learned is part of the solution. This includes permitting patients a voice and some responsibility in their care. It is up to all of us, and leaders such as the boards and the CEOs, to be passionately committed to a different culture. The patients deserve nothing less.

Suppliers of medical products must also make this a priority. Issues have been identified, which they can remedy, in the design, labelling and other features of healthcare equipment, medical supplies and medications. They too must be part of the intricate solutions.

This special issue of *Healthcare Quarterly* is a piece of the puzzle, sharing knowledge and providing hope for each of us that there are solutions. We trust it will help us all become better at caring for our patients and for each other. We have had overwhelming response to this first edition. We thank the authors who have contributed to this publication. We also thank the many who submitted whom we were not able to publish at this time due to space limitations (after expanding to well over 150 pages!). Clearly there will be more to come in the future.

Most importantly, this is dedicated to our patients.

– PHIL HASSAN
President and CEO

References

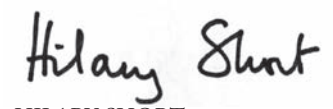
Baker G.R., P.G. Norton, V. Flintoft, R. Blais, A. Brown, J. Cox, E. Etchells, W.A. Ghali, P. Hebert, S.R. Majumdar, M. O'Beirne, L. Palacios-Derflingher, R.J. Reid, S. Sheps and R. Tamblyn. 2005. "The Canadian Adverse Events Study: The Incidence of Adverse Events among Hospital Patients in Canada." *Canadian Medical Association Journal* 170(11): 1678–86.

Canada) to encourage hospitals to remove concentrated KCl (potassium chloride) from patient care areas, and are working with the Quality Healthcare Network to encourage hospitals to participate in the ongoing *"Safer Healthcare Now"* campaign.

Recently, the PSSS launched "Your Healthcare – Be Involved," a program designed to empower patients, enhance patient safety and promote better health outcomes by bringing the advice and expertise of health professionals together in five easy-to-understand "tips" for patients to use in any healthcare setting. In a similar vein, the OHA is today working with Ontario's hospitals, patients and our other partners to ensure that our healthcare system is as safe as it can be.

Like the OHA, readers of *Healthcare Quarterly* make meeting the needs of patients their priority. This special issue features an extensive compilation of articles on key patient safety topics such as culture change, reducing risk, medication safety, information technology, patient safety as an agenda for change, and disclosure and accountability. We hope it will provide you with useful information, expand the body of knowledge about patient safety and lead to new patient safety initiatives across Canada.

Enjoy the read!



– HILARY SHORT
President and CEO

United States of America

2005-06 National (USA) Patient Safety Goals from the new Patient Safety Centre

In March 2005, the Joint Commission on Accreditation of Healthcare Organizations and Joint Commission Resources (JCR) announced the establishment of the Joint Commission International Center for Patient Safety, a virtual entity that draws upon the patient safety expertise, resources and knowledge of both the Joint Commission and JCR. The center will provide patient safety solutions to healthcare organizations worldwide. The mission of the center is to continuously improve patient safety in all healthcare settings.

The Joint Commission on Accreditation of Healthcare Organizations' Board of Commissioners approved the 2006 National Patient Safety Goals this spring. The Joint Commission promotes and provides for the delivery of safe, high-quality care through ambulatory care and office-based surgery, assisted living, behavioural healthcare, critical access hospital, disease-specific care, home care, laboratory, long term care, networks and hospital.

The website of the Patient Safety Center (www.jcipatient-safety.org), launched April 15, 2005, is designed as a major repository of resources and information about all aspects of patient safety for patients, their families, healthcare institutions and allied healthcare professionals, including physicians, nurses and pharmacists.

Reference:www.jcaho.org/ about+us/facts_jcicps.htm)

United States of America

Leavitt: Katrina demonstrates need for e-health records

The majority of the one million people displaced by Hurricane Katrina have no medical records, making it difficult for clinicians working in disaster medical centers to treat them, Mike Leavitt, secretary of the Department of Health and Human Services, told the eHealth Initiative conference today. With paper records destroyed or unavailable, Leavitt said doctors have no idea what drugs Katrina refugees are taking.

Medical personnel working at makeshift hospitals in the hurricane-battered Gulf Coast and at facilities in cities caring for Katrina refugees are handicapped by the lack of medical records, including medications prescribed to former Gulf Coast residents now scattered at shelters nationwide, Leavitt said.

Although some medical experts have warned of catastrophic medical events following Katrina, such as an outbreak of West Nile Virus, Dr. Frederick Cerise, secretary of the Louisiana Department of Health and Hospitals, said he was more concerned about refuges with chronic medical conditions such as cancer not getting the treatment they need because of a lack of medical records.

Cerise, who spoke to the conference via speakerphone from his office in Baton Rouge, La., said he is working with members of the eHealth Initiative, insurers, the Centers for Medicare and Medicaid Services (CMS) and Dr. David Brailer, national coordinator for health information technology at HHS, to electronically re-create patient records.

For example, payment information held by insurers and CMS could help zero in on prescribed medications and lab tests ordered, though not the results of those tests, Cerise said.

Francois de Brantes, the health care initiatives program leader for General Electric's Corporate Health Care and Medical Services, said the difference between electronic and paper health records after Katrina was best illustrated by the time it took to transfer records for patients in Veterans Affairs Department hospitals in the Gulf Coast compared with the records of patients in private hospitals.

It took the VA about 100 hours to transfer electronic health records for its all patients in the South, while it will take thousands of hours for the private sector to reconstitute paper medical records, de Brantes said.

Reference: http://govhealthint.com/ article90691-09-08-05-Web

… this law will implement broad patient safety reforms and improvements in the quality of care…

United States of America

2,500 Hospitals Have Joined IHI's Campaign To Save 100,000 Lives Through Healthcare Improvement

The Campaign is One of the Largest Healthcare Quality Improvement Efforts Ever Undertaken in the U.S.

The Institute for Healthcare Improvement (IHI) announced today that over 2,500 acute care hospitals in the United States have now joined its Campaign to save 100,000 lives. The Campaign encourages hospitals to adopt proven practices and procedures that can dramatically improve patient care and is the first-ever national campaign to promote saving a specified number of lives by a certain date (June 2006). At current enrollment numbers, the Campaign has become one of the largest healthcare quality improvement efforts ever undertaken in the U.S. Hospitals that choose to participate in the Campaign commit to implementing some or all of the following six quality improvement changes:

- Deploy Rapid Response Teams
- Deliver Reliable Evidence-Based Care for Acute Myocardial Infarction
- Prevent Adverse Drug Events
- Prevent Central Line Infections
- Prevent Surgical Site Infections
- Prevent Ventilator-Associated Pneumonia

Reference: www.oho.org

United States of America

Clinical Quality Improvement and Patient Safety

American Medical Association Celebrates Healthcare Safety Win for America's Patients

President George W. Bush signed the Patient Safety legislation in July 2005. This legislation was one of the American Medical Association's top legislative priorities for 2005 and passage represents the culmination of an almost two year effort by the AMA.

"The healthcare community has long been committed to improving patient safety, and significant progress has been made through new technology, research and education. This patient safety law is the catalyst we need to transform the current culture of blame and punishment into one of open communication and prevention," said AMA President J. Edward Hill, M.D.

By establishing a system of voluntary, confidential reporting and analyzing of healthcare errors, this law will implement broad patient safety reforms and improvements in the quality of care for patients across the US. The AMA hopes this new legislation will begin to transform the current culture of blame and punishment into one of open communication and prevention.

Reference: www.ama-assn.org

United Kingdom

National Patient Safety Agency Board Reporting and Learning System Update

Early in 2004 Health Minister Lord Norman Warner launched the National Patient Safety Agency's (NPSA) work to put into place a National Reporting and Learning System (NRLS) for patient safety problems – the first of its kind worldwide. The system is designed to draw together reports of patient safety errors and systems failures from health professionals across England and Wales to help the National Health Service (NHS) to learn from things that go wrong.

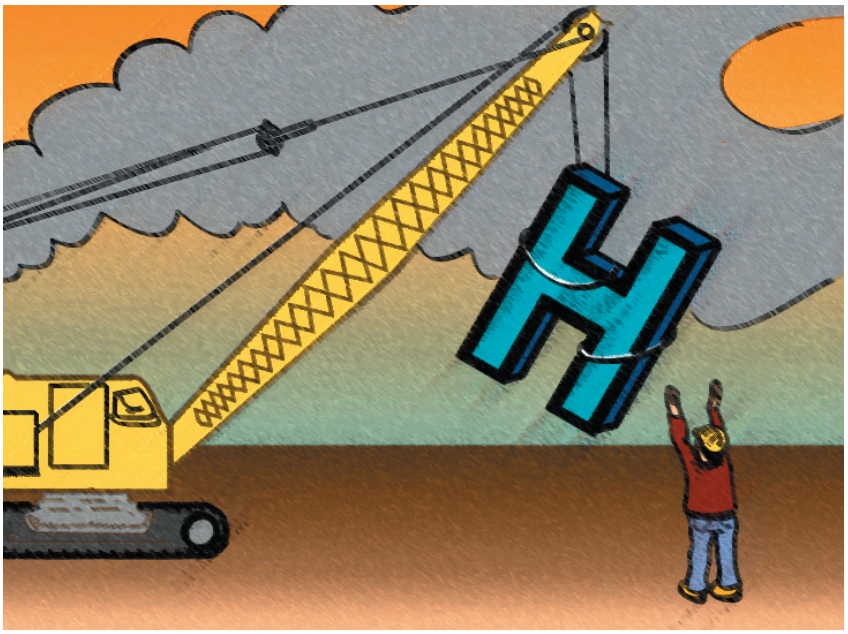
By the end of that year the NPSA put a system into place to allow all 607 NHS organizations the capability to report patient safety incidents to the NRLS. The next step was to work with these organizations to further tailor their reporting route to best suit their needs. The NPSA is delighted to announce that 90% of NHS organizations are now reporting through their chosen route.

Most problems affecting patient safety occur as a result of weaknesses in systems and processes, rather than the acts of individuals. It is essential that incidents are reported locally and that they are investigated and analyzed so that suitable learning and actions can follow. At the national level, the NRLS enables the NPSA to take an unprecedented overview, identify recurring patterns and develop practical national solutions.

Reference: www.npsa.nhs.uk/npsa/display?contentId=4215

Illustrations by Eric Hart

Switzerland



Building stronger health systems key to reaching the health Millennium Development Goals

Building up and strengthening health systems is vital if more progress is to be made towards the Millennium Development Goals (MDGs), the World Health Organization (WHO) said in a new report. Unless urgent investments are made in health systems, current rates of progress will not be sufficient to meet most of the goals.

The report, Health and the Millennium Development Goals, presents data on progress on the health goals and targets and looks beyond the numbers to analyze why improvements in health have been slow and to suggest what must be done to change this. The report points to weak and inequitable health systems as a key obstacle, including particularly a crisis in health personnel and the urgent need for sustainable health financing.

Health systems require not only urgent investment, but also commitments from developing countries to increase accountability and prioritize health in national and poverty reduction plans, and from donors to better coordinate aid. One example of lack of coordination given in the report is that of Viet Nam, where 400 donor missions visited in one year. Lack of coordination renders already fragile health systems even weaker. In an effort to tackle this problem in relation to health statistics, a wide range of partners has come together to form the Health Metrics Network, a global partnership designed to improve the availability and quality of health data and thus enhance accountability.

Reference:www.who.int/mediacentre/news/releases/2005/pr35/en/index.html

Australia

Final Report of the Review of Future Governance Arrangements for Safety and Quality in Healthcare

In July 2005, the Review of the Future Governance Arrangements for Safety and Quality in Healthcare reported to the Australian Health Ministers' Conference. The purpose was to advise Ministers on the future governance arrangements for leadership and national coordination of safety and quality in healthcare prior to the completion of the current term of the Australian Council for Safety and Quality in Healthcare, which finishes in June 2006.

Recommendations include: a new national safety and quality body should be established to succeed the current Australian Council for Safety and Quality in Healthcare; the work of the national body should have a safety and quality improvement focus across the continuum of healthcare; public reporting on the safety and quality of care should be used as a key driver for change; health ministers should determine the appropriate legal form/structure and agree that the new body be established as soon as practicable and transition arrangements should ensure a seamless changeover from the current Council.

The Review Team urges that priority number one be to establish new national governance arrangements for safety and quality improvement as a matter of urgency. For more information and to see the complete report: www.health.gov.au/internet/wcms/publishing.nsf/Content/2D1487CB9BBD7217CA256F18005043D8/$File/Safety and Quality.pdf

Patient Safety Culture Measurement and Improvement: A "How To" Guide

Mark Fleming

O wad some Power the giftie gie us
To see oursels as ithers see us!

(from "To A Louse" by Robert Burns, 1759–1796)

It is widely accepted that the desired improvements in patient safety require a change in the culture within healthcare (CPSI 2004; IOM 2000; NPSA 2004). The Institute of Medicine (IOM) report "*To Err Is Human*" concluded that "the status quo is no longer acceptable ... Health care organizations must develop a culture of safety" (IOM 2000: 14). In the UK, building a safety culture is the first step of the National Patient Safety Agency's (NPSA) seven-step guide to improving patient safety. In Canada, safety culture is one of the Canadian Council on Health Services Accreditation's (CCHSA) five patient safety goals and required organizational practices. It is therefore important that senior administrators and clinical managers have a sound understanding of safety culture, so that they can make informed decisions about improvement strategies.

The recognition of the importance of cultural factors is based on research conducted in other high reliability industries such as nuclear power and petrochemical processing. The investigation into the Chernobyl disaster concluded that a poor safety culture at the facility was a significant causal factor. The Advisory Committee on the Safety of Nuclear Installations produced the most widely accepted definition of safety culture.

> The safety culture of an installation is the product of individual and group values, attitudes, perceptions, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of an organization's health and safety management. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety and by the efficacy of preventive measures. (ACSNI 1993: 23)

The recognition of the importance of cultural factors stimulated a significant amount of research aimed at developing and validating safety culture[1] instruments. These instruments are now used routinely in high reliability industries to assess the current culture and identify actions to improve and track change overtime. There is now good evidence linking responses on these instruments with important health and safety outcomes, such as micro accidents (Zohar 2000), self-report accidents (Lee 1998), safety behaviour (Mearns et al. 2001), company accident statistics (Niskanen, 1994) and safety audit scores (Zohar 1980).

1. There has been considerable debate about the relationship between safety culture and safety climate. It is now generally accepted that the two concepts are closely related and that safety climate consists of the surface elements of the safety culture and can be measured using quantitative measures. The interested reader can refer to Cox and Flin (1998) and Guldmund (2000) for a more detailed discussion.

Within a healthcare context, safety culture influences patient safety by motivating healthcare professionals to choose behaviours that enhance, rather than reduce, patient safety (Nieva and Sorra 2003). Singer and colleagues (2003) identified the following seven patient safety culture elements:

- Leadership commitment to safety
- Organizational resources for patient safety
- Priority of safety versus production
- Effectiveness and openness of communication
- Openness about problems and errors
- Organizational learning
- Frequency of unsafe acts

Ten-Step Process to Successful Safety Culture Measurement and Improvement

Currently, there is relatively little experience in healthcare of implementing safety culture measurement and improvement initiatives. This lack of experience may increase the risk that safety culture interventions may fail to achieve their objectives. Fortunately, safety culture interventions are commonly used in other industries such as nuclear power and the petrochemical industry. The lessons learned from these industries are summarized in the 10-step process outlined below.

1. Build capacity

Conducting a safety culture survey is a major initiative and organizations must develop some expertise in safety culture measurement and improvement before commencing the process. Although it is possible to get support from external experts, they are not familiar with organizational requirements. Specifically, internal expertise is required to decide if a safety culture measurement is appropriate, to select the most suitable measurement approach, to select an external provider (if necessary) and to ensure the sustainability of the process.

It is often useful to create a small team to coordinate the initial phases of safety culture measurement. At this stage, the team should be small and contain representatives from quality, risk management and clinical staff. Team members should develop their knowledge of safety culture by reading key references (e.g., Guldenmund 2000; IAEA 2002; NPSA 2004). The team should review the available measurement instruments and select the one that is most appropriate for their purposes. They should also calculate the resources required to undertake the survey, including key individuals to involve, the need for external support, staff time to complete the survey, data entry and analysis.

2. Select an appropriate survey instrument

Recently, numerous researcher teams have attempted to develop patient safety culture instruments. Early instruments were adapted versions of questionnaires developed in other industries (e.g., Thomas et al. 2003). More recently, instruments have been developed specifically for healthcare (e.g., Sorra and Nieva 2004). There is now a range of safety culture instruments available to healthcare organizations. CCHSA encourages organizations to conduct safety culture surveys and lists three potential questionnaires on their website:

- Safety attitudes questionnaire (Sexton et al. 2004)
- Stanford instrument (Singer et al. 2003)
- Hospital Survey on Patient Safety Culture (Sorra and Nieva 2004)

In addition to the above, a modified Stanford instrument (Gingsburg et al. in press) has been used in a number of Canadian hospitals. The variety of instruments available raises the question: which instrument is the best? Not surprisingly, there is not one best instrument, as they all have strengths and weaknesses. **Table 1** provides an overview of the instruments, including the elements of safety culture that they purport to measure and their strengths and weaknesses. Organizations need to select the instrument that is most appropriate for their purposes.

3. Obtain informed leadership support

Although it is widely accepted that management support is required for an intervention of this nature, it is not uncommon for it to be missing (Nieva and Sorra 2003). It is critical to ensure they are providing informed support, which means they understand the survey process, the resources required, potential problems and typical results. Informed support can be obtained by holding a senior leadership workshop to provide an overview of the project, the resources required, the instrument being used and importance of implementing follow-up actions.

It is also critical that leaders understand that the results are going to be shared widely and, therefore, may enter the public domain. This could produce unwanted media attention, and it is important that leaders are confident that they are willing to share results that may portray the organization in a negative light. For example, how comfortable would they be in releasing a report that included statistics such as: 50% of healthcare staff agreed with the statement, "In the last year, I have witnessed a co-worker do something that appeared to me to be unsafe for the patient, in order to save time." There is often a reluctance to emphasise the potential downsides of conducting the survey, as senior leaders may decide not to support the survey. Clearly, this is a risk, but it is better not to go ahead with the survey than to have a long protracted argument with senior leaders about the publication of the results. This delay in publication will make people cynical and impede the implementation of interventions and, in the end, may damage the culture, not make it better.

Table 1: Patient safety culture instruments

	Safety attitudes questionnaire	Stanford instrument	Modified Stanford instrument	Hospital survey on patient safety culture
Elements measured	• Teamwork • Safety climate • Job satisfaction • Stress recognition • Perceptions of management • Working conditions	• Organization • Department • Production • Reporting/seeking help • Shame/self-awareness	• Valuing safety • Fear of negative repercussions • Perceived state of safety	• Supervisor/Manager expectations & actions • Organizational learning • Teamwork within units • Communication openness • Feedback & communication about error • Non-punitive response to error • Staffing • Hospital management support for patient safety • Teamwork across hospital units • Hospital handoffs & transitions • Self-reported outcome variables
Questionnaire length	60 items	30 items	32 items	79 items
Reliability	Alpha's range from .65–.83	Not published	Alpha's range from .66–.86	Alpha's range from .63–.84
Questionnaires available from:	http://www.uth.tmc.edu/schools /med/imed/patient_safety/surveyandtools.htm	Items published in (Singer et al. 2003)	Liane.Ginsburg@mail.atkinson.yorku.ca	http://www.ahrq.gov/qual/hospculture/
Strengths	• Questionnaire freely available • Tested on a large sample • Detailed report describing instrument • Adequate psychometric properties • Some benchmark data	• Questionnaire freely available • Tested on a large sample • Research paper describes development and factor structure	• Questionnaire freely available • Good psychometric properties • Relatively short questionnaire	• Questionnaire freely available • Good psychometric properties • Tested on a large sample • Comprehensive coverage of safety culture elements • Good supporting documentation • Benchmarking data available
Weaknesses	• Questionnaire relatively long • Not specifically designed to measure safety culture	• Reliability scores not published • The items contained in factors I and II do not seem to fit with the concepts they purport to measure	• Measures limited number of safety culture dimensions	• Questionnaire relatively long

4. Involve healthcare staff

The purpose of the conducting the survey is to bring about the cultural change in healthcare advocated by CCHSA, CPSI, IOM and NPSA. As noted by Carroll (1998), it is important that the safety culture measurement process is consistent with the culture that you are striving to achieve. Since employee involvement is a key aspect of a positive safety culture, it is beneficial to involve key groups in planning and implementing the survey. Employees can be involved in the process by having representation on a steering committee, assisting in survey distribution at departmental level or, at a minimum, being regularly informed about the safety culture survey. The aim is for all healthcare workers to feel vested in the process, as opposed to feeling that this is something that is being done to them.

5. Survey distribution and collection

A key challenge in conducting any survey is obtaining a high response rate. Conducting surveys within healthcare organizations is a logistical challenge given the large numbers of potential respondents, many who are not directly employed by the organization. Although healthcare professionals have a reputation for being reluctant to complete surveys (Donaldson et al. 1999), some patient safety culture surveys have obtained response rates of over 90% (e.g., Boiteau 2005).

The distribution and collection strategy adopted can have a major impact on the response rate obtained. Making participation easy, safe and relevant can enhance response rates. Limiting the length of the survey, dedicating specific time for the participants to complete the survey or paying participants can make participation easier. Although Web-based surveys are cost-effective, this method may not be appropriate in healthcare due to limited access to computers (Nieva and Sorra 2003). Anonymity is the simplest way to ensure that survey participation is perceived to be safe. It is also important to carefully review the demographic questions to ensure that they do not inadvertently identify individuals. The perceived relevance of the survey can be enhanced by a comprehensive information campaign before the survey is distributed. Departmental champions, who distribute surveys and encourage participation, can increase relevance and response rates.

6. Data analysis and interpretation

A safety culture survey can easily result in information overload because of the number of items and the range of ways these data can be analyzed (e.g., by occupation, department or tenure). In addition, it can be difficult to interpret the results, as there is no ideal safety culture profile. For example, is it a good result if 20% of respondents agree with the statement, "My supervisor overlooks patient safety problems that happen over and over"? It is clearly better than 70% agreeing with the statement, but it is not good that a fifth of respondents have concerns about their supervisors taking action to resolve safety incidents. To aid with interpretation, it is important to look at a pattern of responses rather than individual items responses. The items contained in the questionnaires listed in **Table 1** form factors or concepts such as "teamwork." Average scores on these factors provide information about the state of teamwork in general. This still leaves the problem of what is an acceptable level of teamwork. Ideally, organizations would be able to compare their results against organizations with the best patient safety outcomes. Sadly, such a database does not exist. Currently, the best answer to this question is to compare your responses with published data (see Ginsburg et al. in press; Sorra and Neiva 2004; Sexton et al. 2004; Singer et al. 2003).

7. Feedback results

Giving participants rapid feedback of the results can help maintain interest and involvement. Initial communication can include updates on the response rate to encourage participation. Ideally, the main results should be presented orally and include the next steps and a timeline for the improvement actions. Often the feedback of results is delayed by organizing sessions (e.g., getting time in senior managers' diaries). These delays can be reduced by planning the feedback sessions and setting dates (but not announcing) before the surveys are distributed. It is not necessary to know all the improvement actions at this stage, but it is important to outline a timeline and a plan to specify the actions.

Training can improve safety culture perceptions

Currently, there is little empirical research evaluating the effectiveness of patient safety culture interventions. Ginsburg et al. (in press) evaluated the effectiveness of training intervention at improving patient safety culture. Initially, they surveyed 338 nurses in clinical leadership roles. The sample consisted of nurses who voluntarily attended two patient safety workshops (study group) and those who did not attend the workshops (control group). The training included presentation on the rate of adverse events in healthcare, theoretical models of human error, how to learn from errors, teamwork and safety leadership. Both groups were resurveyed 10 months later to assess the impact of the training intervention. There was a significant improvement in safety culture perceptions among nurses who received the training, while there was no improvement in control group perceptions. Training interventions offer a relatively cost-effective way to improve patient safety culture.

8. Agree interventions via consultation

Conducting safety culture surveys have been likened to "describing the water to a drowning man"; in other words, they tell you how bad things are, but provide little assistance in identifying the solutions (Fleming 2003). A useful strategy to assist in identifying practical solutions is to conduct a series of focus groups with a representative sample of participants. For each of the elements measured by the survey, participants can be asked to describe the positive aspects, areas requiring improvement and practical actions that will make a real difference. The information produced can readily be turned into a comprehensive action plan (see Fleming and Meakin 2004).

9. Implement interventions

A common complaint by employees who participate in safety culture assessments is the lack of action based on the results of the survey (Nieva and Sorra 2003). There are a number of reasons for this perception. First, it is often an accurate perception as senior administrators do not know what actions to take and, therefore, do not take action. Second, there is such a time lag between completing the survey and subsequent actions that people have forgotten about the survey. Third, the subsequent interventions are not explicitly linked to the survey results.

10. Track changes

One of the primary reasons given by healthcare organizations for conducting a safety culture survey is to obtain a baseline against which to measure improvement. Tracking changes in perceptions over time is a challenge with anonymous surveys. For example, if there is a 50% response rate to the initial survey, and there is a similar response rate to the follow-up survey, it is very possible that any difference in the responses is due to different people responding on the two occasions. Even when there is a high response rate (e.g., 90%), it is not possible to perform the correct statistical test (a paired sample t-test) to establish if any change is statistically significant, as it is not possible to link respondents from the initial survey with those in the follow-up survey. One solution to this problem is to get participants to generate a code that is unique to them, but cannot be used by the organization to identify them individually. Asking participants a series of questions, which will produce the same responses over time, can be used to create an individual code. For example, their unique code could be generated by asking for the first two letters of their mother's first name, the first two letters of their father's first name and the day of the month that they were born.

Benchmarking safety culture change: An offshore oil industry example

Benching marking performance against other similar organizations is popular among healthcare organizations. Safety culture surveys offer another metric that can be used for benchmarking purposes. Mearns and colleagues (2000) conducted a safety culture benchmarking exercise with nine offshore installations in the UK to assess the impact on safety culture. They used a self-completion survey to assess the safety culture on the nine installations. The questionnaire measured six dimensions of safety culture (e.g., management commitment to safety). Each participating installation was provided with a report summarizing their results including graphs comparing their performance with other participating installations. This provided installations with information on their strengths and weaknesses relative to their peers. Organizations were then expected to use these results to implement change in order to improve their culture. One year later, the nine installations were resurveyed. Installations varied in the degree of improvement. For example, one installation did not improve on any of the six factors, while another installation improved on all six factors. The authors concluded that safety culture improvement was dependent on the actions taken by the installation management. Specifically, the installation with the greatest improvement increased levels of employee involvement in health and safety, took action to demonstrate management commitment and improved health promotion. Benchmarking aids in identifying strengths and weaknesses, but, unless this information is translated into action, the exercise in itself does not improve safety culture.

Conclusion

To borrow Burns's metaphor, safety culture surveys give organizations the gift to see themselves as others see them. They provide invaluable information about how patient safety is viewed within an organization. Correctly implemented, a safety culture measurement and improvement process can act as the tipping point for superior patient safety. This makes conducting a safety culture survey very attractive, but organizations must be cautious, as a poorly implemented survey can damage the culture. For example, if the survey identifies a series of actions to improve and these are not implemented in a timely fashion, then this demonstrates a lack of leadership commitment.

References

Advisory Committee on the Safety of Nuclear Installations (ACSNI). 1993. *Human Factors Study Group Third Report: Organising for Safety.* London: HMSO.

Boiteau, P. 2005, May. Patient Safety Culture Explained – Keynote Presentation at the First *Safer Health Care Now!* Conference. Calgary, AB.

Canadian Patient Safety Institute (CPSI). 2004. *Strategic Business Plan 2004/2005–2007/2008*. Edmonton, AB: Author.

Carroll, J. 1998. "Safety Culture as an Ongoing Process: Culture Surveys as Opportunities for Enquiry and Change." *Work and Stress* 12: 272–84.

Donaldson, G.W., C.M. Moinpour, N.E. Bush, M. Chapko, J. Jocom, M. Siadak et al. 1999. Physician Participation in Research Surveys: A Randomized Study of Inducements to Return Mailed Research Questionnaires. *Eval Health Prof* 22(4): 427–41.

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

Fleming, M. and S. Meakin. 2004, March. Health and Safety Culture Maturity Model: Improvement Through Involvement. Paper presented at the 7th SPE International Conference on Health, Safety and Environment in Oil and Gas Exploration and Production, Calgary, Alberta, Canada.

Gingsburg, L., P.G. Norton, A. Casebeer and S. Lewis. in press. "An Educational Intervention to Enhance Nurse Leaders' Perceptions of Patient Safety Culture." *Health Research and Educational Trust* 1–24.

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

Institute of Medicine (IOM). 2000. "To Err Is Human: Building a Safer Health System." In L.T. Kohn, J.M. Corrigan and M.S. Donaldson, eds. Washington, DC: National Academy Press.

International Atomica Energy Agency, Vienna (IAEA). 2002. *Self-Assessment of Safety Culture in Nuclear Installations: Highlights and Good Practices.* Author.

Lee, T. 1998. "Assessment of Safety Culture at a Nuclear Reprocessing Plant." *Work and Stress* 12: 217–37.

Mearns, K., R. Flin, R. Gordon and M. Fleming. 2001. "Human and Organizational Factor in Offshore Safety." *Work and Stress* 15(2): 144–60.

Mearns, K., S. Whitaker, R. Flin, R. Gordon and P. O'Connor. 2000. *Factoring the Human into Safety: Translating Research into Practice. Vol.1 - Benchmarking Human and Organisational Factors in Offshore Safety.* OTO 2000 061. Sudbury: HSE Books.

National Patient Safety Agency (NPSA). 2004. *Seven Steps to Patient Safety.* London: Author.

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

Niskanen, T. 1994. "Safety Climate in the Road Administration. Safety Science 17: 237–55.

Sexton, J.B., E.J. Thomas, R.L. Helmreich, T.B. Neilands, K. Rowan, K. Vella, J. Boyden and P.R. Roberts. 2004. *Frontline Assessments of Healthcare Culture: Safety Attitudes Questionnaire Norms and Psychometric Properties. Technical Report 04-01.* The University of Texas Center of Excellence for Patient Safety Research and Practice. AHRQ Grant # 1PO1HS1154401.

Singer, S.J., D.M. Gaba, A.D. Geppert, A.D. Sinaiko, S.K. Howard and K.C. Park. 2003. "The Culture of Safety: Results of an Organization-Wide Survey in 15 California Hospitals." *Quality and Safety in Healthcare* 12: 112–18.

Sorra, J.S. and V.F. Nieva. 2004, September. Hospital Survey on Patient Safety Culture. (Prepared by Westat, under Contract No. 290-96-0004). AHRQ Publication No. 04-0041. Rockville, MD: Agency for Healthcare Research and Quality.

Thomas, E.J., B.J. Sexton and R.L. Helmreich. 2003. "Discrepant Attitudes About Teamwork Among Critical Care Nurses." *Critical Care Medicine* 31(3).

Zohar, D. 1980. "Safety Climate in Industrial Organizations: Theoretical and Applied Implications." *Journal of Applied Psychology* 65(1): 96–102.

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

About the Author

Mark Fleming, PhD, is Director CN Centre for Occupational Health and Safety, Saint Mary's University, Halifax, Nova Scotia. Contact: Mark.fleming@smu.ca

Changing a Culture with Patient Safety Walkarounds

Guna Budrevics and Catherine O'Neill

Background

It is evident within Canada and abroad that healthcare is a high-risk industry not unlike aviation, nuclear energy and offshore oil drilling. The results from the Canadian Adverse Events Study (Baker et al. 2004) found an adjusted adverse event rate of 7.5% in Canadian hospitals. The consequences of these adverse events include prolonged length of stay, varying degrees of injury, and in some instances death. These injuries and deaths are not attributable to the patients' diagnoses but are, in fact, a result of the care provided to them by healthcare practitioners. This study is a part of a growing body of literature that has provided the momentum in many healthcare organizations, including Sunnybrook & Women's College Health Science Centre (S&W), to ensure patient safety is a priority.

S&W is dedicated to becoming the safest hospital in Canada. In order to achieve this goal, we must create a culture of safety, which requires significant organizational change. We have implemented several initiatives which have created the impetus for this culture change. One of the most influential initiatives is a patient safety walkarounds program. This well-tested concept has been used in many other healthcare organizations in the United States and in other nonhealthcare-related industries. We have created a model that is an adaptation of the original WalkRounds™ framework created by Dr. Allan Frankel, (2003) Director of Patient Safety for Partners HealthCare System in Boston, Massachusetts.

Representatives from the Patient Safety Service at the Partners HealthCare System in Boston were instrumental in our understanding the effectiveness of the walkarounds model. By sharing their experiences and openly discussing the merits and development of WalkRounds™, we were able to construct a similar model that was applicable to a Canadian healthcare delivery system. Some of the adaptations that we made included: a revision of the documentation and communication tools; a modified list of questions to guide the dialogue; inviting managers and directors to hear the walkaround session; and the creation of a handbook to orient the senior leadership team.

Patient safety walkarounds provide any healthcare organization a unique opportunity to facilitate the foundation of a safe culture. Walkarounds in their very essence connect frontline staff with senior leaders in an open dialogue concerning patient safety. This interaction allows frontline staff to share their safety concerns with senior leaders, as well as creating a forum to promote the awareness of patient safety. Conversely, it is an opportunity for senior leaders to demonstrate their commitment by hearing concerns and removing the barriers to safe care.

Roles and Responsibilities – Senior Leadership

The primary focus of walkarounds is to promote patient safety, yet in order for the mechanics to work, trust and a cultural

acceptance of disclosure and accountability is critical. In order to promote disclosure and accountability, the S&W Board of Directors passed two fundamental policies: a Disclosure of Adverse Events policy, and an Accountability for Patient Safety policy. Both policies are the cornerstones of our overall patient safety program and have paved the way for other operational initiatives, such as walkarounds, to be considered and implemented. The role and support of the senior leaders is critical in the success of walkarounds, as they must demonstrate these new behaviors of disclosure and accountability by addressing unit-specific issues in a proactive and responsive manner.

The senior leaders are assigned to units on a rotational schedule. Once each week a senior leader conducts walkarounds in a patient care area. The walkarounds are conducted in a meeting room adjacent to the patient care unit or in the patient care area itself. After introductions and a brief outline of the process, the senior leader guides the dialogue with the use of questions that have been pre-circulated to the staff. These questions stimulate the discussion and encourage participants to share their concerns about patient safety as well as their suggestions for improvement. Throughout the discussion it is likely that the conversation may divert to nonsafety matters, and so the senior leader must focus strictly on patient safety and refrain from discussing competing priorities such as budgets, staffing and other operational crises.

Once the walkarounds are completed, a list of all the comments and issues raised are sent to the manager and staff. From this list they are asked to select the three issues they feel have the most significant impact on their ability to provide safe care. These issues are then delegated to the senior leader who conducted the walkarounds and is responsible for taking the necessary actions to resolve them. Throughout the resolution phase, the senior leader is expected to provide timely feedback on actions. Some issues make take weeks (and perhaps months) to resolve; therefore direct communication to the managers and frontline staff on the progress of the priority issues demonstrates commitment to the initiative. Successful resolution of identified issues shows that patient safety is a high priority for the organization and assists in building a trust between frontline staff and senior leaders.

The role and support of the senior leaders is critical in the success of walkarounds, as they must demonstrate these new behaviors of disclosure and accountability by addressing unit-specific issues in a proactive and responsive manner.

Preparation/Expectations

To prepare for walkarounds, we took several steps to ensure that participants felt prepared and knew what to expect. Articulating the true intent of these rounds at the outset was critical, as there was a risk that they may be viewed as an inspection of the unit versus a nonthreatening discussion about patient safety. We met with the managers of the patient care areas individually and explained the purpose, flow, expectations and outcomes. It was made clear to the managers at the outset that any efforts they had made to date to improve safety concerns would be recognized at the senior level. This new senior-level interaction at the frontline level was dealt with in a sensitive manner, so as not to be viewed as undermining the managers' operations of their units. The managers had an opportunity to debrief with the senior leader after the walkaround to clarify the progress made on any of the issues. Frontline staff was provided with a list of questions two days prior to the walkarounds. This allowed them to consider issues on their unit, and thus feel at ease when meeting with the senior leaders, which is a rare and potentially intimidating occurrence.

We also took measures to prepare the senior leaders. There was some initial apprehension amongst the senior leader group that not everyone had a clinical background and whether this would impact the effectiveness of the walkarounds. We reinforced the belief that in order for our organization to create and sustain a culture of safety, each and every senior leader had to demonstrate that they "walked the talk." We emphasized that leading a walkarounds session would be a visible and concrete method of accomplishing this, and would reinforce the message that everyone is accountable for patient safety. An information session was held with the senior leaders, during which the purpose and objectives were discussed, along with a script with suggested opening comments, questions to guide the conversation, and tips on how to redirect the dialogue if it were to divert to nonsafety matters.

Once the senior team clearly understands the mechanics of walkarounds, and the coordination of schedules is accomplished, the actual walkaround can be a dynamic and fruitful experience. When the participants are fully cognizant of the patient safety focus of this interaction, a skilled leader can elicit meaningful comments and suggestions for improvements. Good listening skills and constructive probing yield insights to the critical issues around patient safety on the units. The dialogue that develops over the space of an hour produces an opportunity to build a level of trust and understanding between the administrative arm of the organization and the clinical team. If the senior leader is able to effectively remove barriers and resolve issues identified by the participants, both the participants and the senior leader win.

The senior leaders that have led walkaround sessions to date have been impressed with how dedicated caregivers are in providing a safe environment for patients. Amongst these leaders is a blend of those who have a clinical background and those that do not. It became clear at the outset that despite their background these senior leaders have an ability to use their expertise in understanding the clinical components of the issues and have an intuitive sense for the issues related to process and the barriers to providing safe care. Many examples of good communication and teamwork surface during these dialogues. As in any complex system, gaps in service delivery and communication are also fully evident. The interfaces between humans, their physical environment and advanced medical technology provide ample opportunities for improvements. Frontline staff see these gaps best.

By taking these steps to prepare all of the participants, we discovered that the senior leaders and the frontline staff were able to have a meaningful dialogue that was open and honest. There remains some apprehension among the managers; they are in a difficult position, in that their improvement efforts may be overshadowed by constraints at their level of management. We continue to work on this in order to alleviate any uneasiness and have found that providing an opportunity for the manager and senior leader to debrief at the end of walkarounds has yielded some success in addressing this issue. We feel confident that when well prepared, senior leaders do not require a clinical background in order to successfully conduct walkarounds. It appears that the remaining members of our senior leader team are keen to participate and connect with frontline staff, and thus make a contribution to safer patient care.

Barriers and Challenges

Throughout the implementation of walkarounds, we have faced several barriers and challenges. One of the earliest challenges was the coordination of the various participants' schedules. It is important that walkarounds are conducted at a time that is convenient for the patient care area so that patient care is not compromised. However, coordinating the ebbs and flows of a busy patient care area and the hectic schedule of a senior leader proved to be more difficult than it appeared at the onset. Scheduling walkarounds with participants well in advance (3 to 6 months) may relieve some of these timing pressures.

Ensuring good communication and data flow is always a challenge, and contributes to the complexity of the walkarounds. There are five transfers of data within a short period of time, all requiring confirmation, prioritization and delegation (see Figure 1). We encountered some obstacles in ensuring the right personnel were contacted with enough information to move the process along. We imposed timelines in an effort to reduce bureaucratic delays. Making this flow of information seamless has proven to be an intricate task.

Another challenge was our ability to compile the data in a preexisting database. Spreadsheets and databases are required to store all comments, filter and sort data and create various reports. Given our organizational structure and need for communication at many different levels, it was necessary to develop methods of handling the data storage and communication needs.

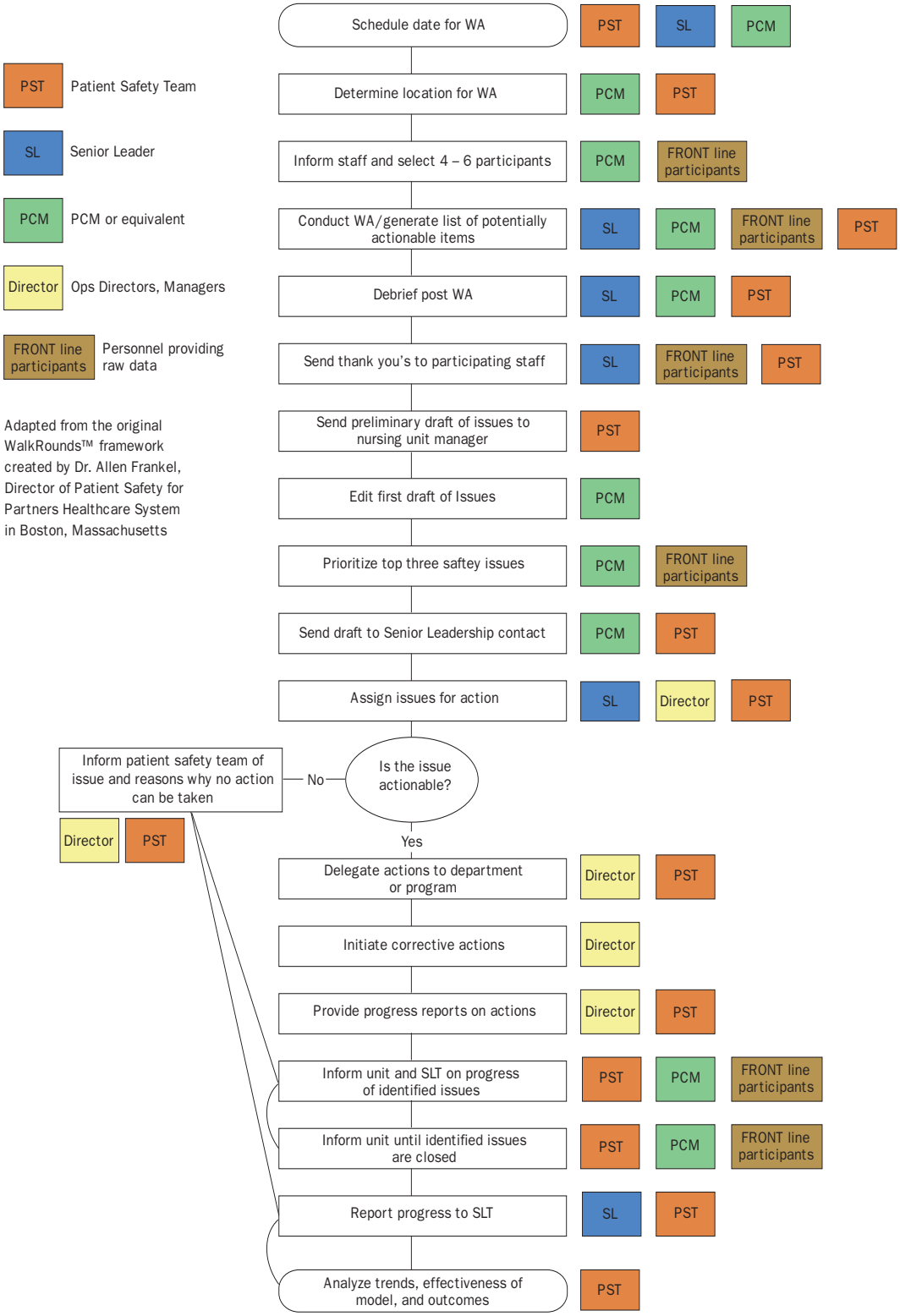
Findings/Learnings

The data we collected from the first cycle of walkarounds has already demonstrated trends, the most significant being *environmental gaps* and a*ging facility infrastructures.* This is consistent with other organizations that conduct walkarounds, and symptomatic of the more complex patient safety issues, such as teamwork and communication. We found that many times the environmental issues raised were longstanding and due to poor communication structures that remained unresolved. Participants' comments confirmed that organizations and services operating on multiple sites face challenges around communication and service delivery. Comments received from all of the sites indicate delays in obtaining various support services and equipment. It is important to view this as a systemic malfunction, as otherwise it may appear to be a non patient-safety-related issue. These environmental and equipment concerns may, in fact, have significant safety issues buried within. We anticipated that staff during their first encounter with senior leaders would raise environmental issues, which are less threatening and not as complex as clinical processes and safety-focused communication and teamwork.

It is our belief that initially staff are inclined to focus on basic environmental needs and issues that others are responsible for prior to addressing self-reflective professional practice related concerns. For example, various units expressed concerns relating to infection and prevention protocols, specifically focused on cleaning rooms, equipment, etc. With increasing volumes of patients (necessitating short turnaround times for cleaning rooms, beds and equipment), and the awareness of MRSA and other infectious diseases, staff need reassurance that appropriate monitoring and auditing of appropriate cleaning protocols is maintained. Consultations with both our IPC team and housekeeping services resulted in better clarity and communication about expectations and standards. We continue to improve the auditing processes that ensures staff and patients are protected and comfortable in isolation settings.

Beyond the trends in environmental gaps and aging facility infrastructures, we discovered a recurring level of dissatisfaction and opportunities for improvement around medication administration practices. The area designated for medication preparation and dispensing in one patient care area was not satisfactory compared to the unit-dose system that exists on all other patient care units. A unit-dose-based medication system has proven to

Figure 1: Flow Schema for Patient Safety Walkarounds April 2005



reduce the occurrence of medication errors. An assessment was completed and an application was submitted requesting the required updates. The application was approved and we are currently in the process of converting the medication delivery system in this patient care unit to a unit-dose system.

Outside of the data that we have collected and the trends that have emerged, we have also learned many valuable lessons regarding the process and implementation of patient safety walkarounds. First and foremost, the development of trust between staff and senior leaders must be fostered and visible before a truly meaningful dialogue will occur during walkarounds. Despite the Accountability for Patient Safety policy and the Disclosure of Adverse Events policy, we recognized that it will take time for staff to feel safe in expressing their ideas and concerns on more difficult matters such as teamwork and communication. Until we reach this level, it is imperative that we continue to build trust by taking action and resolving the more cosmetic safety issues, such as broken equipment, in order to demonstrate the commitment of senior leadership to constructing a safer S&W healthcare organization.

Examples of priority comments include:	Priority comment solutions:
Older model ice machine no longer meets infection control and prevention standards.	→ Capital acquisition process reviewed: requisitioned ice machine purchase.
Unit providing critical care is not on unit-dose medication administration protocols.	→ Resources realigned to provide and implement unit-dose medication administration.
Lights in labor & delivery suites malfunction.	→ Capital Management Committee consulted: priorities reconsidered, allowing for the purchase of new lighting.
Family members visiting patients after midnight.	→ Consultation with nursing, patient-focused care experts and unit to clarify expectations and communication strategies re: visiting hours.

Another lesson learned was that once a patient care area had selected their priority issues there remained many valuable comments and issues. In a few instances these issues were cause for concern amongst the Patient Safety Leadership Team, as they had the potential for negative outcomes. In order to avert such outcomes, the team decided to create a priority parking lot list where issues of concern are reviewed by the team on a monthly basis. If there were a consensus that an issue required immediate attention, the team would take the appropriate actions. All comments were then themed and compiled into a list to be reviewed by the senior leadership team. This provides the senior leaders with an overview of the ongoing trends.

One of the more encompassing lessons learned in implementing the walkarounds process is demanding in a large and complex organization. Having a clear understanding of the multiple layers in an organization and who owns which piece of the puzzle is critical when it comes to delegating the issues for action. At the outset actions and information were flowing through several layers of individuals, which inevitably resulted in mixed messages and incomplete feedback. To streamline and avoid miscues, we reduced the number of individuals through which information flows, reducing confusion and creating a more fluid process. This is not to say that we have a seamless process; however, it is much improved, and will likely require further adjustments as we proceed and maneuver around future curves.

An organization must be patient while developing these new information flows, as it will take some time to reach truly meaningful dialogues pertaining to patient safety processes.

Recommendations

It is our firm belief that every healthcare organization has the ability to integrate patient safety walkarounds within their organization and have favourable outcomes. For any organization that is considering this type of program, we would make the following recommendations based on our experiences.

Another requirement for a successful implementation is to have a policy that defines the organization's commitment to patient safety, and articulates how staff is completely supported in reporting all near misses, safety hazards and adverse events. This policy must lay a foundation on which the conversation during walkarounds can be more open and honest, without staff fearing that they will be punished for sharing their experiences. During the intro-

duction of each walkarounds, the senior leaders need to reiterate to the participants that their conversation will remain confidential, and to encourage them to speak openly and honestly about their experiences as care providers.

Walkarounds actively demonstrate the development of a culture of safety, where staff feel they are supported in patient safety initiatives, and where senior leaders are seen as partners in patient safety. When frontline staff and senior leaders have contracted to perform walkarounds, both will have invested significant resources to the process. To allow this focused energy to dissipate will imply to frontline staff that management is not deeply committed to patient safety at the bedside. Therefore, it is important to commit to a schedule, and provide replacement leaders should last-minute events otherwise cause a cancellation. It is imperative to understand that once this process takes root in the organization, walkarounds should not be discontinued, nor phased out. Once this happens it would become difficult to motivate staff to participate in any further patient safety initiatives.

Ensure that middle managers understand the focus and purpose of walkarounds, so that they do not feel undermined during this process. One needs to recognize the managers' efforts in resolving issues, and identify barriers that the manager has not been able to overcome. A debriefing after the rounds between the manager and the senior leader can reduce the amount of time a senior leader spends collecting background information. In time the senior leaders may be able to resolve systemic and communication blockages, provided they share their responses with other leaders.

An organization must be patient while developing these new information flows, as it will take some time to reach truly meaningful dialogues pertaining to patient safety processes. Be tolerant with resolving environmental and equipment issues: it is likely an organization will have to first address many such safety issues as bed brakes failing and showers flooding before tackling large systems issues such as communication processes during patient transfers. By addressing the environmental and equipment-related issues, the eventual yet essential trust between frontline staff and senior leadership takes shape. The corollary recommendation to the environmental issues is to prepare the support service staff for increased requests for services and better communication between service providers and units.

Further recommendations include agreeing on workable data management tools and communication strategies for identified priorities and improvements. Adapting communication tools to fit your organization's style and speed of response is important to ensure buy-in, but more importantly for staff to see results from this type of interaction. Also start with a small number of pilot units and engage the early adopters within the organization: doing so will provide critical feedback on what your organization requires in order to achieve success.

Conclusion

Walkarounds are used as a tool to unify the organization in solving systemic problems of communication and sharing common areas of concern. They are an excellent opportunity to address systemic patient safety issues in an effective project management /quality improvement framework. When conducted successfully, they serve to demonstrate the organization's commitment and accountability for safety in a very real, and visible, frontline manner.

References

Baker, R., Norton, P., Flintoft, V., Blais, R., Brown, A., Cox, J., Etchells, E., Ghali, W., Hebert, P., Majumdar, S., O'Beirne, M., Palacios-Derflingher, L., Reid, R., Sheps, S., Tamblyn, R. 2004. "The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada." *Canadian Medical Association Journal*. 170 (11): 1678–1686.

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

About the Authors

Guna Budrevics, C.C.H.S.A.(A), CPHQ, Coordinator, Quality and Patient Safety, Sunnybrook and Women's College Health Sciences Centre has led numerous quality improvement and patient safety initiatives at Sunnybrook and Women's College Health Sciences Centre.

Catherine O'Neill, RN, Patient Safety Specialist, Sunnybrook and Women's College Health Sciences Centre co-founded the Patient Safety Service at Sunnybrook and Women's Health Sciences Centre in July 2002. The Patient Safety Service is dedicated to identifying, understanding, and reducing errors related to patient care, as well as, promoting a culture of safety through leadership, education and support for continuous improvement to all staff within our organization.

Corresponding Author: Guna Budrevics, Sunnybrook and Women's College Health Sciences Centre, 2075 Bayview Avenue, Toronto, Ontario M4N 3M5. Email: guna.budrevics@sw.ca Tel: 416-480-5918

How Quality Improvement Projects Influence Organizational Culture

Leona R. Zboril-Benson and Bernice Magee

A culture of blame has thrived for decades within the healthcare system. When incidents occurred, we looked for the person to blame; the proverbial bad apple. Research findings have shown that this "blaming culture" persists and continues to operate in many healthcare organizations (Lawton and Parker 2002; Ricci et al. 2004; Stanhope et al. 1999; Vincent et al.1999). A culture of safety in healthcare is strongly emphasized in the patient safety literature (Baker et al. 2004; Mohr et al. 2004; National Steering Committee on Patient Safety [NSCPS] 2002) and elsewhere (Canadian College of Health Services Executives [CCHSE] 2005; Canadian Council for Health Services Accreditation [CCHSA] 2004). Culture shapes patient safety by influencing employees' readiness to question the actions of others, challenge authority and freely disclose one's own mistakes (Helmreich and Merritt 1998). To transition towards an organizational culture of safety and quality requires the commitment of leaders, physicians and staff. The Insulin Project at the University of Alberta Hospital (UAH) within the Capital Health region (Edmonton, AB and area) is an example of how a quality improvement project can influence organizational culture.

Organizational culture has been defined as "shared basic assumptions" (Schein 1992). Culture conveys a sense of what is valued and how things should be done within the organization; it represents "how things are done around here" (Schein 1992). Organizational culture has been described as collective phenomena that embody individuals' responses to uncertainty and chaos (Sleutel 2000). Culture includes the norms, values and rituals that characterize a group or organization. Culture serves as a social control mechanism that sets expectations about appropriate attitudes and behaviours of group members, thus guiding and constraining their behaviour. Organizational culture is transmitted to organizational members and subsequently reinforced through stories, rituals and language.

In healthcare, subcultures often develop. Subcultures develop around a subset of organizational members who identify themselves as a distinct group and interact regularly (Van Maanen and Barley 1985). Subcultures are important since they suggest that an organization's culture is not unitary, but rather consists of numerous, small cultures all existing within the same organization (Riley 1983). Many hospital cultures are composed of many subcultures (e.g., departments or programs, patient care units, disciplinary groups) (Coeling and Simms 1993a, 1993b; Deal et al. 1983).

Westrum (2004) distinguished three levels of organizational safety culture that vary systematically in how an organization responds to the problems and opportunities encountered: (1) pathological, (2) bureaucratic, (3) generative (learning). Pathological organizations are characterized by hiding information, "shooting" the messenger, covering up failures and actively crushing new ideas. The second type of organization – the bureaucratic – ignores information, tolerates messengers, promotes itself as being just and merciful, and believes that new ideas create problems. The most sophisticated organization, the

learning organization, is one in which information is actively sought, messengers are trained, failures result in inquiry and new ideas are welcomed. Westrum (2004) asserted that organizations move through the levels as they mature in terms of their approach to safety issues. We believe that, at the beginning of the project, the pilot units were faced with significant cultural change to make the shift toward the generative level by the conclusion of the project.

In this paper, we will describe how hospital leadership, the Insulin Project and the project team helped to transform the culture within the medicine and transplant programs by fostering an atmosphere of transparency and trust. In addition to the cultural transformation within these specific programs, news of the project and the impressive results achieved by the project team spread quickly to other program areas; boosting the patient safety movement throughout the hospital.

Overview of the Project

The project began as a pilot on two medicine units, with a high population of diabetic patients, with the implementation of several practice and educational changes (described later). Preliminary results, established through chart audits, from the two initial pilot units indicated that the practice changes decreased errors in insulin administration and increased consistency in insulin therapy practices. Based on these preliminary results, the project was extended to include the remaining eight medicine units and one transplant unit. The changes were piloted for a six-month period (October 2003 – March 2004) and post-implementation chart audits were then conducted for a four-week period.

Background

Clinical nurse leadership within the medicine program were concerned that patient care was being compromised by insulin errors, in many instances stemming from inconsistent processes (e.g., lack of consistent identification of insulin orders as a separate priority within ordering procedures, charting, etc.). To verify the reality of these concerns, an Insulin Project team consisting of 10 core members (including an endocrinologist, clinical nurse specialist – medicine, clinical nurse educator – medicine, quality consultant, pharmacist, dietician, diabetes nurse clinician, clinical supervisor and additional medical and quality representatives) was created with endorsement from the medical and operational program leads.

Team members selected were viewed as experts in the areas of diabetes or quality improvement and/or had an interest in reducing insulin medication errors. The major goal of the team was to enhance diabetic patient safety and well-being within the pilot units at UAH by reducing the incidence of errors related to insulin therapy.

Improvement Methodologies

The project team utilized two different improvement methodologies – first, the Path of Work Flow and, second, the PDSA (Plan, Do, Study, Act) Model – to develop the project plan, determine the direction of the project and facilitate the project process. The main focus of the project was to address the barriers associated with the administration of insulin, rather than actual glycemic control, which was deemed to be beyond the scope of the project.

Project Goal

Appropriate benchmarks for the outcomes to be achieved by the Insulin Project were determined by reference to the Institute for Safe Medication Practices (ISMP) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Insulin is considered a "high-alert" medication by the ISMP. High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error with these medications are clearly more devastating to patients (ISMP 2003). While there is no specific target for insulin errors identified in the expert literature, the Insulin Project team believed that the implicit target should be zero errors, based on the seriousness of the issue and the fact that the process should be entirely under effective management control. For this first effort at improvement, the team decided that a realistic working goal would be to reduce actual prevalence for all the targeted processes combined by 50%.

Assessment of errors

Incident reports. To determine the magnitude of errors associated with adult diabetic patients and insulin therapy, a review of the hospital's incident report data was first undertaken. Given that medication errors are often under-reported (Bates et al. 1995; Brennan et al. 1991; Lawton and Parker 2002; Ricci et al. 2004; Stanhope et al. 1999; Walker and Lowe 1998; Weingart et al. 2000), the results were deemed unreliable. The under-reporting of errors is often attributed to the "blame culture" perceived to exist within the healthcare system. In this case, when questioned, staff on the pilot units readily admitted their reluctance to submit incident reports citing concerns that they would be judged to be an inadequate practitioner and/or held responsible for the incident; demonstrating that a "culture of blame" was perceived by the staff on the pilot units.

However, in order to submit an incident report, one must first recognize that an error has been made. Prior to any changes being made, in order to assess knowledge about diabetes and its management, a questionnaire was administered to nursing staff and medical residents. The findings demonstrated a knowledge gap related to insulin therapy and subsequently identified why the incident report data were unreliable. In many cases,

insulin dose and/or glucometer errors had occurred, yet the individual involved was unaware that an error had been made. As a result, education was identified as an essential component of the Insulin Project.

Chart audits. As incident report data were considered unreliable, baseline measures of diabetes-related errors within the pilot units were established through pre-implementation chart audits. The chart audits encompassed all adult insulin-dependent diabetic patients and were conducted for four weeks in early 2003 (April 4, 2003 – May 1, 2003) on 10 inpatient medicine units. Pre-implementation chart audits were also completed on the transplant unit, prior to any changes being made.

Types of errors captured in the chart audits included glucometer reading (chemstrip) errors (too early, too late, missing, inappropriate extra reading), insulin timing errors (too early, too late), incorrect insulin doses (too high, too low, extra, missed), incorrect type of administered insulin (wrong insulin), transcription errors and errors with written orders (illegible, incomplete). In addition, inconsistent insulin administration times for patients receiving enteral feeding and variable physician ordering practices were identified through the audits.

Post-implementation chart audits were conducted for a four-week period in 2004 (April 4, 2004 – May 1, 2004) on the 11 pilot units. These audits proved to be a reliable method for assessing the impact of the changes on the rate of diabetic-related errors, and selecting one individual (clinical nurse educator) to perform the audits ensured consistency of measures. The same audit tool was utilized in the pre- and post-implementation chart audits to ensure results were comparable.

The findings demonstrated a knowledge gap related to insulin therapy and subsequently identified why the incident report data were unreliable.

Practice and Educational Changes

Before large-scale changes could be implemented in blood glucose management, the basic procedural steps in diabetes patient care needed improvement to provide a standardized and systematic approach. To identify these steps, a detailed flow chart was completed that identified a number of inconsistent practices with regards to insulin therapy; for instance, forms were located in various sections of the patient care record creating inefficiencies. There was an absence of pre-printed forms, which created opportunities for errors during transcription. As well, the practice of faxing insulin orders to the hospital pharmacy for review by the pharmacists had declined.

Upon completion of the flow chart, several multidisciplinary practice and educational changes were implemented:

- developing a decision algorithm for insulin dosing
- educating the clinical pharmacists in the decision algorithm for insulin dosing
- changing the format of the pre-printed intravenous insulin orders
- designing a pre-printed sliding scale insulin order form
- reinforcing the practice of faxing insulin orders to pharmacy for clinical pharmacists to review
- revising the insulin/blood glucose monitoring record
- placing the insulin and insulin/blood glucose monitoring records in a separate section of the patient care record
- developing guidelines for insulin administration for diabetic patients receiving tube feeds
- developing a Web site for physicians to access guidelines for insulin therapy in order to standardize treatment
- incorporating diabetes and insulin education into physicians' rounds and nursing education

Several forms were created and/or revised over the course of the project to increase knowledge and to reduce diabetes-related errors. In particular, the decision algorithm was designed for use as a quick reference or as a basic template for appropriate insulin dosing, and as an education tool for nursing staff, physicians, nurse practitioners and pharmacists.

Along with the practice changes, several educational initiatives were implemented. Medical residents attended a half-day educational session on management of diabetes and "Suggestions for In-Hospital Management of Patients with Diabetes" were posted on the Division of Endocrinology Web site. Education on diabetes was also added to the medicine orientation for new nursing staff and 17 additional one-hour inservices were held with a total of 115 staff from the pilot units attending.

Results

There have been substantial improvements in care associated with adult insulin-dependent diabetic patients admitted to the pilot units at UAH. Error reductions have improved patient safety and enhanced the quality of diabetic patient care through the application of a standardized and consistent process for ordering and administering insulin. Errors were reduced by 22 – 94% depending on the type of error. These outcomes cumulatively met the 50% reduction target in the prevalence of diabetic-related errors in the pilot units. More importantly, the most promising improvements occurred in the attitudes and perceptions of the staff and physicians towards errors and patient safety; an indication of a cultural shift.

Organizational Culture Measures

A range of organizational culture measurement tools exists in the literature however, there appears to be little agreement on which of these instruments accurately measures organizational culture (Gershon et al. 2004; Scott et al. 2003). Therefore, the project team decided to approach the assessment of organizational culture through the use of proxy measures. These proxy measures included subsequent changes observed through the use of communication boards, feedback from the staff survey and an examination of the narrative portion of the incident report forms.

Communication board. A communication board was initiated on each of the pilot units to allow staff to provide feedback on the practice changes as they occurred during the implementation phase of the project. The communication boards were heavily utilized and proved to be a powerful education tool. Receptiveness and responsiveness of team members to staff questions/comments helped to cultivate knowledge of insulin therapy and diabetes management, and helped to build trust and transparency within the pilot units.

Units that emphasize good information flow will have a shaping influence, particularly on patient safety (Westrum 2004). The free flow of information between project team members and staff via the communication boards heightened staff members' awareness of the project and kept them informed about the changes that were occurring and why. Staff realized early on that some of the changes introduced were in direct response to their feedback. As a result, staff felt empowered to speak up and to become active participants in the project. Staff viewed the project as an opportunity to improve patient care processes; an opportunity they did not feel existed prior to its initiation.

Another improvement related to the communication boards and dialogue exchange was increased verbal reporting of diabetic-related near misses. Staff members had an increased awareness of unsafe practices and were empowered to alert others such that process or system changes promoting patient safety could be developed. Not only did staff report near misses, they cited contributing factors and recommended possible changes, thereby averting the potential for subsequent incidents. This behavioural change represented a marked departure from that which occurred prior to the project (i.e., when near misses were not acted on); an indication of a shift towards a "culture of safety."

Surveys. Feedback was obtained from staff to determine if the changes improved the care of hospitalized patients with diabetes. Surveys were conducted for a three-week period on the 11 pilot units with nursing staff, unit clerks, staff physicians, medical residents and pharmacists. Surveys were also mailed to UAH staff physicians who attended patients on the units for endocrinology, general internal medicine, hematology, nephrology and pulmonary medicine.

There were 189 survey responses returned (142 hospital staff, 26 medical residents and 21 attending physicians). Survey results showed an overwhelming positive response (>90%) to permanently implement the following changes:

- separate section of chart for insulin orders
- different coloured paper for insulin orders
- glucometer readings performed 30 minutes prior to insulin administration
- insulin sliding scale template

Attending physicians responded favourably to the changes with such survey comments as "this is a very good project and improved patient safety," and "having the pertinent information...is essential to help eliminate errors and improve decision making – better quality of care."

Cumulative responses to three specific survey questions were also positive; an indication of the culture shift. There were 56% (105/189) of respondents who agreed/strongly agreed that the changes implemented as part of the project had improved patient care. As well, 44% (83/189) of respondents agreed/strongly agreed that there had been fewer errors related to diabetes management during the project. Finally, 43% (82/189) of respondents felt that the education provided had improved staff knowledge of diabetes management. There was a highly positive response (>85%) to permanently implement several recommendations (new glycemic record, insulin drip protocol, complete physician orders).

Incident reports. Incident reports for the periods April 4 – May, 1, 2003 and April 4 – May 1, 2004 were reviewed. While the number of diabetes-related incident reports filed did not differ dramatically during the pre- and post-implementation phases of the project, the type of incidents reported did. For example, a 2004 incident was reported because one extra unit of insulin (six units instead of five) was administered. Another report was filed because the insulin and chemstrip had not been charted appropriately in the patient care record. These types of incidents were a sharp contrast from what had been reported in 2003, which tended to focus on outdated orders being used for insulin dosing; errors which could have serious ramifications for any diabetic patient. This finding echoed previous research results, which revealed that only serious errors in healthcare are likely to be reported (i.e., when a patient has been injured; when willful violation of established protocol has occurred, etc.) (Lawton and Parker 2002; Ricci et al. 2004; Stanhope et al. 1999). Clearly, there is more work to be done to further improve incident reporting. However, the disparities in the types of incidents reported between the two time periods represent both the learning that has been achieved and the culture shift that occurred as a result of this project. The team remains optimistic that incident reporting will continue to improve with increased

staff recognition of the value of completing incident reports, the associated learning that comes from reporting, and the implementation of a new Web-based incident reporting system (netSAFE) throughout the Capital Health region.

To encourage incident reporting throughout the region, Capital Health has recently approved a Just Culture (non-punitive) policy. This policy was drafted in response to a recommendation put forth by the NSCPS in their 2002 publication, "Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Healthcare," that healthcare organizations develop an atmosphere of safety and trust in order to enhance the reporting and identification of incidents or near misses. This recommendation was echoed by the CCHSA with the release of its 2005 Patient Safety Goals and Required Organizational Practices (CCHSA 2004). Developing organizational cultures of safety that emphasize trust and transparency will help to resolve the issue of under-reporting currently plaguing many healthcare organizations.

Role of Leadership

Strong leadership support at all levels has been essential throughout the development, implementation and completion phases of this project. Senior leadership at UAH enthusiastically adopted all of the recommendations put forth by the project team for site-wide implementation. Leadership support is necessary for culture change (CCHSE 2005; Weingart and Page 2004; Westrum 2004) and to mitigate errors in healthcare. Further, healthcare executives are well-positioned to shape the culture of safety through commitment to quality improvement projects such as this one. The decision to implement all of the recommendations site-wide communicated a powerful message to the team and others about UAH leadership's commitment to patient safety. It is through this commitment to quality and safety that the UAH is transitioning toward Westrum's generative organization.

Conclusion

The Insulin Project has demonstrated extremely positive results in the management of in-hospital adult patients requiring insulin, but also in the broader potential to redesign processes to improve quality and safety. The practice changes and associated education implemented by the project team resulted in substantial decreases in the number of clinical errors. The application of a standardized and consistent process for ordering and administering insulin improved diabetic patient safety within the pilot units at UAH, and the process developed during this project is indeed transferable to other areas both within and possibly outside the hospital. The success of the Insulin Project, dissemination of results and commitment of leadership have helped to "fire" the enthusiasm for patient safety and quality improvement at UAH, and, most importantly, launch a shift in culture from that of blame to safety.

References

Baker, G.R., P.G. Norton, V. Flintoft, R. Blais, A. Brown, J. Cox et al. 2004. "The Canadian Adverse Events Study: The Incidence of Adverse Events Among Hospital Patients in Canada." *CMAJ* 170(11):1678–86.

Bates, D.W., D.J. Cullen, N. Laird, L.A. Petersen, S.D. Small, D. Servi et al. 1995. "Incidence of Adverse Events and Potential Adverse Drug Events. Implications for Prevention." ADE Prevention Study Group. *JAMA* 27: 29–34.

Brennan, T.A., L.L. Leape, N. Laird, L. Hebert, A.R. Localio, A.G. Lawthers et al. 1991. "Incidence of Adverse Events and Negligence in Hospitalized Patients. Results of the Harvard Medical Practice Study I." *New England Journal of Medicine* 324: 370–76.

Canadian College of Health Services Executives. 2005. Position Statement on the Health Executive's Role in Patient Safety. Retrieved May 30, 2005. <http://www.cchse.org>.

Canadian Council for Health Services Accreditation. 2004, December. CCHSA Patient Safety Goals and Required Organizational Practices: Communique #2. Retrieved May 30, 2005, <http://www.cchsa.ca/default.aspx?group=p+section=PatientSafetyGoals>.

Coeling, H., and L. Simms. 1993a. "Facilitating Innovation at the Nursing Unit Level through Cultural Assessment: Part 1: How to Keep Management Ideas from Falling on Deaf Ears." *JONA* 23(4): 46–53.

Coeling, H., and L. Simms. 1993b. "Facilitating Innovation at the Nursing Unit Level through Cultural Assessment: Part 2: Adapting Managerial Ideas to the Unit Work Group." *JONA* 23(5): 13–20.

Deal, T., A. Kennedy and A. Spiegel. 1983. "How to Create an Outstanding Hospital Culture." Hospital Forum 26: 21–34.

Gershon, R.R.M., P.W. Stone, S. Bakken and E. Larsen. 2004. "Measurement of Organizational Culture and Climate in Healthcare." *JONA* 34(1): 33–40.

Helmreich, R.L. and A.C. Merritt. 1998. *Culture at Work: National, Organizational and Professional Influences.* Aldershot, UK: Ashgate.

ISMP's List of High Alert Medications. 2003, December. Retrieved May 20, 2005. <http://www.ismp.org/msaarticles/highalert.htm>.

JCAHO Strikes Proposed Insulin Goal. 2005, June. Retrieved May 30, 2005. <http://www.jcaho.org>.

Lawton, R. and D. Parker. 2002. "Barriers to Incident Reporting in a Healthcare System." *Quality & Safety in Health Care* 11:15–18.

Mohr, J., P. Batalden and P. Barach. 2004. "Integrating Patient Safety into the Clinical Microsystem." *Journal of Quality & Safety in Health Care* 13: ii34–ii38.

National Steering Committee on Patient Safety. 2002. Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Healthcare. Retrieved May 30, 2005. <http://rcpsc.medical.org/main_e.php?vtype=gp>.

Ricci, M., A.P. Goldman, M.R. de Leval, G.A. Cohen, F. Devaney and J. Carthey. 2004. "Pitfalls of Adverse Event Reporting in Paediatric Cardiac Intensive Care." *Archives of Disease in Childhood* 89: 856–59.

Riley, P. 1983. "A Structurationist Account of Political Culture." *Administrative Science Quarterly* 28(3): 414–37.

Schein, E.H. 1992. *Organizational culture and leadership* (2nd ed.). San Francisco, CA: Jossey-Bass Inc.

Scott, T., R. Mannion, H. Davies and M. Marshall. 2003. "The

Quantitative Measurement of Organizational Culture in Health Care: A Review of Available Instruments." *Health Services Research* 38(3): 923–45.

Sleutel, M. 2000. "Climate, Culture, or Work Environment? Organizational Factors that Influence Nursing Practice." *JONA* 30(2): 53–58.

Stanhope, N., M. Crowley-Murphy, C. Vincent, A.M. O'Connor and S.E. Taylor-Adams. 1999. "An Evaluation of Adverse Incident Reporting." *Journal of Evaluation in Clinical Practice* 5: 5–12.

Van Maanen, J. and S. Barley. 1985. "Cultural Organization: Fragments of a Theory." In P. Frost, L. Moore, M. Louis, C. Lundberg and J. Martin (eds.), *Organizational Culture* (pp. 31–54). Beverly Hills, CA: Sage.

Vincent, C., N. Stanhope and M. Crowley-Murphy. 1999. "Reasons for not Reporting Adverse Incidents: An Empirical Study." *Journal of Evaluation in Clinical Practice* 5(1): 13–21.

Walker, S.B. and M.J. Lowe. 1998. "Nurses' Views on Reporting Medication Incidents." *International Journal of Nursing Practice* 4: 97–102.

Weingart, S.N. and D. Page. 2004. "Implications for Practice: Challenges for Healthcare Leaders in Fostering Patient Safety." *Quality & Safety in Health Care* 13: ii52–ii56.

Weingart, S.N., A.N. Ship and M.D. Aronson. 2000. "Confidential Clinician Reported Surveillance of Adverse Events Among Medical Inpatients." *Journal of General Internal Medicine* 15: 470–77.

Westrum, R. 2004. "A Typology of Organisational Cultures." *Quality & Safety in Health Care* 13: ii22–ii27.

About the Authors

Leona R. Zboril-Benson RN, PhD (c), is a Quality Consultant at the University of Alberta and Stollery Children's Hospitals, Capital Health, Edmonton, Alberta.

Bernice Magee RN, MN, is the Clinical Nurse Specialist - Medicine at the University of Alberta Hospital, Capital Health, Edmonton, Alberta. She was the Project Team Leader and spear-headed the development, implementation and evaluation phases of the Insulin project.

Corresponding Author: Bernice Magee, MN, RN, Medicine Program, University of Alberta Hospital, WMC – 5H2.24, 8440 -112 Street, Edmonton, AB T6G 2B7, Phone: (780) 407-6728, FAX: (780) 407-8298, Email: bmagee@cha.ab.ca

Sources of Funding: Grant from Capital Health, University of Alberta Hospital and Stollery Children's Hospital Patient Safety Project and the operating budget of the Medicine program.

Acknowledgements: This paper is based on a project endorsed by the Medicine Business Unit at the University of Alberta Hospital, the UAH site Quality Council, and the Capital Health Regional Quality Council. Thanks to Michele T. Lahey, Senior VP Capital Health, Dr. Tom Marrie, Dean – Faculty of Medicine and Dentistry, and Deb Gordon, Chief Operating Officer for their leadership and support. The success of the project is owed to the Insulin Project team, with special thanks to Brenda Bond, Clinical Nurse Educator – Medicine for her extra-ordinary efforts as a project champion. Finally, thanks to Shannon Scott-Findlay, Doctoral candidate – Faculty of Nursing for her thoughtful review of this paper.

Patient Safety – Worker Safety: Building a Culture of Safety to Improve Healthcare Worker and Patient Well-Being

Annalee Yassi and Tina Hancock

Abstract

Patient safety within the Canadian healthcare system is currently a high national priority, which merits a comprehensive understanding of the underlying causes of adverse events. Not least among these is worker health and safety, which is linked to patient outcomes. Healthcare workers have a high risk of workplace injuries and more mental health problems than most other occupational groups. Many healthcare professionals feel fatigued, stressed, in pain, or at risk of illness or injury – factors they feel impede their ability to provide consistent quality care.

With this background, the Occupational Health and Safety Agency for Healthcare (OHSAH) in British Columbia, jointly governed by healthcare unions and healthcare employers, launched several major initiatives to improve the healthcare workplace. These included the promotion of safe patient handling, adaptive clothing, scheduled toileting, stroke management training, measures to improve management of aggressive behaviour and, of course, infection control – all intended to improve the safety of workers, but also to improve patient safety and quality of care. Other projects also explicitly promoting physical and mental health at work, as well as patient safety are also underway.

Results of the projects are at various stages of completion, but ample evidence has already been obtained to indicate that looking after the well-being of healthcare workers results in safer and better quality patient care. While more research is needed, our work to date suggests that a comprehensive systems approach to promoting a climate of safety, which includes taking into account workplace organizational factors and physical and psychological hazards for workers, is the best way to improve the healthcare workplace and thereby patient safety.

Patient safety and access to high quality patient care are the top priorities for the healthcare system. However, according to the Canadian Adverse Events Study, approximately 7.5% of Canada's 2.5 million hospital patients experienced at least one adverse event in 2000 and up to 23,750 patients died as a result (Baker et al. 2004). Many of these events were potentially preventable. In addition, access to healthcare is regularly impeded, not only by inadequate availability of qualified staff due to time loss from injuries, illness and long-term disability, but also ever-increasing infection-control required quarantines.

It is well-documented that the healthcare sector is plagued by high rates of work injuries and illnesses, absences from work and related costs (Koehoorn et al. 2002; Yassi et al. 2002a). Healthcare workers (HCWs) face a wide range of occupational health and safety hazards causing musculoskeletal injuries (MSIs), infectious diseases, chemical-induced disorders and mental stress, among other work-related illnesses and injuries (Yassi et al. In press). They also have more mental health problems than most other occupational groups. Many healthcare professionals feel fatigued, stressed, overburdened, at risk and/or in pain and do not feel able to provide consistent quality care (Nicklin and McVeety 2002). In the United States, more than three quarters of respondents in a 2001 survey conducted by the American Nurses Association indicated that unsafe conditions interfere with their ability to deliver high-quality care (ANA 2001). There is increasing recognition that both patient safety and access to high quality healthcare is linked to healthcare worker well-being.

In British Columbia (BC), the healthcare sector accounted for more injuries and time loss than any other sector until 2003, and remains today as the second biggest source of time loss injury in the province. However, the injury rate in the BC healthcare sector has declined dramatically since 1998 (WCB 2004). This article examines how this was accomplished, linking how the occupational health and safety factors addressed in BC apply to patient safety.

Organizational Culture and Safety Climate

Organizational culture and safety climate are emerging as important determinants of both caregiver well-being and patient safety (Goetzel et. al. 2004; Piirainen et al. 2003; Landsbergis 2003). It is known that common causes of errors leading to adverse events include organization factors such as lack of communication or miscommunication, lack of attention to safety procedures, inadequate supervision, breaks in continuity of care, excessive workload and inadequate numbers of staff for specified tasks (Johnson and Hudson 2004). Furthermore, fatigue of healthcare providers is emerging as an important determinant of patient safety, suggesting that work schedules may affect patient safety. A recent study demonstrated increased error rates in nurses working longer shifts (Rogers et al. 2004), and studies of errors committed by medical residents found strong correlation with sleep deprivation (Lockley et al. 2004). Moreover, a recent randomized controlled trial demonstrated that modification of intern work schedules reduced rates of serious medical errors by 26% (Landrigan et al. 2004). Also, fatigue has been implicated in the occurrence of worker injuries, including needle-stick injuries and nodding off while driving to or from work (Barger et al. 2005; Gold et al. 1992). Feuerberg (2000) found strong associations between low nurse staff levels and workload, poor resident outcomes, low job satisfaction and high turnover of resident-care staff. Hillmer et al. (2005), Harrington et al. (2000) and McGregor et al. (2005) also found associations of staffing levels with quality of care. A systematic review on the effects of nurse staffing on patient, nurse employee and hospital outcomes found evidence suggesting richer nurse staffing is associated with lower failure-to-rescue rates, lower inpatient mortality rates and shorter hospital stays, as well as fewer needle-stick injuries to staff (Lang et al. 2004).

With the recognition that to improve safety in healthcare, system changes are necessary (Baker et al. 2004) "creating a healthy healthcare workplace" has become the target of major Canada-wide efforts; at a workshop hosted by the Canadian Health Services Research Foundation, autonomy, empowerment, leadership, organizational structure, resources, workload, relationships and professional development were highlighted as factors contributing to a healthier healthcare workplace (CHSRF 2005).

It is well-documented that the healthcare sector is plagued by high rates of work injuries and illnesses, absences from work and related costs

Meanwhile, the 2003 Health Accord (Health Canada 2003) called for strategies to improve recruitment and retention to ensure the supply of HCWs; a part of this strategy highlighted the urgent need to improve working conditions and minimize loss of skilled HCWs due to disability. A large portion of Registered Nurses are retiring early, citing difficult working conditions as a major cause (ANA 2001). Studies have also shown that in hospitals with low turnover, HCWs do indeed report a healthier workplace with less work stress (Gleason et al. 1999; Laschinger et al. 2003; Koehoorn et al. 2002; Upenieks 2002). A healthy workplace is defined as one in which HCWs are able to deliver higher quality care, and worker health and safety and patient health and safety are mutually supportive (Eisenberg et al. 2001; Koehoorn et al. 2004). An important part of promoting patient safety must therefore focus on how to promote a healthy healthcare workplace (El-Jardali and Lagace 2005).

The Occupational Health and Safety Agency for Healthcare (OHSAH) in BC was conceived in 1998 and established in 1999, with joint governance by healthcare unions and employers with a shared goal of decreasing injuries and time loss, and improving

working conditions. The Accord that created OHSAH states as one of its objectives the promotion of a safe and healthy work environment through healthy workforces, safe workloads and promotion of safer work practices. In every project OHSAH undertakes (Yassi et al. 2002), attention is paid to promoting a culture of safety and improving organizational culture in healthcare by considering policies, procedures and communication methods that enhance participation, training, respect and the qualities of healthy organizational climate.

One OHSAH project, for example, was conducted to determine the factors that cause some intermediate care facilities to have higher injury rates than others, using ergonomic, organizational and psychosocial measures (Cohen et al. 2004; Yassi et al. 2004). We found that safer work environments are promoted by favourable staffing levels, convenient access to mechanical lifts, workers' perceptions of employer fairness in care provision and management practices that support caregivers. Most notably, however, was the finding that perceived quality of care was strongly correlated with burnout (correlation coefficient of 87, p<. .01), self-rated health (88, p<. .01) and job satisfaction (87 p<. .01).

Workers in high-injury rate facilities had more negative perceptions of their job demands and workload pressures than workers in low injury facilities.

We also found a major difference between care facilities with low staff injury rates versus facilities with high injury rates regarding front-line staff's beliefs about the facility's quality of care and their own capacity to deliver good care. Workers in high-injury rate facilities had more negative perceptions of their job demands and workload pressures than workers in low injury facilities. They were more likely to report that they did not have enough time to get their work done, to work safely, to find a partner or to use a mechanical lift. Workers in high injury rate facilities also reported more pain, more burnout, poorer personal health and less job satisfaction. Conversely, workers at facilities with low injury rates were more likely to agree that their facility had enough staff to provide good quality care and did indeed provide good to excellent care.

Other projects focusing on improving organizational culture and safety climate, along with results achieved are illustrated in the more targeted examples below.

Reducing Musculoskeletal Injuries

Systematic reviews have consistently found that HCWs are at high risk of musculoskeletal injuries (MSIs), with patient handling posing particularly high risk (Hoogendoorn et al. 1999; Lagerstrom et al. 1998). Lifts and transfers of patients using awkward postures; adverse psychosocial aspects of work such as high job demands with low decision authority and job control, and low social support at work and low job satisfaction are all deemed to contribute. Although less studied, staff injuries and disabilities may also jeopardize patients; and patient falls are determined by the same set of ergonomic concerns and safety climate factors faced by staff.

OHSAH prioritized reducing MSIs in initiatives to improve worker health and safety, taking into account what was known and had been recently learned about the proximate causes. Four OHSAH-partnered initiatives in particular can be highlighted for their link to patient safety and clinical outcomes, each suggesting that reducing the risk of MSIs in HCWs can also result in an associated improvement in patient safety and clinical outcome.

Ceiling Lifts

Over the past five years, we conducted several evaluations of ceiling lift installations to ascertain the effect of ceiling-mounted patient lifting devices on reducing worker injury (Ronald et al. 2002; Engst et al. 2005; Miller et al. 2005; Chhokar et al. 2005). We found that the installation of ceiling lifts indeed had a dramatic impact on MSI rates among BC HCWs. For example, the impact of the "no unsafe lifts" program resulted in an 83% reduction in lost hours resulting from lift and transfer injuries (Ronald et al. 2002). At the same site, while the staff were surveyed to determine history of pain and injury, preferred patient handling techniques and perceived exertion during various patient lifts and transfers, patients – the residents of this extended care facility – were also surveyed pre- and post-intervention. These surveys showed that residents' satisfaction increased from 80% to 95% after ceiling lifts were installed, and 80% of residents stated they felt comfortable while being moved, versus 65% pre-intervention.

In another ceiling lift project (Engst et al. 2005), the use of ceiling lifts to lift and transfer residents was found to significantly reduce the perceived risk of injury and discomfort to the neck, shoulders, upper and lower back, and arms/hands for care staff. In addition, staff were asked to assess resident perceptions of the safety and effectiveness of ceiling lifts during resident handling. Approximately 85% of staff believed the ceiling lifts to be safer for residents.

Scheduled Toileting Program in Long-Term Care

Another project assessed a scheduled toileting program for its impact on clinical outcomes for residents, and reducing the risk

of injury to care providers (Engst et al. 2004). A 75-bed unit in a long-term care facility participated in the program, with another unit in the same hospital acting as the control group. Data related to MSIs and to resident aggression were collected eight months prior to the introduction of the toileting schedule, and again eight months after it had been put in place.

Staff used mechanical lifts to toilet residents, which reduced the physical demands associated with handling residents, and also increased the physical distance between the worker and the resident. The post-intervention questionnaire revealed that staff working in the unit with the new toileting schedule showed a significantly lower perception of risk of injury to their head and neck than staff in the control unit, and the toileting program reduced staff injuries related to resident handling. The toileting program increased the percentage of residents toileting regularly, and reduced resident agitation expressed as verbal behaviours and emotional upset, further supported by staff perception that resident agitation had been reduced by the program. This project suggested that a toileting program, which had a positive impact on the well-being of staff by reducing risk of MSI and risk of injury due to aggressive behaviour, also can improve the quality of clinical care.

Adaptive Clothing

Nursing staff at intermediate and long-term care facilities are frequently required to help dress residents. Due to the limited physical capabilities of many of the residents, dressing often entails repositioning and manual handling. Repositioning patients has been found to be the second most stressful task for nursing staff (Owen et al. 1992; Garg and Owen 1992), and studies have shown that up to 24% of all low back injuries to nursing staff are due to repositioning (Vasiliadou et al. 1995). An adaptive clothing program was developed at two facilities in the Interior Health Authority of BC in response to the high number of injuries to nursing staff that perform dressing tasks, and the fact that many residents consider dressing an unpleasant or painful experience. Residents' own clothing was adapted to make the dressing process easier for residents and caregivers. The evaluation of the program indicated that the adaptive clothing program was effective in reducing the risk of injury to workers. Of note, however, was that, when being dressed with adaptive clothing, the residents' shoulder and other joint movements were considerably reduced, helping also to minimize resident pain and discomfort. Residents were noticeably less agitated and appeared more comfortable throughout the dressing process (OHSAH 2003).

Stroke Recovery Project

A project was initiated to improve stroke care on medical wards and to reduce injuries to nursing staff arising from patient handling. This program involved a physiotherapist teaching nurses about care and specific handling skills for stroke patients. These teaching sessions were followed with bedside teaching during actual patient care. Training caregivers in basic skills of moving and handling, facilitation of activities of daily living and simple nursing tasks has been shown to reduce the burden of care and improve quality of life in patients and caregivers; it reduces the cost of stroke care, and a higher proportion of patients achieve independence at an earlier stage (Kalra et al. 2004). Preliminary assessment of this project suggested that it, too, was effective in improving worker and patient safety and quality of care. Further work is planned in this area.

Promoting Mental Health at Work

Mental disorders are the fastest growing cause of long-term disability in HCWs in BC, as elsewhere. Studies on the impact of cost-reduction strategies (Landsbergis et al. 1999; Sochalski et al. 1997; Woodward et al. 1999; Muntaner et al. 2004) report significant increases in staff depression, anxiety and emotional exhaustion among HCWs. Key job stress factors associated with ill health among HCWs were work overload, pressure at work, lack of participation in decision-making, poor social support, unsupportive leadership, lack of communication/feedback, staff shortages or unpredictable staffing, scheduling or long work hours and conflict between work and family demands. Evidence suggests these factors not only directly impact the psychological well-being of the workforce, but also impact patient care (Suzuki et al. 2004; Rogers et al. 2004). Conversely, the compromise in patient safety caused by organizational change could significantly impact the psychological well-being of healthcare providers. Studies have also documented that the perception of having made an error causing an adverse patient outcome creates substantial emotional distress that can cause longstanding feelings of fear, guilt, anger and embarrassment (Blendon et al. 2002; Firth-Cozens and Greenhalgh 1997). Because of organizational culture, adequate coping mechanisms (such as accepting responsibility, discussion with colleagues, disclosure to patients, etc.) are usually not readily available to HCWs. Indeed HCWs are usually hesitant to admit errors because of worry of blame, punishment and humiliation by their colleagues. These organizational shortcomings may result in dysfunctional methods of dealing with errors, such as alcohol and drug use. It has been suggested that promotion of a "climate of safety" in which HCWs are encouraged to discuss their mistakes with colleagues in a non-judgemental format could not only lead to the detection and elimination of root causes of these errors, but could also dramatically improve worker psychological well-being (Firth-Cozens 2001; Sexton et al. 2000).

In BC, there is considerable interest in addressing the mental health of healthcare workers. For example, almost at its inception, OHSAH was granted funding from the Canadian Institutes for Health Research for a five-year program of nine

interconnected projects, several of which explored occupational psychosocial factors. "*Caring for the Caregivers of Alternate Level Care Patients*," for example, examined how the organization of care for Alternate Level Care (ALC) patients impacts several patient care factors, focusing not only on staff injury rates, but also on job satisfaction, emotional exhaustion and nurse recruitment and retention. While patient outcome was not explicitly studied, we examined the perception of healthcare providers as to the quality of care provided under the various models of care provision, as well as their job satisfaction. Perceived management attention to health and safety was found to be associated with improved staff satisfaction with the hospital and decrease in emotional exhaustion (Yassi et al. 2002b).

More recently, OHSAH's mental health and organizational development team embarked on a four-year, five-phase intervention study to conduct a survey to test a comprehensive work stress and service use model and implement a pilot intervention based on the evidence gathered from the survey. This project was designed by OHSAH explicitly at the request of the health authorities, in recognition not only of the cost to healthcare of not addressing this issue, but also the impact of mental disease on the safety and well-being of patients.

Infectious Disease Exposures

Perhaps the link between worker and patient safety is most clear in the area of infectious disease prevention. The emergence of SARS highlighted the unique vulnerability of HCWs. The hospital setting amplifies the spread of respiratory-borne pathogens, and protecting HCWs became the main defence against further spread to vulnerable patients and the community. Prompt action in BC – establishing and promoting guidelines to protect HCWs – was likely a factor in preventing the secondary spread of SARS; while BC had three imported cases of SARS, only one secondary case occurred – a healthcare worker – and appropriate measures were taken to quickly limit its spread (Yassi et al. 2003). We also formed a multi-agency interdisciplinary team to examine what was known, what was learned and what still needs to be studied in this area. Indeed, emphasis on improving organizational culture and safety climate figured prominently in the findings (Gamage et al. 2005; Moore et al. 2005a; Moore et al. 2005b; Yassi et al. 2005).

It is well-known that vaccinating HCWs against influenza not only protects them and reduces absenteeism (NACI 2004), but there is also evidence that vaccinating HCWS protects patient safety by reducing the likelihood of influenza outbreaks (Nicholson 1998; Potter et al. 1997; Carman et al. 2000). Nonetheless, vaccine rates for HCWs have remained low. With the likelihood of a pandemic influenza outbreak, it is essential that we better understand determinants of vaccine uptake, and ensure that systems are in place to track compliance. We therefore have a project underway to address this issue.

Safety climate had also previously been correlated with better compliance with universal precautions against blood-borne pathogens (Gershon et al. 1995), and studies demonstrated that adherence to blood and body fluid exposure control procedures are related to key organizational and job stress variables. In BC, major initiatives are now underway to implement exposure control plans (OHSAH 2005). Preliminary analysis of survey data will be published shortly.

What Next?

While there is anecdotal and qualitative evidence suggesting that attending to the health and safety of healthcare workers has a positive impact on patient health and safety, this is an area that merits further attention. The conceptual link has now been established, but now interventions are needed that can target this link and be evaluated. In BC, the process of developing measures to better understand this link is in place. The Workplace Health Indicator Tracking and Evaluation (WHITE) database, developed by OHSAH, is already tracking health indicators among the BC healthcare workforce. This database is in the process of being designed for linking to an incident management and reporting information system (IRIS), which will track adverse events and other patient incidents in tandem with worker health and safety indicators.

Good science and good will is needed to improve patient safety. The experience in BC suggests that adopting a collaborative evidence-based approach in which taking care of the well-being of the healthcare workforce is paramount is an important component of improving the quality and safety of the patient care provided.

References

American Nurses Association. 2001. "Health and Safety Survey." *Nursing World* ANA 32.

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

Barger, L.K., B.E. Cade, N.T. Ayas, J.W. Cronin, B. Rosner, F.E. Speizer and C.A. Czeisler. 2005. "Extended Work Shifts and the Risk of Motor Vehicle Crashes Among Interns." *N Engl J Med* 352(2): 125-34.

Blendon, R., C. DesRoches, M. Brodie, J. Benson, A. Rosen, E. Schneider, D.E. Altman, K. Zapert, M.J. Herrmann, A.E. Steffenson. 2002. "Views of Practicing Physicians and the Public on Medical Errors." *N Engl J Med* 347(24):1933-40.

Canadian Health Services Research Foundation. 2005, June 9. Healthcare Workplace: Bringing more Health into It! (Knowledge exchange workshop). Ottawa: Author.

Carman, W.F., A.G. Elder, L.A. Wallace, K. McAulay, A. Walker, G.D. Murray and D.J. Stott. 2000. "Effects of Influenza Vaccination of Health Care Workers on Mortality of Elderly People in Long Term Care: A Randomized Controlled Trial." *Lancet* 355: 93-97.

Chhokar, R., C. Engst, A. Miller, D. Robinson, R.B. Tate and A. Yassi. 2005. "The Three-Year Economic Benefits of a Ceiling Lift Intervention Aimed to Reduce Healthcare Worker Injuries." *Applied Ergonomics* 36(2): 223-29.

Cohen, M., J. Village, A.S. Ostry, P. Ratner, Y. Cvitkovich and A. Yassi. 2004. "Workload as a Determinant of Staff Injury in Intermediate Care." *Int J Occup Environ Health* 10: 375–83.

Eisenberg, J., C. Bowman and N. Foster. 2001. "Does a Healthy Health Care Workplace Produce Higher-Quality Care?" *Jt Comm J Qual Improv* 27(9): 444–57.

El-Jardali, F. and M. Lagace. 2005. "Making Hospital Care Safer and Better: The Structure-Process Connection Leading to Adverse Events." *Healthc Q* 8(2): 40–48.

Engst, C., R. Chhokar, A. Miller, R.B. Tate, A. Yassi. 2005. "Effectiveness of Overhead Lifting Devices in Reducing the Risk of Injury to Care Staff in Extended Care Facilities." *Ergonomics* 48(2): 187–99.

Engst, C., R. Chhokar, D. Robinson, A. Earthy and A. Yassi. 2004. "Implementation of a Scheduled Toileting Program in a Long-Term Care Facility." *AAOHN* 52(10):427–35.

Feuerberg, M. 2000, July 20. Report to Congress: Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes (Vol. 1, Chapters 1-6). Baltimore, MD: Health Care Financing Administration. Washington, DC: U.S. Congress.

Firth-Cozens J. 2001. "Interventions to Improve Physicians' Well-Being and Patient Care." *Social Science & Medicine* 52(2): 215–22.

Firth-Cozens, J. and J. Greenhalgh. 1997. "Doctors' Perceptions of the Links Between Stress and Lowered Clinical Care." *Soc Sci Med* 44(7): 1017–22.

Gamage, B., D. Moore, R. Copes, A. Yassi and E. Bryce. 2005. "Protecting Health Care Workers from SARS and Other Respiratory Pathogens: A Review of the Infection Control Literature." *Am J Infect Control* 33(2): 114–21.

Garg, A. and B. Owen. 1992. "Reducing Back Stress to Nursing Personnel: An Ergonomic Intervention in a Nursing Home." *Ergonomics* 35(11): 1353–75.

Gershon, R., D. Vlahov and S. Felknor. 1995. "Compliance with Universal Precautions Among Health Care Workers at Three Regional Hospitals." *Am J Infect Control* 23(4): 225–36.

Gleason, S.J., J. Sochalski and L. Aiken. 1999. "Review of Magnet Hospital Research: Findings and Implications for Professional Nursing Practice." *Journal of Nursing Administration* 29(1): 32–42.

Goetzel, R.Z., S.R. Long, R.J. Ozminkowski, K. Hawkins, S. Wang and W. Lynch. 2004. "Health, Absence, Disability, and Presenteeism Cost Estimates of Certain Physical and Mental Health Conditions Affecting U.S. Employers." *JOEM* 46(4).

Gold, D.R., S. Rogacz, N. Bock, T.D. Tosteson, T.M. Baum, F.E. Speizer and C.A. Czeisler. 1992. "Rotating Shift Work, Sleep, and Accidents Related to Sleepiness in Hospital Nurses." *Am J Public Health* 82(7): 1011–14.

Harrington, C., C. Kovner, M. Mezey, J. Kayser-Jones, S. Burger, M. Mohler, R. Burke, D. Zimmerman. 2000. "Experts Recommend Minimum Nurse Staffing Standards for Nursing Facilities in the U.S. "Gerontologist 40: 5–16.

Health Canada. 2003. *First Ministers' Accord on Health Care Renewal.* Government of Canada.

Hillmer, M.P., W.P. Wodchis, S.S. Gill, G.M. Anderson and P.A. Rochon. 2005. "Nursing Home Profit Status and Quality of Care: Is There any Evidence of an Association?" *Medical Care Research and Review* 62(2): 139–66.

Hoogendoorn, W., M. van Poppel, P.M. Bongers, B.W. Koes and L.M. Bouter. 1999. "Physical Load During Work and Leisure Time as Risk Factors for Back Pain." *Scand J Work Environ Health* 25(5): 387–403.

Johnson, K. and M.A. Hudson. 2004. "Keeping Patients Safe: An Analysis of Organizational Culture and Caregiver Training." *J Healthc Manag* 49(3): 171–79.

Kalra, L., A. Evans, I. Perez, A. Melbourn, A. Patel, M. Knapp and N. Donaldson. 2004. "Training Carers of Stroke Patients: Randomised Controlled Trial." *BMJ* 328(7448): 1099.

Koehoorn, M., G.S. Lowe, V.R. Kent, G. Schellenberg and T.H. Wager. 2002 Creating High Quality Healthcare Workplaces. Vancouver, BC: Canadian Policy Research Networks discussion paper.

Koehoorn, M. and T. Sullivan. 2002. *The Health of Nursing Personnel: A Summary of Research Findings to Inform the Development of a National Survey in Canada.* Working paper #172, Institute for Work and Health, University of Toronto.

Koehoorn, M., G.S. Lowe, K.V. Rondeau, G. Schellenberg and T.H. Wagar. 2004. *Creating High Quality Healthcare Workplaces.* Canadian Policy Research Networks discussion paper no w/14.

Lagerstrom, M., T. Hansson and M. Hagberg. 1998. "Work-Related Low-Back Problems in Nursing." *Scand J Work Environ Health* 24(6): 449–64.

Landrigan, C.P., J.M. Rothschild, J.W. Cronin, R. Kaushal, E. Burdick, J.T. Katz, C.M. Lilly, P.H. Stone, S.W. Lockley, D.W. Bates and C.A. Czeisler. 2004. "Effect of Reducing Interns' Work Hours on Serious Medical Errors in Intensive Care Units." *New Eng J Med* 351: 1838–48.

Landsbergis, P.A. 2003. "The Changing Organization of Work and the Safety and Health of Working People: A Commentary." *JOEM* 45(1): 61–72.

Landsbergis, P.A., J. Cahill and P. Schnall. 1999. "The Impact of Lean Production and Related New Systems of Work Organization on Worker Health." *J Occup Health Psychol* 4(2): 108–30.

Lang, T.A., M. Hodge, V. Olson, P.S. Romano and R. Kravitz. 2004. "Nurse-Patient Ratios: A Systematic Review on the Effects of Nurse Staffing on Patient, Nurse Employee, and Hospital Outcomes." *JONA* 34(7/8): 326–37.

Laschinger, H., J. Almost and D. Tuer-Hodes. 2003. "Workplace Empowerment and Magnet Hospital Characteristics – Making the Link." *Journal of Nursing Administration* 33(7/8): 410–22.

Lockley, S.W., J.W. Cronin, E.E. Evans, B.E. Cade, C.J. Lee, C.P. Landrigan, J.M. Rothschild, J.T. Katz, C.M. Lilly, P.H. Stone, D. Aeschbach and C.A. Czeisler. 2004. "Effect of Reducing Interns' Weekly Work Hours on Sleep and Attentional Failures." *New Eng J Med* 351(18): 1829–38.

Mcgregor, M.J., M. Cohen, K. McGrail, A.M. Broemeling, R.N. Adler, M. Schulzer, L. Ronald, Y. Cvitkovich and M. Beck. 2005. "Staffing Levels in Not-For-Profit and For-Profit Long-Term Care Facilities. Does Type of Ownership Matter?" *CMAJ* 172(5): 645–49.

Miller, A., C. Engst, R.B. Tate and A. Yassi. In press. "Evaluation of the Effectiveness of Portable Ceiling Lifts in a New Long-Term Care Facility." *Applied Ergonomics.*

Moore, D., B. Gamage, E. Bryce, R. Copes and A. Yassi. 2005a. "Protecting Health Care Workers from SARS and Other Respiratory Pathogens: Organizational and Individual Factors that Affect Adherence to Infection Control Guidelines." *Am J Infect Control* 33(2): 88–96.

Moore, D., M. Gilbert, S. Saunders, E. Bryce and A. Yassi. 2005b. "Occupational Health and Infection Control Practices Related to Severe Acute Respiratory Syndrome: Health Care Worker Perceptions." *AAOHN Journal* 53(6).

Muntaner, C., Y. Li, X. Xue, P. O'Campo, H.J. Chung and W.E. Eaton. 2004. "Work Organization, Area Labor-market Characteristics, and Depression among U.S. Nursing Home Workers: A Cross-classified Multilevel Analysis." *Int J Occup Environ Health* 10: 392–400.

NACI. 2004. "Statement on Influenza Vaccination for the 2004-2005 Season." *CCDR* 30: 1–32.

Nicholson, K.G. 1998. "Human Influenza." In K.G. Nicholson, R.G. Webster, A.J. Hay, eds. *Textbook of Influenza* (pp. 219–64). London: Blackwell Science.

Nicklin, W. and J.E. McVeety. 2002. "Canadian Nurses' Perceptions on Patient Safety in Hospitals." *Can J Nurs Leadersh* 15(3): 11–21.

Occupational Health and Safety Agency for Healthcare in BC. 2003. *Adaptive Clothing Project: Final Report.* Vancouver, BC: Author.

Occupational Health and Safety Agency for Healthcare in BC. 2005. Blood and body fluid exposure control. Vancouver, BC: Author. Retrieved June 25, 2005. <http://www.ohsah.bc.ca/index.php?section_id=25080&>.

Owen, B.D., A. Garg and R.C. Jensen. 1992. "Four Methods for Identification of Most Back-Stressing Tasks Performed by Nursing Assistants in Nursing Homes." *International Journal of Industrial Ergonomics* 9(3): 213–20.

Piirainen, H., K. Rasanen and M. Kivimaki. 2003. "Organizational Climate, Perceived Work-Related Symptoms and Sickness Absence: A Population Based Survey." *J Emerg Med* 45(2): 175–84.

Potter, J., D.J. Stott, M.A. Roberts, A.G. Elder, B. O'Donnell, P.V. Knight and W.F. Carman. 1997. "Influenza Vaccination of Health Care Workers in Long Term Care Hospitals Reduces the Mortality of Elderly Patients." *J Infect Dis* 175(1): 1-6.

Rogers, A.E., W.T. Hwang, L.D. Scott, L.H. Aiken and D.F. Dinges. 2004. "The Working Hours of Hospital Staff Nurses and Patient Safety." *Health Aff* (Millwood) 23(4): 202–12.

Ronald, L.A., A. Yassi, J. Spiegel, R.B. Tate, D. Tait and M.R. Mozel. 2002. "Effectiveness of Installing Overhead Ceiling Lifts. Reducing Musculoskeletal Injuries in an Extended Care Hospital Unit." *Aaohn J* 50(3): 120-27.

Sexton, J., E. Thomas and R. Helmreich. 2000. "Error, Stress, and Teamwork in Medicine and Aviation: Cross Sectional Surveys." *British Medical Journal* 320(7237): 745–49.

Sochalski, J., L. Aiken and C. Fagin. 1997. "Hospital Restructuring in the United States, Canada, and Western Europe: An Outcomes Research Agenda." *Med Care* 35(10):.13–25.

Suzuki, K., T. Ohida, Y. Kaneita, E. Yokoyama, T. Miyake, S. Harano, Y. Yagi, E. Ibuka, A. Kaneko, T. Tsutsui and M. Uchiyama. 2004. "Mental Health Status, Shift Work, and Occupational Accidents Among Hospital Nurses in Japan." *J Occup Health* 46(6): 448–54.

Upenieks, V. 2002. "Assessing Differences in Job Satisfactions of Nurses in Magnet and Nonmagnet Hospitals." *Journal of Nursing Administration* 32(11): 564–76.

Vasiliadou, A., G.G. Karvountzis, A. Soumilas, D. Roumeliotis and E. Theodosopoulou. 1995. "Occupational Low-Back Pain in Nursing Staff in a Greek Hospital." *J Adv Nurs* 21(1): 125–30.

Whitney, B., A. Laporte and V. Valdmanis. 2005. "Observations on Institutional Long-Term Care in Ontario: 1996–2002." *Canadian Journal on Aging* 24(1): 71–84.

Woodward, C.A., H.S. Shannon and C. Cunningham. 1999. "The Impact of Re-Engineering and Other Cost Reduction Strategies on the Staff of a Large Teaching Hospital." *Med Care* 37(6): 556–69.

Workers' Compensation Board (WCB) of British Columbia. 2004. *Statistics 2003.* Richmond, BC: Author.

Yassi, A., M. Cohen, Y. Cvitkovich, I.H. Park, P.A. Ratner, A.S. Ostry, J. Village and N. Pollak. 2004. "Factors Associated with Staff Injuries in Intermediate Care Facilities in British Columbia, Canada." *Nurs Res* 53(2): 87–98.

Yassi, A., D. Moore, J.M. Fitzgerald, P. Bigelow, C.Y. Hon and E. Bryce. 2005. "Research Gaps in Protecting Healthcare Workers from SARS and Other Respiratory Pathogens: An Interdisciplinary, Multi-Stakeholder, Evidence-Based Approach." *J Occup Environ Med* 47(1): 41–50.

Yassi, A., M.A. Noble, P. Daly and E. Bryce. 2003. "Severe Acute Respiratory Syndrome: Guidelines Were Drawn up Collaboratively to Protect Healthcare Workers in British Columbia." *BMJ* 326(7403): 1394–95.

Yassi, A., A. Ostry, J. Spiegel, G. Walsh and H.M. de Boer. 2002a. "A Collaborative Evidence Based Approach to Making Healthcare a Healthier Place to Work." *Hospital Quarterly* 5(3): 70–78.

Yassi, A., A. Ostry, P. Ratner, R. Tate, I.H. Park, A. Kazanjian, H. MacLeod, C. Kidd, D. Keen, L. Felkar, S. Saunders, M. Arbogast, M. Cohen and R. Notley. 2002b. Caring for the Caregivers of "Alternate Level Care" (ALC) Patients: The Impact of Healthcare Organizational Factors in Nurse Health, Well Being, Recruitment and Retention in the South Fraser Health Region of British Columbia. Vancouver, BC: OHSAH. Retrieved June 25, 2005. <http://www.ohsah.bc.ca/media/ALC_Final%20_Report.pdf>.

Yassi, A., D. Pawson, T. Leary, J. Sikorski, D. Parent and M. Gilbert. In press. "Trends in Workplace Injuries, Illnesses, and Policies in Healthcare Across Canada." *Canadian Journal of Public Health.*

About the Authors

Dr. Annalee Yassi, MD, MSc, FRCPC, is the Founding Executive Director of the Occupational Health and Safety Agency for Healthcare in British Columbia and Director of the Institute of Health Promotion Research at the University of British Columbia.

Tina Hancock is the Manager of Communications with the Occupational Health and Safety Agency for Healthcare in British Columbia.

Corresponding Author: Dr. Annalee Yassi, MD, MSc, FRCPC, Founding Executive Director, Occupational Health and Safety Agency for Healthcare in British Columbia, 301 – 1195 West Broadway, Vancouver BC V6H 3X5, Phone: 778-328-8000, Fax: 778-328-8001

Preventing and Managing Conflict: Vital Pieces in the Patient Safety Puzzle

Pam Marshall and Rob Robson

Introduction

A common theme in the recent patient safety reports *To Err is Human and Crossing the Quality Chasm* (IOM 2000 and 2001) and the Canadian Adverse Events Study (Baker and Norton 2004) is the need for healthcare organizations to create a culture of safety. However, as Lucian Leape (2004) has noted, it is an axiom still much in need of being adopted because the predominating culture of most healthcare organizations is not one of safety but of fear. Healthcare professionals fear litigation, professional discipline and coroner's inquests. Patients fear becoming one of the statistics of the unsafe system that they hear about in the media. Administrators fear bad publicity, lawsuits and increased insurance premiums. What this really means is that people fear being blamed and punished for making a mistake, and most of all they fear being seen as incompetent. Unlike the popular television show, this "Fear Factor" has no winner at the end, but only losers; losers in the form of healthcare professionals, administrators and most of all patients.

Fear creates anxiety and mistrust, which leads to failures in communication and a lack of collaboration and teamwork (Baggs 1992; Spears 2005). The inevitable result is high levels of conflict among and between healthcare professionals. And while conflict is a daily, often hourly experience for most healthcare professionals, it is rarely acknowledged, and even more rarely dealt with. As a result, mistrust persists, anxiety grows and conflict increases, creating and perpetuating an unsafe culture. While the experts in the field of patient safety identify the need for culture change in order to improve patient safety (Baker and Norton 2001, 2004; Reason 2000; Leape 1994), little has been written about the fact that a significant contributor to unsafe cultures is the presence of unacknowledged and unresolved conflict. In this article, we will discuss how the prevalence of conflict in healthcare organizations is a leading cause of unsafe cultures and a serious threat to patient safety. We will illustrate how training and education in conflict resolution can provide healthcare professionals with skills to help them deal with the workplace conflicts that they face and in turn allow them to provide a safer environment for patients.

A Culture of Fear Is a Culture of Conflict

As healthcare conflict specialists, the authors have experienced firsthand the reluctance of healthcare professionals, administrators and clients to acknowledge and admit that unresolved conflict is pervasive in today's healthcare system. Healthcare professionals are not alone in avoiding conflict; most people fear conflict and do their best to keep out of and away from it, despite the fact that conflict is an inevitable factor in our daily personal and professional lives.

Conflict is a normal result of interacting with our fellow humans. And yet most of us have never learned how to prevent it, keep it from escalating when it starts, or manage it when it develops. Most of us are loath to admit we are in the middle

of conflict. We suggest that we are having a "discussion" or a "disagreement" or a "difficult situation." Many of our clients in healthcare facilities are quite prepared to hire us to facilitate meetings, or assist with teambuilding or work on organizational strategic planning. Few are willing to admit that they need help in managing the conflict within their organizations.

As Mayer (2000) suggests, "to say that we are in conflict is to admit a failure and to acknowledge the existence of a situation we consider hopeless." This attitude towards conflict is remarkably similar to the attitude towards the need to improve patient safety. If we accept the findings of the IOM reports and those of the Canadian Adverse Events study, the situation can seem hopeless and unsolvable. Healthcare professionals feel they are being judged as failures and may respond by questioning the accuracy of the findings (Leape 2004). However, conflict and patient safety issues do not improve through avoidance and denial; in fact they escalate and get worse.

ments lead to an increase in errors, and we also know that positive working relationships within healthcare teams has a significant effect on the safety and efficacy of the care given to patients (Dekker 2001; IOM 2001; Kritek 2002; Spears 2005).

We have ample and longstanding evidence of the importance of communication, collaboration and respect among healthcare team members as a vital component contributing to providing safe quality care to patients (Baggs 1992). Yet healthcare professionals have little or no training in or understanding of the factors that can help to prevent and manage conflict. Healthcare facilities do not routinely include conflict management as a required competency when hiring staff. An understanding of the uniqueness of healthcare organizations may assist in bringing this issue to a state of greater attention and awareness.

Fear creates shame, which leads to silence and missed opportunities for learning, change and improvement.

Fear and Conflict: Safety Enemies

In this climate of fear, doctors and nurses are loath to report their errors or even their close calls. And patient care suffers not only because of error, but because of what healthcare professionals do or do not do as a result of fear. In a recent study, 51% of physicians believe that as a result of medical malpractice fears their ability to care for patients has gotten worse (Common Good 2002). Nearly half (43%) of all nurses also feel prohibited or discouraged from doing what they think is right for the patient because of rules or protocols set up for legal liability protection. Only one-fourth or fewer of physicians, nurses and hospital administrators think that their colleagues are very comfortable discussing adverse events or uncertainty about proper treatment with them (Common Good 2002).

Other research has shown that organizational and individual barriers to communication creates under reporting and self-blame as a response to error rather than system improvement (Arndt 1994; Spears 2005). Fear creates shame, which leads to silence and missed opportunities for learning, change and improvement.

All of this unspoken fear and anxiety creates an environment of disarray and dysfunction. This dysfunctional state leads to conflict within disciplines, between teams and between clients and care providers. We know that poor-quality work environ-

Healthcare: A Unique and Complex System

Patients and providers alike have no trouble understanding that healthcare service delivery is a complex multilevel system. There are a number of characteristics in the healthcare system that help to generate misunderstandings and disputes:

- Healthcare is a classic example of a complex adaptive system (CAS). Such systems are prone to generate errors on a regular basis; they are also capable of achieving innovation if the correct conditions are created.
- Within healthcare, misunderstandings and conflict usually involve several distinct parties and occur at multiple levels at the same time.
- The healthcare system involves the wide disparity of knowledge, power and control experienced by the various players. While most conflicts involve some disparity between parties, it is unusual for this to be as markedly institutionalized, as is the case in healthcare.
- The ethnic diversity of both consumers and providers of healthcare services in many communities is striking and can generate potential barriers to helping parties create solutions.
- Strong gender inequities remain in healthcare in terms of the services offered to patients, the research done, opportunities for staff and the diversity (or lack thereof) within provider groups.

- Healthcare involves people interacting with other people to repair and preserve the health and personal integrity of patients. Often this involves issues about which people may have strongly held personal or religious values that may seem to be, and often are, irreconcilable.

All of these factors combine to make healthcare environments particularly prone to conflict. It is therefore important for healthcare professionals and administrators to understand the origins of conflict and to develop strategies to manage the conflicts that they will experience.

What Will Help?

The rapid development of the patient safety field in the last 15 years has yielded several useful insights that are gradually being translated into practical guidance for clinical providers and healthcare systems designers. One of these insights concerns the use of rapid cycle improvement techniques (PDSA cycle) and the application of various techniques that have been shown to assist clinicians in making it easy to do the right thing and hard to do the wrong thing. These include interventions such as forcing functions, direct and indirect constraints, process standardization and simplification, building in redundancy factors, effective communication training (SBAR being one of the examples often cited), and team resource management training, to name only some of the most tried and true (Leonard, Frankel et al. 2004).

While it is useful to have validated techniques that will concretely reduce unnecessary patient deaths and injuries, it is also useful to appreciate the extent to which unresolved conflict contributes to the many factors which create traps and hazards for healthcare providers and lead to undesired patient outcomes. It is our thesis that having a better understanding of conflict in healthcare and the ways in which it can be successfully prevented, managed and when necessary resolved, will lead to significant further improvement in the safer delivery of healthcare services.

Case Example

A 57-year-old school teacher had a longstanding complex nevus on her shoulder. Changes in the nevus led to concerns that it might be undergoing melanomatous transformation. She elected to have the resection done under regional scalene block due to previous difficulties with general anaesthetic. She was very anxious to have it dealt with, as her favourite niece was being married in two months.

She was on no medications and had no known allergies. She was taken to the OR for a scalene block and was fully conscious. Anaesthetist A was an expert with regional blocks. Nurse B was his direct assistant and had worked with him for many years. They had a comfortable bantering relationship. Other nurses found him difficult to deal with. This was the experience of Nurse C, who was circulating in the OR. Nurse C had found Anaesthetist A to be very brittle and unwelcoming of questions or suggestions.

B had already begun the initial prep of the left shoulder when A entered the OR. They had been discussing the recent PGA tour results. C was concerned that the block was being done on the contra-lateral side to the lesion. When he (C) tried to raise this concern, first with B ("Are you sure you want to start the prep on the left side?") and then with A ("I didn't realize that a scalene block would work when started...."), he was abruptly interrupted by A ("I'll explain this to you after the surgery – interruptions are not helpful when we are working.").

The scalene block was successfully completed on the wrong side. The patient was very upset to learn that the procedure would have to be postponed for several weeks, as the OR was descheduling procedures for the summer break.

This example points out how unresolved conflict can lead to an adverse patient outcome. It illustrates the need for positive communication between colleagues and effective collaboration amongst team members. A patient safety review of the incident might conclude that it reflects a "loss of situational awareness" that needs to be addressed. In addition, such a review might also recommend structured communication training for all parties or team resource management workshops for staff in the OR as well as making "time-outs" or safety huddles mandatory in the OR prior to procedures.

On the other hand, a conflict management review of the example might ask the simple question. "Were all the necessary parties present and involved in the process?" The case is a vivid example of how noncollaborative teams with poor communication skills create the conditions for adverse events to occur. It also clearly demonstrates how vitally important it is to connect with the patient and include her in the process; if she had only been consulted, they could have averted a negative outcome. We will discuss these elements of conflict prevention and management below. We will also outline the steps that organizations need to take in order to design and implement conflict management processes.

Conflict-Resolution Skills as Patient Safety Tools

Simple conflict-resolution skills such as structured communication and collaboration as well as more formal processes such as mediation are being used to resolve conflict in a wide range of formal and informal manners. These conflict-resolution skills and processes have been used in many domains, including business, legal affairs, neighbourhood disputes, international conflict, national policy discussions, and aboriginal claims, to name just a few. In fact, court-based processes such as litigation and binding arbitration are more the exception than the rule when it comes to problem-solving. It is finally becoming evident that the best way to resolve difficulties is for the parties involved to get together and talk through their issues.

The use of alternative processes in the healthcare field is relatively new. Many healthcare organizations are still using hierarchical, legalistic and punitive-based approaches at the same time that their vision statements declare their commitment to open communication, collaboration and patient involvement.

Lack of awareness may partly explain healthcare's slow acceptance of alternative conflict-resolution processes. As well, it may also be the case that traditional legalistic and adversarial approaches are seen as more appropriate in this area due to a widespread fear of and desire to avoid litigation. While people fear retaliation and legal action if they are open about errors, in our experience this fear is exaggerated and misplaced. Many professionals in healthcare are realizing that open and honest dialogue is preferable to secrecy and that positive communication produces favourable results for both patients and caregivers.

Effective Communication and Collaboration

As Mayer (2000) has noted, "Communication is at the heart of conflict and resolution." Conflict often arises from ineffective communication; effective or assisted communication and positive collaboration promotes successful resolution of differences. Numerous studies have highlighted the connection between poor communication and failures to collaborate as contributors to adverse outcomes as well as affecting staff morale and staff retention.

In a study of communication among ICU clinicians, Baggs (1992) and colleagues examined the association between nurse–physician collaboration and patient outcomes. Negative outcomes were defined as death or ICU readmission. Three hospital ICUs were compared. At the time of patient discharge from one of these units, questionnaires were completed to assess the extent to which decision-making had been a shared or collaborative process. The risk of negative outcome decreased from 16% of cases when the decision-making was felt to be noncollaborative to 5% when the nurses reported a collaborative process. Working collaboratively seemed to have a major impact (more than threefold decrease in risk) on patient outcomes.

In another study (Sutcliffe et al. 1999), a sample of 26 residents stratified by medical specialty, year of residency and gender was randomly selected from a population of 85 residents at a 600-bed U.S. teaching hospital. The study design involved face-to-face interviews with the residents about their routine work environments and activities, the medical mishaps in which they recently had been involved and a description of both the individual and organizational contributory factors.

Residents reported a total of 70 mishap incidents. Aspects of "communication" and "patient management" were the two most commonly cited contributing factors. Residents described themselves as embedded in a complex network of relationships, playing a pivotal role in patient management vis-à-vis other medical staff and healthcare providers from within the hospital and from the community. Recurring patterns of communication difficulties occur within these relationships and were associated with the occurrence of medical mishaps.

The study concluded that the occurrence of everyday medical mishaps is associated with faulty communication; but poor communication is not simply the result of poor transmission or exchange of information. Communication failures are far more complex and relate to hierarchical differences, concerns with upward influence, conflicting roles and role ambiguity, and interpersonal power and conflict.

A review undertaken by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) reported that the root cause of more than 65% of reported sentinel events ("unanticipated events that result in death, injury, or permanent loss of function") in the period 1995–2004 (more than 2,900 cases reported) was directly attributable to a problem of communication (JCAHO website).

Finally, Thomas (2003) surveyed 320 nurses and physicians in eight nonsurgical ICUs in Texas. The outcome showed considerable discrepancies in the two groups' perceptions of the quality of "interprofessional communication." While 73% of physicians reported that the quality of collaboration was high or very high, only 33% of nurses responded in kind. Compared with physicians, nurses were more likely to report that disagreements weren't resolved appropriately, that their input was poorly received, and that they found it difficult to assert themselves.

These studies highlight the fact that effective communication and collaboration are not merely about addressing techniques, or being a better listener, or a good team player, but rather that these skills and attitudes are a crucial part of the larger issue of culture. If the culture is one in which hierarchy is maintained, power gradients are not dealt with and conflict is not acknowledged and managed, no amount of communication skills training or teamwork workshops will be helpful.

Connection: Ensuring the Right Parties Are at the Table

One of the fundamental tenets of conflict resolution is ensuring that the right people are involved in any attempt at problem-solving (Fisher and Ury 1981: Moore 1996). This is reflected in the questions, "Who should be at the table? Who is affected by and involved in this problem? And how do we get them to buy into the process?" Usually it is readily apparent who the parties to the dispute are. However, there are also situations in which there are powerful players behind the scenes who are integral to a resolution, yet are not officially at the table. In addition, there is the problem of the so-called "weak or invisible players" who are being excluded from participating at the table. Patients are still not routinely included in healthcare decision-making,

patient safety initiatives and conflict-management processes.

The importance of getting the right parties to the table is crucial in complex multiparty situations. In our experience, most healthcare disputes are multiparty conflicts. Rare are the situations where there is one physician and one nurse in dispute. More often there are numerous physicians and nurses as well as member of administration and support staff. In disputes involving patients, there are also multiple parties such as the patient, family members, nurses, physicians, allied health workers as well as administration. Any effort to resolve conflicts in which all the appropriate parties are not present is doomed to failure.

The recommendations of IOM (1999) clearly identified the extent of patient safety challenges in the healthcare system. IOM (2001) laid out a roadmap to get us from the present situation to one in which patient safety is a core value. Among the 10 simple rules for the design of the 21st-century healthcare system are the following, which reflect patient-centred approaches.

PRESENT	FUTURE
Professional autonomy drives variability	Care is customized according to patients' needs and values
Professionals control care	The patient is the course of control
Secrecy is necessary	Transparency is necessary
Preference is given to professional roles over the system	Cooperation among clinicians is a priority
Information is a record	Knowledge and information flows freely

It almost seems as if a healthcare mediator was involved in devising these simple rules. The patient has been placed squarely at the centre of the patient safety challenge. The future design has incorporated many of the conflict-resolution principles that have been outlined above. Open, transparent communication, cooperation and patient involvement are all identified as crucial components in transforming the current system to a safer one.

How to Incorporate Conflict-Resolution Skills in Healthcare Workplaces

Clearly the ideas and skills discussed above can be useful in improving healthcare environments and culture. Yet organizations may still experience difficulty in putting these ideas into practice. We suggest a multifaceted approach that would include the following steps to building conflict management strength (for a detailed discussion, see Slaikeu 1992 and Slaikeu and Hasson 1998).

1. Conduct an organizational conflict assessment
   - Determine how your organization deals with conflict currently. Most organizations deal with conflict through avoidance, power plays, resorting to higher authorities or less commonly by collaboration. An organization needs to determine which method or option is encouraged and rewarded. High-reliability organizations are more likely to use collaboration as the preferred problem-solving method. Organizations need to determine where they are now and where they want to be. They must also identify the current resources available to assist with culture change and decide what extra resources will be required to move towards a culture of conflict management and positive collaboration.

2. Design a conflict management system that incorporates prevention and early intervention as key components
   - Staff and patients should have multiple entry points within the conflict-resolution process; that is, there should be various ways in which a problem could be handled, including direct contact between individuals, access to senior management or human resources assistance as well as identified internal conflict-resolution mentors.
   - The process should be designed to have loop-backs throughout. For example, if a patient has an issue with a physician, she may wish to first discuss it with the nurse manager. The nurse manager would encourage the patient to loop-back and discuss the matter directly with the physician. If this was unsuccessful, the patient could then access an internal mediator who could bring the parties together to discuss the situation.

3. Provide training in conflict prevention and management
   - To ensure that staff, management and physicians are adept at managing conflict, organizations must commit resources to train everyone in basic conflict-resolution and communication skills. This training must include opportunities for role playing and group exercises that give individuals practice in dealing with difficult situations. In addition, yearly "touch-ups" should be held so that everyone can renew their skills.
   - Identify talented internal individuals who can receive additional training to act as internal conflict coaches and mediators. Maintain a roster of these individuals and ensure that their availability is widely known by staff and patients.

4. Provide ombuds services
   - Identify internal individuals who can act as fair reviewers of issues that arise.
   - Provide external ombuds services that can be easily accessed for those situations that can not be resolved internally.

Again this process should provide for a loop-back to the internal ombuds or conflict coaches to complete the process if the external ombuds is able to resolve some of the outstanding issues. From a purely practical point of view, smaller facilities may find an external ombuds an economically more viable solution than trying to provide this service in-house.

5. Provide external mediation services as necessary
   - A well-developed internal conflict management process should be able to handle most of the conflicts that arise. However, there will still be situations that require the assistance of trained, experienced healthcare mediators. The goal should always be that disputes will be handled internally, but people should also know that there is expert assistance available if required.

Conclusion

Conflict resolvers are experts at listening to parties, exploring needs, reframing problems and helping the parties to devise solutions to the issues that face them. Conflict-resolution specialists are adept at helping to resolve a myriad of disputes such as family matters, business issues, neighbourhood disputes, landlord–tenant issues and even criminal matters. Conflict-resolution skills are perfectly suited to the healthcare field, and are easily understood and adopted by healthcare professionals once they have been explained, demonstrated and practiced.

The authors are often challenged by healthcare professionals, administrators and academics who doubt that such simple measures as effective communication, positive collaboration and the involvement of the affected parties can have any measurable effect on patient safety. Healthcare organizations resist the need to design and implement conflict-management processes and argue that there are already well-defined processes within union agreements, individual contracts or in HR policies. Conflict-management processes are not used in place of already existing contracts and policies, but as complementary additions. In many instances, conflict-resolution processes allow for early resolution of issues so that other, more adversarial options are not required.

While we are clearly strong proponents of conflict-management processes, we are not suggesting that these ideas are the sole answer to the patient safety conundrum; patient safety is a complex problem that requires a multifaceted and nuanced approach. At the same time, we reject the notion that our suggestions are self-evident and easily implemented. While the conflict-resolution skills, processes and approaches that we have discussed in this article may appear simple and obvious to many, they are skills that require ongoing education, training and practice. Most people do not communicate effectively, especially when they are under stress. Collaboration is often ignored in favour of individual decisiveness, even though such decisions may not create optimum results. And getting all the parties to the table is avoided for fear of emotional reactions and time-consuming discussions.

Most organizations do not have well-developed conflict-management systems in place, even though addressing the issue of conflict management is inherent in improving the culture of healthcare organizations. Moving away from hierarchical, secretive, blame-focused structures to create cultures of learning and openness requires all of the skills that we have discussed. High-reliability organizations have generally incorporated effective conflict-management processes and principles into their fabric and culture. Healthcare cultures that manage conflict positively and place a priority on continuing education and training in conflict resolution are equipping themselves with vital pieces to solve the patient safety puzzle.

We have not talked at all in this article about how conflict-resolution skills can be used to great advantage in difficult disclosure discussions and ethical decision-making (Dubler and Liebman 2004). Nor have we discussed the need to begin to use these skills in beginning the process of directly involving patients in devising initiatives and programs. This is a discussion for another article. Here we have clearly identified conflict management as an essential element for successful culture change within healthcare. And while these tools and processes are useful in many avenues and for many situations inside and outside of healthcare, we believe this roadmap to transformation in healthcare delivery systems is particularly useful for patient safety advocates.

References

Slaikeu, K.A . 1992. "Conflict Management: Essential Skills for Health Care Managers." *Journal of Health Care Material Management,* Nov-Dec.: 36–38.

Slaikeu, K.A., and R. Hasson. 1998. *Controlling the Costs of Conflict: How to Design a System for Your Organization.* San Francisco, CA: Jossey-Bass.

About the Authors

Pam Marshall is registered nurse, a lawyer with a master's degree in dispute resolution and a healthcare mediator. She is the associate director of the part-time LLM in ADR at Osgoode Hall Law School and adjunct faculty to the program.

Rob Robson is an emergency physician, the chief patient safety officer for the Winnipeg Regional Health Authority and a Harvard-trained healthcare mediator. He is adjunct faculty to the University of Manitoba Medical School. They have assisted in the resolution of numerous healthcare conflicts.

Corresponding Author: Pam Marshall RN LLB LLM, Dispute Resolution Specialist, Marshall Robson Group, pjmarshall@shaw.ca, (204) 944-8246 (Winnipeg office), (416) 483-5897 (Toronto office)

Implementing a Policy for Practitioners Infected with Blood-Borne Pathogens

Virginia Roth and Jim Worthington

Abstract

Healthcare practitioners infected with blood-borne pathogens may pose a risk to patients. There is disagreement about how to best protect the health of patients without unjustifiably restricting the autonomy of infected practitioners. There are no accepted national standards to guide Canadian hospitals in policy development. We implemented a policy for practitioners infected with blood-borne pathogens based on available scientific evidence and review of current practices. The policy was well-received by our physicians and dentists, and serves as a template for other organizations and hospitals tackling this issue.

Background

Healthcare practitioners (including physicians, dentists, residents and medical students) are at risk for occupationally acquired hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV). Infected practitioners, in turn, pose a risk to patients during invasive procedures. Hospitals have a duty ensure that patients are not subject to unacceptable risks. However, there is passionate debate around how to protect patients without unjustifiably restricting the autonomy of the infected practitioner.

Practices vary widely between countries. In the UK, testing is mandatory following a potential exposure (e.g., needlestick injury or unprotected sexual contact), and failure to be tested may be considered a breach of duty (UK Health Departments 1993; Communicable Disease Report 2000; UK Health Departments 2002). Infected healthcare workers are not permitted to perform exposure-prone procedures. In the US, infected healthcare workers who continue to perform exposure-prone procedures are required to inform patients of their serologic status (CDC 1991). Compliance is poor, and it is argued that the requirement to disclose does not improve patient safety and is discriminatory to infected healthcare workers (Gostin 2000). US professional organizations have since recommended rescinding the disclosure requirement and allowing infected healthcare workers to practise without restriction (SHEA 1997).

Many Canadian hospitals have no policy for practitioners infected with a blood-borne pathogen. This situation likely reflects the complex emotional, legal and human rights issues involved. Hospital administrators are often uncertain of their authority to request such testing, their ability to recruit and retain physicians if testing is mandated and the liability risk of allowing an infected practitioner to continue practising. Practitioners, in turn, are concerned about discrimination, loss of livelihood and tarnished reputations. The Canadian Medical Protective Association (CMPA) requires physicians to follow hospital policy on blood-borne pathogens, but does not offer specific guidance to support hospital policy development (CMPA 2002).

Objectives

Our objectives were to review the risk of blood-borne pathogen transmission, develop a policy for testing and vaccination of practitioners, and provide an acceptable framework in which infected practitioners can practice in a manner that will safeguard their rights and protect the patient.

Setting

The Ottawa Hospital is a 1,000-bed tertiary care centre with 1,225 physicians, 570 residents, 250 medical students and 22 dentists. Over 60,000 surgical procedures are performed annually.

Table 1: Estimated Risk of Blood Borne Pathogen Transmission by an Infected Practitioner

	Number of transmissions per 1,000,000 procedures	Estimated life-time risk of infecting at least one patient
Hepatitis B (if e-Antigen positive)	240 – 2,400	57 – 100%
Hepatitis C (if detectable viral load)	50 – 500	88%
HIV (risk is higher if transmission to a patient has occurred in the past)	2.4 – 24*	0.8 – 8.1%*

*From: Bell 1991; Bell 1992; Ross 2000

Sequence of Events

In 1996, Health Canada developed national guidelines on infected healthcare workers. However, these guidelines were not adopted as standard practice owing to rebuttals by the Canadian Medical Association and Canadian Dental Association (Health Canada 1998). In particular, these organizations expressed concern that the guidelines imposed unwarranted intrusion on the rights of privacy, confidentiality and autonomy of the infected practitioner.

Given the lack of consensus, several provincial Colleges of Physicians and Surgeons developed policies, but these lacked uniformity (CMA 1999). In 1998, the College of Physicians and Surgeons of Ontario undertook to establish a regulatory mechanism for infected physicians (CPSO 1998). However, this process is ongoing and several issues remain unresolved, including an expert panel process to assess the infected physician's ability to practise.

In 2002, the CMPA issued a statement requiring each hospital board to pass by-laws establishing protocols for healthcare workers infected with communicable diseases (CMPA 2002). The CMPA clearly stated that physicians must comply with these protocols and that failure to do so would be considered a breach of duty and possibly criminal negligence. However, this statement fell short of offering guidance to support local hospital protocol development or to promote consistency between hospitals. In light of the impetus placed by the CMPA on hospitals to address the risk of disease transmission from infected practitioners, and the potential liability of inaction, we developed a policy to address these issues.

Methods

We surveyed other Ontario tertiary care hospitals in 2002 and found a lack of hospital-specific policies addressing infected practitioners. A literature review was undertaken to assess the risk of blood-borne pathogen transmission (**Table 1**) and current practices in other jurisdictions. We received legal advice that hospitals do not have the authority to violate the individual's right to privacy or protection from discrimination by mandating testing for blood-borne pathogens. The onus rests on the hospital to demonstrate that it has reasonable grounds for suspecting that the individual is a danger to himself or others, or is unfit to perform his duties, before requiring such testing.

A policy was developed based on these findings (**Table 2**) and approved by the Medical Advisory Committee. It emphasizes preventative measures including immunization, adherence to universal precautions and medical treatment of infected practitioners to reduce the risk of transmission to others. Pre-appointment testing for blood-borne pathogen infection is not required, but the hospital may request testing of practitioners implicated in a case or cluster of patient infections. In compliance with current provincial regulations, practitioners who perform exposure-prone procedures are expected to know their own serologic status. Practitioners infected with a blood-borne pathogen must notify their regulatory body and Medical Affairs who will keep this information strictly confidential. Medical Affairs is responsible for arranging an independent expert panel review to determine under what circumstances the infected practitioner may perform exposure-prone procedures. There is no scientific evidence to restrict the medical practice of infected practitioners who do not perform exposure-prone procedures unless they fail to follow universal precautions or transmission to a patient is documented.

Constraints

The most important limitation with our policy is that the expert panel process remains untested, as we have not yet had occasion

Table 2: The Ottawa Hospital Policy for Practitioners Infected with a Blood-Borne Pathogen

All practitioners (regardless of serostatus) must:

- Adhere to universal precautions.
- Provide evidence of HBV immunity at the time of appointment or initiation of training. Pre-appointment screening for HIV, HBV or HCV infection is unwarranted.
- Undergo HBV vaccination if unable to provide evidence of immunity.
- Undergo post-immunization testing to establish need for re-immunization.
- Seek post-exposure follow-up if exposed to a patient's blood.
- Report events of patient exposure to a practitioner's blood so both practitioner and patient can be tested. The source of exposure will not be revealed to the patient.
- Undergo testing for blood borne pathogens as requested by the hospital, if implicated in patient infections.

Practitioners who perform exposure-prone procedures* must:

- Know their HIV, HBV and HCV status.
- Undergo annual testing for HBV infection if vaccine nonresponders or unimmunized.
- Procure disability insurance to provide coverage for blood borne pathogen infection.

Practitioners infected with a blood borne pathogen must:

- Notify their regulatory body and Medical Affairs. Medical Affairs will:
  - Keep this information strictly confidential.
  - Assist the practitioner to obtain medical care to maximize their health and reduce transmissibility.
  - Assist the practitioner to obtain advice from an expert review panel regarding under what circumstances, if any, they may perform exposure-prone procedures.
  - Ensure the expert panel's recommendations are followed.
  - Ensure the practitioner understands and can adhere to universal precautions. The medical practice of practitioners who do not perform exposure-prone procedures and can comply with universal precautions will not be restricted unless patient transmission is documented.
- Report any break in universal precautions to allow for anonymous notification and follow-up testing of the exposed patient.
- Stop performing exposure-prone procedures until the expert panel advises otherwise.

*Exposure-prone procedures are procedures where there is a risk that injury may result in the exposure of a patient's open tissues to the blood of the practitioner as defined by Health Canada (1998).

to use it. To ensure an arms-length approach, assistance will be requested from the provincial College of Physicians and Surgeons in the event that an expert panel is required. An expert panel review is generally considered preferable to a global prohibition on performing exposure-prone procedures. However, it should be recognized that inconsistency in panel decisions from one situation to the next may arise owing to differing opinions of panel members.

The second unresolved issue is the responsibility of the hospital to accommodate a physician or surgeon who becomes infected with a blood-borne pathogen and can no longer perform exposure-prone procedures. This is particularly relevant if the infection was occupationally acquired while providing services to the hospital. Some physicians have inadequate disability insurance coverage against income loss due to blood-borne pathogen infection.

Finally, our policy reflects statements from Canadian medical and regulatory bodies that healthcare providers who perform invasive procedures have an ethical duty to know their serologic status (CPSO 1998; OMA 1999; OHA 2000; CMA 2001). However, we allow practitioners to self-determine the frequency of testing since guidelines are unavailable, and there is a lack of scientific evidence on which to base recommendations. Furthermore, we are unable to monitor compliance with self-testing, since requiring test results or proof of testing could be considered unwarranted invasion of personal privacy.

Options and Alternatives

In an effort to control liability risk, hospitals may opt for mandatory testing and practice-restriction of infected practitioners. However, such intrusion on the rights of the practitioner may be unwarranted in the absence of evidence that widespread testing improves patient safety. Furthermore, there are circumstances where practice-restriction could be considered unjustifiable (e.g., an infected surgeon with excellent technique and an undetectable viral load).

An alternative approach is to avoid testing but emphasize good infection control technique and prevention of percutaneous injuries (Gostin 2000). Such measures protect both patients and healthcare workers from blood-borne pathogens and should be the standard of care in all hospitals. However, compliance with standard precautions and hand hygiene is often below acceptable levels and is not well enforced. Furthermore, in an era of heightened public concern, this approach is likely to be viewed as insufficiently proactive to protect patient interests. Although the probability of transmission of blood-borne pathogens from an infected practitioner is extremely low, public opinion continues to support disclosure and restriction of practice (Tuboku-Metzger 2005).

Solutions

Given the wide range of approaches across jurisdictions, our policy strikes a reasonable balance between protecting the autonomy and privacy of the practitioner and promoting patient safety. This policy provides a proactive approach in the absence of provincial or national guidelines, and has been well received locally. It also provides a starting point for discussion for others grappling with this issue.

Discussion

Transmission of blood-borne pathogens from infected practitioners to patients is extremely rare, but is of great public concern. Practitioner testing, patient disclosure and restriction of medical practice are complex issues that pit the hospital's responsibility to protect the health of the patient against the practitioner's right to privacy and protection from discrimination. The lack of comprehensive and consistent direction from regulatory bodies and the absence of a national standard have left hospitals struggling to deal with this problem in isolation. Our policy provides one solution to this dilemma, but a national approach is needed to ensure consistent practice among Canadian hospitals.

References

Bell, D.M. 1991. "Human Immunodeficiency Virus Transmission in Health Care Settings: Risks and Risk Reduction." *Am J Med* 91(3B): 294S–300S.

Bell, D.M., C.N. Shapiro, D.H. Culver, W.J. Martone, J.W. Curran and J.M. Hughes. 1992. "Risk of Hepatitis B and Human Immunodeficiency Virus Transmission to a Patient from an Infected Surgeon due to Percutaneous Injury During an Invasive Procedure: Estimates Based on a Model." *Infect Agents Dis* 1(5): 263–69.

CDC (Centers for Disease Control and Prevention). 1991. "Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures." *MMWR Morb Mortal Wkly Rep* 40(RR08):1–9.

CMA (Canadian Medical Association). 1999. "Physicians with Infectious Diseases - Patchwork of Policies will likely Persist." *CMA* News 9(8): 5.

CMA (Canadian Medical Association). 2001. "Prevention of Transmission of Hepatitis B in the Health Care Context (Update 2001)." CMA Policy. Retrieved June 7, 2005. <http://www.cma.ca//multimedia/staticContent/HTML/N0/l2/where_we_stand/hepatitis_b_transmission.pdf>.

CMPA (Canadian Medical Protective Association) and OMA (Ontario Medical Association). 2002. "Communicable Disease Surveillance Protocols for Ontario Physicians: Revised CMPA-OMA Statement." *Ontario Medical Review* (Nov): 40.

CPSO (College of Physicians and Surgeons of Ontario). 1998. "Physicians with Blood-Borne Pathogens." *CPSO Policy Statement Policy* #I–98.

Communicable Disease Report. 2000. "New Guidance Protects against Transmission from Hepatitis B Infected but e-Antigen Negative Health Care Workers." *CDR Weekly* 10(28): 249.

Gostin, L.O. 2000. "A Proposed National Policy on Health Care Workers Living with HIV/AIDS and Other Blood-Borne Pathogens." *JAMA* 284(15): 1965–70.

Health Canada. 1998. "Proceedings of the Consensus Conference on Infected Health Care Workers: Risk for Transmission of Bloodborne Pathogens." Can Comm Dis Rep 24(S4). Retrieved June 7, 2005. <http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/98vol24/24s4/index.html>.

OHA (Ontario Hospital Association). 2000. "Blood-borne Diseases Surveillance Protocol for Ontario Hospitals." *OHA/OMA Communicable Disease Surveillance Protocols Publication* #206 (Rev May 2000): 1–14.

OMA (Ontario Medical Association). 1999. "OMA Support Program for the Physician Infected with a Blood-borne Pathogen." *Ontario Medical Review* (Feb): 36.

Ross, R.S., S. Viazov and M. Roggendorf. 2000. "Risk of Hepatitis C Transmission from Infected Medical Staff to Patients: Model-based Calculations for Surgical Settings." *Arch Intern Med* 160(15): 2313–16.

SHEA (Society for Healthcare Epidemiology of America) AIDS/TB Committee. 1997. "Management of Healthcare Workers Infected with Hepatitis B Virus, Hepatitis C Virus, Human Immunodeficiency Virus, or Other Bloodborne Pathogens." *Infect Control Hosp Epidemiol* 18(5): 349–63.

Tuboku-Metzger, J. 2005. "Public Attitudes and Opinions Toward Physicians and Dentists Infected with Bloodborne Viruses: Results of a National Survey." *Am J Infect Control* 33(5): 299–303.

UK Health Departments. 1993. "Protecting Health Care Workers and Patients from Hepatitis B: Recommendations of the Advisory Group on Hepatitis." HSG 23(40). Retrieved June 7, 2005. <http://www.dh.gov.uk/PublicationsAndStatistics/LettersAndCirculars/HealthServiceGuidelines/HealthServiceGuidelinesArticle/fs/en?CONTENT_ID=4084234&chk=fut3ai>.

UK Health Departments. 2002. "AIDS/HIV Infected Health Care Workers: Guidance on the Management of Infected health Care Workers and Patient Notification." Retrieved June 7, 2005. <http://www.dh.gov.uk/Consultations/ClosedConsultations/ClosedConsultationsArticle/fs/en?CONTENT_ID=4076770&chk=1Nnbz2>.

About the Authors

Dr. Virginia Roth is the Director of the Infection Prevention and Control Program and Hospital Epidemiologist at the Ottawa Hospital, and Assistant Professor of Medicine at the University of Ottawa.

Dr. Jim Worthington is the Vice-President of Medical Affairs, Quality and Patient Safety and the Ottawa Hospital, and Assistant Professor of Medicine at the University of Ottawa.

Corresponding Author: Dr. Virginia R. Roth, Director, Infection Prevention and Control Program, The Ottawa Hospital, 501 Smyth Road, Room G-12, Ottawa, ON K1H 8L6, Tel: (613) 737-8606, Fax: (613) 739-6187

Enhancing Patient Safety Through a Standardized Model of Physiologic Monitoring

Mary-Anne Davies and Heather Tales

Abstract

The use of physiologic monitoring (e.g., cardiac monitoring) as an important component in providing safe patient care has escalated over the past two decades. It enables the clinician to detect physiologic changes in the patient's condition before they become clinically significant, thus allowing anticipation and prevention of adverse events. Issues and concerns regarding physiologic monitoring were raised throughout the London Health Sciences Centre (LHSC) leading to the approval of a project to develop a policy and guidelines for its use: the focus being standardization of processes and patient safety improvements. This article describes the underlying issues, the execution and results of the project, and its impact on patient safety within LHSC.

Patient monitoring is pivotal for the appropriate assessment, diagnosis and treatment of patients. It ranges from basic vital signs and visual assessment to the use of sophisticated physiologic monitoring equipment that can measure a number of parameters such as cardiac rhythm, oxygen saturation and central venous and pulmonary artery pressures. Patients today present with higher acuity and are more complex in their care requirements, thus healthcare practitioners often rely on sophisticated monitoring technology. The use of physiologic monitoring enables the clinician to detect changes in a patient's condition before they become clinically significant, so that adverse outcomes to the patient can be anticipated and prevented. The progress of technology to include flexible monitoring has now made it preferable in some care settings to bring the technology to the patient instead of moving the patient to a critical care unit (Macready and Evans 1997). Modern monitoring systems are complex and require adequately trained staff to ensure the equipment is functioning properly and to be able to analyze monitoring data to prevent misdiagnoses (Drew et al. 2004). Regardless of where the patient is located, the process for monitoring the patient should be consistent. The assurance of patient safety depends on the appropriate, consistent and proper use of physiological monitoring.

Over the years, as our healthcare organization has expanded and changed, monitoring practices have not evolved to keep pace with the expansion in patient care areas or advances in technology. This article describes one healthcare organization's efforts to identify the underlying issues regarding monitoring, develop strategies to standardize monitoring practices and recognize the impact on patient safety within the organization.

Background

London Health Sciences Centre (LHSC) is a large tertiary care teaching hospital with over 8,000 healthcare professionals located in southwestern Ontario. The organization has 744 acute care beds and is located on two sites throughout the city of London, Ontario. LHSC underwent a merger of two large hospital systems 10 years ago. In addition to this merger, the delivery of services changed to a program management format. As a result, personnel, practices, procedures and staff development were decentralized to the programs, unintentionally creating duplication of several different monitoring practices. Examination of LHSC's monitoring practices was triggered by the review of a coroner's report that involved monitoring and patient assessment at another large Canadian teaching hospital. As a result, a number of issues in the current practice of physiologic monitoring were raised through leadership and nursing practice committees. Concerns expressed were related to inadequate surveillance of monitoring equipment (e.g., continuous pulse oximetry, central ECG monitors) and the knowledge, skill and expertise of staff to appropriately respond to monitoring information and equipment, particularly in non-critical care areas.

These identified concerns prompted the establishment of an interdisciplinary task group with two part-time project leaders to lead the Monitoring Project. The mandate of this group was to develop evidence-based principles and guidelines for the use and practice of physiologic monitoring throughout the organization. The project methodology included distribution of an organizational survey, literature review including coroners' reports, review of standards, practices and education materials within and outside of LHSC, development of a physician consultant group and consultation with key stakeholders providing physiologic monitoring at LHSC.

The Project

The Monitoring Inventory Survey

In order to validate and fully understand the monitoring issues and explore current monitoring practices within the organization, a monitoring inventory survey was conducted. The aim of the survey was to determine the types of monitoring in place, the clinical areas using monitoring, the location of any pre-existing guidelines, the level of education in place, staffing patterns and responsibilities for monitoring. The survey was widely distributed by hospital mail and e-mail of an on-line survey link to all clinical areas throughout the organization. Due to the type of distribution, the response rate is unknown; however, the surveys returned represented all clinical areas within the organization. Several issues were identified or validated during the process, including lack of standard guidelines for monitoring, unclear responsibilities/ accountabilities for monitoring, surveillance of central monitors, inadequate and inconsistent education of staff, lack of a standardized curriculum, unclear process for assessing impact of new monitoring equipment, inconsistent documentation practices, and inactivation of alarms and setting alarm parameters. Interestingly, almost 70% of respondents had concerns about monitoring, which supports the need for a standardized approach for safe monitoring practices.

The implementation of the monitoring standards hospital-wide will ensure the care of all patients will be consistent from shift to shift

Framework

It became apparent that there were numerous interpretations about physiologic monitoring and the type of care that was required for patients. Thus, a framework was developed to guide the creation of monitoring standards to support the healthcare practitioner when caring for patients requiring physiological monitoring. The goal of the framework was to ensure that there were appropriate conditions established for any type of monitoring in any patient care area, allowing every patient the provision of consistent, safe care. The framework included a definition of the type of physiologic monitoring, patient criteria, staffing and education requirements and healthcare team responsibilities. Each physiologic monitoring standard was created using this framework. In total, 16 standards were created within the organization, including bedside ECG, telemetry, pulse oximetry and arterial blood pressure. Specialized monitoring, such as fetal heart rate monitoring, was not included in the project as standards have already been established by national bodies. Clinical areas using specialized monitoring will be required to develop a monitoring standard using the monitoring framework to ensure that there is consistency for physiologic monitoring. The implementation of the monitoring standards hospital-wide will ensure the care of all patients will be consistent from shift to shift, regardless of changing healthcare practitioners.

Practice Standards and Policy

With a framework established to guide the work, a review of the literature, benchmarking within Ontario and the United States, and review of existing protocols enabled the task group members to develop standards for practice. Established guidelines were incorporated where appropriate and updated with evidence from the literature. Consultation with key stakeholders was an important component of the process and included respiratory therapists, staff nurses, clinical educators, advanced practice

nurses and physicians. There were three physician consultants who worked closely with the project leaders to ensure that the standards would reflect appropriate practice. In addition, a policy has been developed that applies to all of the standards and provides the overriding principles to guide the practice of monitoring. The guiding principles that are inherent in the policy include the need to have patients reassessed after a specific period of time to ensure patients are being monitored appropriately, documentation and communication of monitoring data, clinical assessment of the patient, activation of appropriate alarm parameters and education for staff.

Education

In order to address the concerns regarding the inconsistencies with education, work is underway to develop standardized curricula for each of the monitoring standards. The learning materials are based on the education requirements stipulated in the practice standards and are derived from a combination of current learning packages and suggestions from the literature. Work on the standardized curricula for basic arrhythmia analysis and telemetry monitoring is in progress. Use of this learning material has been piloted in a variety of clinical programs and is undergoing revisions to ensure that it meets the needs of the learner and the requirements identified in the standards. All of the curricula will include a standardized test to assess competence. A separate group has developed learning material for pulse oximetry. Plans are to continue to develop standardized teaching materials for all types of monitoring and make those available in hard copy and as interactive on-line learning.

Implications for Patient Safety

The intent of the project was to develop monitoring practices to support patient safety. Examination of James Reason's Swiss Cheese Model of Defences (1997) provides some context for the issues identified and solutions developed for monitoring. Reason describes the use of barriers as a way of preventing potential hazards from resulting in a poor outcome. Latent conditions can produce holes in these barriers and thus weaken the defences. When an active failure, described as an unsafe act, is introduced into the system, the result can be devastating.

Through the work of the Monitoring Project, the latent conditions related to physiologic monitoring at LHSC were identified. These included deficient or limited guidelines and policies, inconsistent training and practices and staffing issues. The lack of consistency in practice and education for monitoring resulted in confusion about appropriate monitoring practices. While there were no specific documented errors recorded at LHSC, there were likely near misses that had gone unreported. However, the potential for an adverse event was very real especially since latent conditions can create factors that promote errors (Reason 1997). Introduction of an unsafe act, such as deactivating an alarm and leaving the patient unattended, could result in an adverse event if a patient develops a lethal cardiac rhythm. Alternatively, lack of documentation or communication of significant findings amongst care providers could lead to an inappropriate treatment plan and ultimately a negative outcome.

The lack of consistency in practice and education for monitoring resulted in confusion about appropriate monitoring practices.

A standardized approach to monitoring practices and education will improve patient safety. Standardization is known to decrease the chance of errors because it limits the variety of methods in performing a task (Porto 2001). Adequate training that is planned, provided during non-work hours and allows for the appropriate interaction with a qualified educator is necessary to prevent errors. This is especially needed with advances in technology and high staff turnover (Porto 2001). Providing healthcare practitioners with the skills and knowledge for interpreting monitoring information and a process for monitoring patients will increase their capacity to respond to the information and decrease the opportunities for adverse outcomes (Walsh and Beatty 2002). Standardizing the approach to physiologic monitoring throughout the organization will also support the implementation of safety principles within LHSC (Kohn, Corrigan and Donaldson 1999).

Conclusion

The purpose of the Monitoring Project was to develop evidence-based principles and guidelines to ensure safe monitoring for all patients. This was achieved by developing a standardized approach to physiologic monitoring that includes practice standards, a corporate policy and standardized education. It is clearly articulated in the policy and standards that monitoring is an adjunct to patient care and to be used as a tool in assisting clinicians with their assessment of the patient. While it is recognized that removing hazards is a more effective way of preventing errors, the development of policies, procedures and staff education are necessary to address the latent conditions that can weaken our defensive barriers (Reason 1997). By addressing these issues in the policy and standards, LHSC will strengthen the defences necessary to ensure the hazards of physiologic monitoring do not result in an adverse event.

Acknowledgements

The authors of the paper would like to acknowledge Margaret Nish, Executive Vice-President, Clinical Care and Academic Affairs, Dr. Ian Herrick, Chief of Staff, Dr. Murray Girotti, Senior Medical Advisor, Carol Wong, RN, MScN and the members of the Monitoring Guidelines Task Force for their contributions, guidance and support provided to this initiative. They were instrumental in identifying the monitoring issues within the organization and lobbying for a plan to allocate the appropriate resources to support monitoring practices.

References

Drew, B.J., R.M. Califf, M. Funk, E.S. Kaufman, M.W. Krucoff, M.M. Laks, P.W. Macfarlance, C. Sommargren, S. Swiryn, G.F. Van Hare. 2004. "AHA Scientific Statement. Practice Standards for Electrocardiographic Monitoring in Hospital Settings." *Circulation 110: 2721–46.*

Kohn, L.T., J.M. Corrigan, M.S. Donaldson. 1999. "Institute of Medicine (IOM) Committee on Quality of Health Care in America." *To Err is Human: Building a Safer Health System.* Washington, DC: National Academy Press.

Macready, N. and A. Evans. 1997. "Flexible Monitoring: Mobilizing Critical Care." *American Journal of Critical Care* 6(4): 3–15.

Porto, G.G. 2001. "Safety by Design: Ten Lessons From Human Factors Research." *Journal of Healthcare Risk Management* Fall: 43–50.

Reason, J. 1997. *Managing the Risks of Organizational Accidents.* Hampshire, England: Ashgate Publishing Limited.

Walsh, T. and P.C.W. Beatty. 2002. "Human Factors Error and Patient Monitoring." *Physiologic Measurement* 23: R111–R132.

About the Authors

Mary-Anne Davies, MScN, RN, is Patient Safety Specialist, Quality and Patient Safety at London Health Sciences Centre, London, Ontario, Canada.

Heather Tales, BScN, RN, is Nursing Professional Practice Specialist at London Health Sciences Centre, London, Ontario, Canada.

Corresponding Author: Mary-Anne Davies, Email: maryanne.davies@lhsc.on.ca, Tel: (519) 685-8500

An Effective Tool to Enhance a Culture of Patient Safety and Assess the Risks of Medication Use Systems

Julie Greenall, David U and Robert Lam

Introduction

Adverse events involving medication use represent a significant patient safety issue in Canada. This was most recently identified through the findings of the Canadian Adverse Events Study, released in May 2004 (Baker et al.) One strategy for addressing this issue is to utilize a systems approach to patient safety rather than focusing on individual performance. Practitioners, however, need tools to assist them in identifying system weaknesses as well as guidance and direction for improvement. This paper describes the Canadian experience with such a tool; namely, the acute care hospital Medication Safety Self-Assessment™ (MSSA), which was designed to assist hospitals to identify areas of risk in their medication use systems.

The MSSA, originally developed by the Institute for Safe Medication Practices (ISMP) in the United States, was adapted for use in Canada in 2002 by ISMP Canada (with support from the Ontario Ministry of Health and Long-Term Care). The MSSA is a comprehensive survey tool for use by a multidisciplinary hospital team. The tool consists of 195 evaluative characteristics that serve to assess the safety of medication practices within the hospital and identify opportunities for improvement. Most of the characteristics represent system improvements ISMP and ISMP Canada have recommended in response to analysis of medication errors or problems identified during on-site consultations.

Survey Format and Methodology

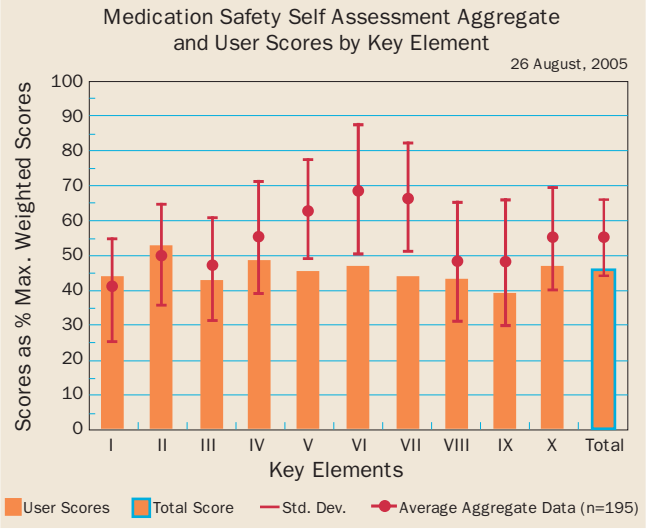
The MSSA is divided into 10 key elements of safe medication use and then subdivided into 20 core characteristics (see **Appendix 1**). Each core characteristic section is made up of representative individual characteristics. Hospitals are asked to rate their compliance with each individual characteristic using the following scale:

A: No activity to implement this characteristic
B: Discussed, but not implemented
C: Partially implemented in some or all areas
D: Fully implemented in some areas
E: Fully implemented throughout

Each response is assigned a weighted score. The scores were developed by ISMP through an assessment of the impact on patient safety and the ability of the characteristic to ensure sustained improvement (Smetzer 2003.) The higher weighted score indicates a greater impact on the safety of the medication use system as a whole. Completion of the self-assessment requires a three- to five-hour commitment by a team of physicians, pharmacists, nurses and senior administrative staff. Once the completed survey has been submitted via the ISMP Canada website, individual users can compare their results to those of other respondents, on both a national aggregate and provincial/regional aggregate basis.

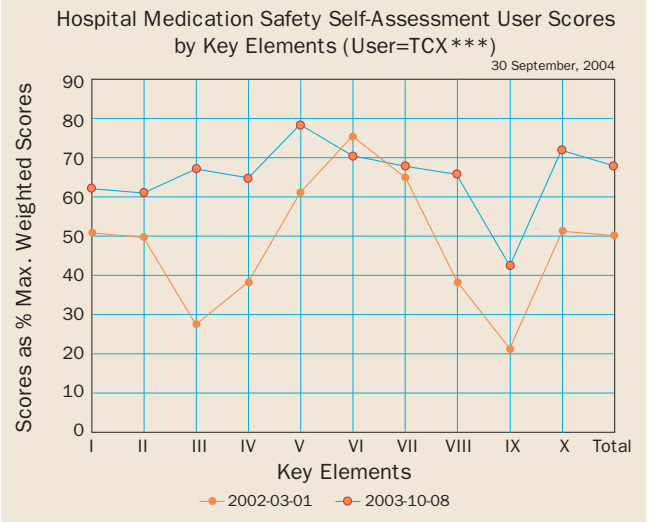
Figure 1 shows a sample comparison of one hospital to the national aggregate. The individual hospital's results are displayed as a bar graph with the national aggregate and standard deviation superimposed. Similar graphs can be obtained for comparison to provincial/regional data.

Figure 1: Aggregate and User Scores by Key Elements



If more than one self-assessment is conducted and the data entered, hospitals are able to track their quality improvement efforts over time. **Figure 2** shows a sample comparison of an individual hospital's results after two surveys.

Figure 2: User Scores by Key Elements (User=TCX*): Comparison of Repeat Surveys**



Results and Interpretation

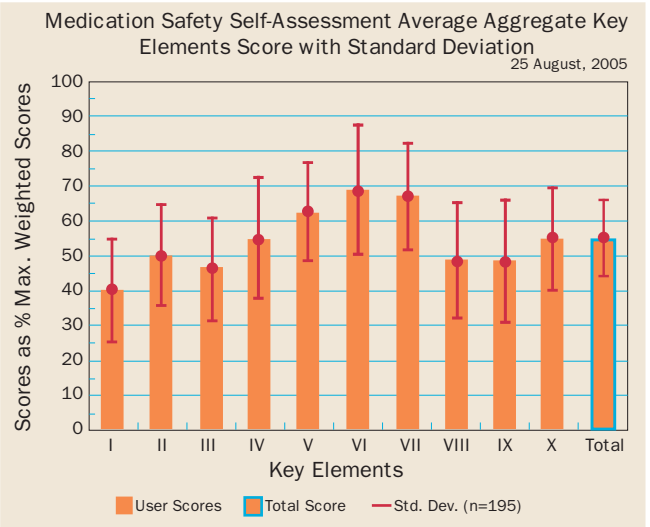
The provinces of British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Nova Scotia and Newfoundland and Labrador support the participation of their hospitals in the MSSA, while in other provinces participation is by individual hospital. At the time of writing, approximately one-third of Canadian hospitals (a total of 195) had completed the MSSA.

The MSSA data have provided insight into the status of medication use systems in Canadian hospitals. The average aggregate score for participating hospitals is 672.2 (or 55% of the achievable score of 1224). There is a substantial variation in scores, which range from 347 to 1039. Analysis of the responses generated three levels of results, broken down by key elements, core characteristics and individual characteristics. Only a portion of the key issues (items receiving the highest and lowest scores) will be highlighted in this paper.

Key Elements

Hospitals demonstrated the highest scores in areas related to the management of medication delivery devices, environmental factors and drug standardization, storage and distribution (Key Elements V, VI and VII). A nationwide MSSA survey completed in the US by ISMP in 2000 and published in 2003 found the same three key elements received the highest scores (Smetzer et al. 2003). Canadian scores were lowest in the key elements related to: patient information, communication of drug orders and other drug information, staff competency and education, and patient education (Key Elements I, III, VIII and IX), where the aggregate responses were between 40 and 50% of the achievable score. Comparison with the US survey results identified the same areas of low scores with the exception of staff competency and education (VIII). The aggregate scores by key element are shown in Figure 3.

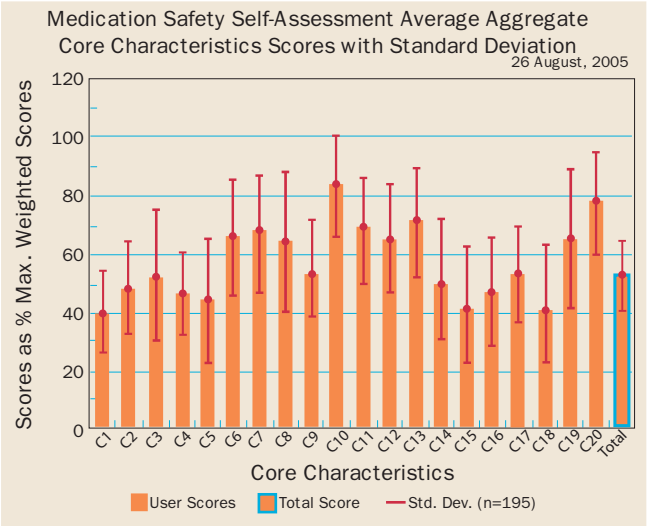
Figure 3: Average Aggregate Key Element Scores



Core Characteristics

Assessment of Canadian aggregate scores for the core characteristics, shown in **Figure 4**, indicates that only 9 of 20 core characteristics had an average aggregate result greater than 60% of the achievable score. Furthermore, wide ranges in responses indicate significant variability in the level of implementation of various medication safety strategies across the country.

Figure 4: Average Aggregate Core Characteristics Scores



The highest core characteristic score was related to sequestering of hazardous chemicals from patients and drug preparation areas. The average aggregate response indicated 85% of the achievable score. The next highest scoring was in the use of proven infection control practices in storage, preparation and administration of medications, with an average aggregate score of 80%.

The lowest core characteristic response was related to the availability of essential patient information, having an average aggregate score of 40% of that achievable score. Communication of drug orders in a standardized way, strategies for look-alike/sound-alike drug products, provision of ongoing education about medication error prevention, encouragement of practitioner reporting and multidisciplinary analysis of errors all demonstrated aggregate scores of less than 50% of the achievable score.

Comparisons of aggregate scores for core characteristics, by hospital demographics such as bed size, type and specialty, revealed very similar patterns of response, suggesting that hospitals of all sizes and types face similar challenges regarding their medication use systems.

Specific Characteristics

A review of aggregate scores for individual characteristics provides additional information about the status of medication use systems across the country. Some example scores for individual characteristics are noted below and demonstrate how individual hospitals can use the information to target improvements. The finding that characteristics related to management of error in a nonpunitive way showed average aggregate responses of 80% or greater is an encouraging result that suggests that a safety culture is becoming more evident, at least in participating hospitals.

A 90% average aggregate response was obtained for limiting the number of patient controlled analgesia (PCA) pumps to two or fewer within an institution and an 80% response for the development and implementation of monitoring criteria for PCA. Safety issues with PCA use and strategies for reducing the risk associated with administration of opioids by this route were addressed in several safety bulletins published by ISMP and ISMP Canada in 2003 and 2004.

A great deal of attention has been focused on removing potassium chloride concentrate from patient care areas, in response to several highly publicized deaths. The average aggregate response for this characteristic was 80%. Challenges continue to exist with the management of potassium chloride concentrate in paediatric and dialysis care areas.

Automatic screening of medication orders for patient allergies received an average aggregate response of 80% of achievable score. However, less than 20% of achievable score was obtained for the step of making patient allergies a mandatory field which must be filled in before orders can be entered. Mandatory entering of patient weights and a direct interface between the pharmacy and laboratory computer systems to automatically alert practitioners to the need for potential drug therapy changes also received aggregate scores of less than 20% of achievable scores.

Other findings showed that Canadian hospitals were lacking in implementing high leverage safety strategies such as bar coding for medication administration, computerized physician order entry (CPOE) and creation of designated medication safety positions. The average aggregate scores of these characteristics were less than 35% of achievable scores. Anecdotal follow-up by ISMP Canada suggested that high cost and complexity posting barriers to implementation of these technologies. On the other hand, there has been good acceptance of the importance of clinical pharmacist functions, with an average aggregate response of 70% for inpatient services and 45% for outpatient services. A recent study by Forster et al. (2004) reinforces the value of clinical pharmacist involvement in identifying and preventing adverse drug events.

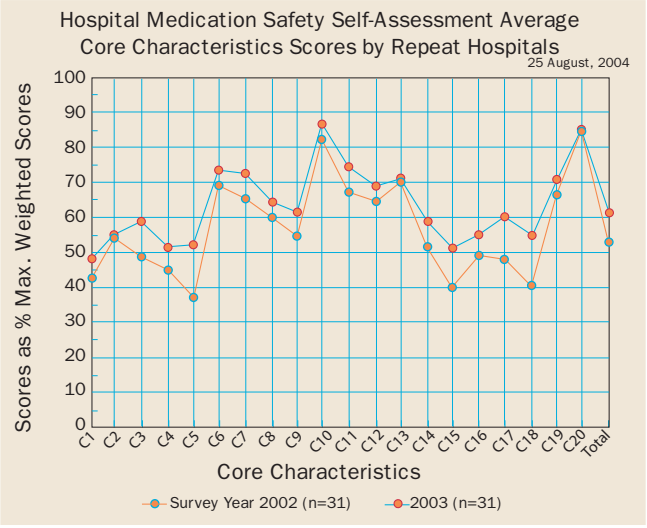
Provincial MSSA Initiatives

In addition to the national aggregate responses, it is worthwhile to share some findings from the Ontario and the British Columbia provincial MSSA initiatives since these two provinces had a very high level of participation. Regional surveys were also conducted in Winnipeg and Halifax, and other new provincial projects will be completed in Alberta and Newfoundland during the fall of 2005.

Ontario

Thirty-one Ontario hospitals completed an initial survey in 2002 plus a repeat survey in 2003 as part of a larger study protocol. The average aggregate score for these hospitals was 657 (53.7% of achievable score) in 2002 and 743.6 (60.8%) in 2003, demonstrating a relative improvement of 13.2%. Gains were achieved in 18 of 20 core characteristics, as illustrated in **Figure 5**. The total number of Ontario hospitals participating has increased to 75, which represent 39% of the Canadian aggregate. A comprehensive medication safety collaborative with the Ontario Ministry of Health and Long-Term Care raised the profile of medication safety, and might explain the higher participation rate.

Figure 5: Average Core Characteristic Scores by Repeat Hospitals in Ontario



The review of MSSA results for Ontario helped to identify a number of issues requiring intervention. The first intervention undertaken in Ontario in November 2002 focused on removing potassium chloride concentrate from patient care areas. This provincial safety initiative resulted in a significant increase in compliance with safe practice. As a result, similar initiatives were undertaken by other provinces. A second intervention, designed to improve the management of narcotic (opioid) medications, was initiated in 2004 and is still underway.

British Columbia

The Patient Safety Task Force of British Columbia (BC) invited 54 hospitals in their six regions to complete the Medication Safety Self-Assessment™ in 2004. Ninety-three percent of invited hospitals participated in the survey. ISMP Canada provided data analysis comparing results within and amongst the six regions. The BC aggregate score was 673, or 55% of the total achievable score, which, coincidentally, is identical to the current national aggregate score.

The following priority areas for action were identified based on review of MSSA results for BC:

- Manufacturer labelling/packaging and look-alike/sound-alike drug names
- Provision of ongoing safe medication education for practitioners
- Active analysis of errors for system redesign

A follow-up survey of the BC hospitals will be conducted in early 2006.

Discussion

There are limitations to the interpretation of these Medication Safety Self-Assessment™ results. The sample size, although representing approximately one-third of Canadian hospitals, is still small and thus may not be generalizable. As no statistical analysis has been performed, the confidence interval and significance of data differences have not been determined. The goal of this paper was to provide an overview of some of the Canadian data and demonstrate the value of the tool for assessing risk issues and developing priorities for individual hospitals and for provinces and regions. The tool is not designed for individual hospitals to make success comparisons with their peers. Rather, it is intended to allow hospitals to assess their medication use system weaknesses and to contribute to an aggregate database to assist in determining the areas of the medication use process that require more effort for improvement.

It is understandable that some may challenge the scientific validity of the safe practices contained in the Medication Safety Self-Assessment™. But while the characteristics contained in this tool are not proven by formal research methodology, it has been argued that many medication safety practices are "common sense" and well supported by human factors literature in other industries (Leape et al. 2002). The tool has been well accepted by Canadian hospitals and has been referenced within the guidelines to the 2005 Canadian Council on Health Services Accreditation Standards. Internationally, 1,435 hospitals in the

Appendix 1: Key Elements and Core Characteristics of the Medication Use System

Key Element	Core Characteristic	Description
I/ Patient Information	1	Essential patient information is obtained, readily available in useful form, and considered when prescribing, dispensing, and administering medications.
II/ Drug Information	2	Essential drug information is readily available in useful form and considered when ordering, dispensing, and administering medications
	3	A closed drug formulary system is established to limit choice to essential drugs, minimize the number of drugs with which practitioners must be familiar, and provide adequate time for designing safe processes for the use of new drugs added to the formulary.
III/ Communication of Drug Orders and Other drug Information	4	Methods of communicating drug orders and other drug information are standardized and automated to minimize the risk for error.
IV/ Drug Labelling, Packaging and Nomenclature	5	Strategies are undertaken to minimize the possibility of errors with drug products that have similar or confusing manufacturer labelling/packaging and/or drug names that look and sound alike.
	6	Clear and readable labels that identify drugs clearly are on all drug containers, and drugs remain labelled up to the point of actual drug administration.
V/ Drug Standardization, Storage and Distribution	7	IV solutions, drug concentrations, doses, and administration times are standardized whenever possible.
	8	Medications are delivered to patient care units in a safe and secure manner and available for administration within a time frame that meets essential patient needs.
	9	Unit-based floor stock is restricted.
	10	Hazardous chemicals are safely sequestered from patients and not accessible in drug preparation areas.
VI/ Medication Delivery Device Acquisition, Use and Monitoring	11	The potential for human error is mitigated through careful procurement, maintenance, use, and standardization of medication delivery devices.
VII/ Environmental Factors	12	Medications are prescribed, transcribed, prepared, dispensed, and administered in a physical environment that offers adequate space and lighting and allows practitioners to remain focused on medication use without distractions.
	13	The complement of qualified, well-rested practitioners matches the clinical workload without compromising patient safety.
VIII/ Staff Competency and Education	14	Practitioners receive sufficient orientation to medication use and undergo baseline and annual competency evaluation of knowledge and skills related to safe medication practices.
	15	Practitioners involved in medication use are provided with ongoing education about medication error prevention and the safe use of drugs that have the greatest potential to cause harm if misused.

continued

continued

Key Element	Core Characteristic	Description
IX/ Patient Education	16	Patients are included as active partners in their care through education about their medications and ways to avert errors.
X/ Quality Processes and Risk Management	17	A non-punitive, system-based approach to error reduction is in place and supported by senior administration and the Board of Trustees.
	18	Practitioners are stimulated to detect and report errors, and multidisciplinary teams regularly analyze errors that have occurred within the organization and in other organizations for the purpose of redesigning systems to best support safe practitioner performance.
	19	Simple redundancies that support a system of independent double checks or an automated verification process are used for vulnerable parts of the medication system to detect and correct serious errors before they reach patients
	20	Proven infection control practices are followed when storing, preparing, and administering medications.

United States participated in a national survey in 2000 and over 1,600 in a repeat survey in 2004 (Smetzer et al. 2003; ISMP Alert 2005). The State of New South Wales in Australia has recently received approval and funding to adapt and implement an Australian version of the MSSA. ISMP (US) has also developed a community practice version, currently being modified for use in Ontario. A long-term care version is in the development phase in Canada.

The MSSA offers a comprehensive structured process for assessing the safety of a hospital's medication use system in a manner that is proactive, unbiased and encourages consensus building. It provides a mechanism to enhance the perspective of healthcare practitioners towards a system-based approach to preventing adverse events. The ISMP Canada web-based access feature allows for an overview of system issues from provincial and national perspectives, which can be used to develop provincial and national priorities for safe medication practices.

References

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

Forster, A.J., R.B. Halil and M.G. Tierney. 2004. "Pharmacist Surveillance of Adverse Drug Events." *Am. J. Health. Syst. Pharm.* Jul 15 61(14): 1466–72.

"High Alert Drugs and Infusion Pumps: Extra Precautions Required." 2004. *ISMP Canada Safety Bulletin* 4(4).

"Latent Failures Identified with CADD® Pump Error Analysis." 2004. ISMP *Canada Safety Bulletin* 4(9).

Leape, L.L., D.M. Berwick and D.W. Bates. 2002. "What Practices Will Most Improve Safety? Evidence-based Medicine Meets Patient Safety." *JAMA* 288(4): 501–7.

"Looking Forward: Making 'Pro-change' Your New Year's Resolution." 2005. *ISMP Medication Safety Alert!* 10(1).

"Misprogram a PCA Pump? It's Easy!" 2004. *ISMP Medication Safety Alert!* 9(15).

"Safety Issues with Patient-controlled Analgesia, Part I." 2003. *ISMP Medication Safety Alert!* 8(14).

"Safety Issues with Patient Controlled Analgesia: Part II – How to Prevent Errors. " 2003. *ISMP Medication Safety Alert!* 8(15).

Smetzer, J.L., A.J. Vaida, M.R. Cohen, D. Tranum, M.A. Pittman and C.W. Armstrong. 2003. "Findings from the ISMP Medication Safety Self-Assessment for Hospitals." *Jt. Comm. J. Qual. Saf.* 29(11): 586–97.

Approaches to Improving the Safety of the Medication Use System

Stacy Ackroyd-Stolarz, Nicole Hartnell and Neil J. MacKinnon

Abstract

Problems associated with medication use have been consistently identified in the patient safety literature internationally. The purpose of this paper is to review components of the medication use process and offer suggestions for transforming it into a safer system. Prevention strategies are suggested for improving medication use at each stage of the system. Decision criteria are proposed that can be used by administrators and healthcare providers to allocate resources for prevention strategies that will improve medication safety.

Introduction

The body of literature concerning the safety, or lack thereof, of the medication use system, has increased substantially in the last decade. In Canada, some recently published studies have provided insight into the safety of our medication use system. The Canadian Adverse Events Study, a systematic review of hospital charts from randomly selected hospitals in five provinces, revealed an adverse event rate of 7.5 per 100 hospitalizations, which extrapolates to 141,250 to 232,250 hospital admissions per year in Canada that are associated with an adverse event (Baker et al. 2004). Drug- or fluid-related events were the second single largest category of adverse events, accounting for 23.6% of all events. In a prospective study of 328 patients, Forster et al. (2004) used telephone interviews and chart reviews to determine the incidence, severity, preventability and ameliorability of adverse events among patients recently discharged from hospital. In this study, 23% of patients experienced an adverse event after discharge from hospital, 72% of which were attributable to medications. The most common preventable adverse events in this patient population involved the concomitant use of medications with known interactions, contraindicated medications and inadequate monitoring of medication-related treatments. In a sample of 253 patients from the Moncton Hospital in New Brunswick, Nickerson et al. (2005) determined that patients averaged 3.5 drug-related problems at the time of hospital discharge. The most common problems were noncompliance, the need for additional drug therapy, and drug treatment that was not indicated.

The clinical impact of adverse drug-related complications is undoubtedly of first and foremost concern, but the economic impact of these problems cannot be ignored. Adverse drug events (ADEs) have been found to result in an additional average length of stay of 2.2 days for hospitalized patients; this increase was even higher for preventable ADEs (4.6 days). Furthermore, ADEs have been found to result in excess costs of $3,244 USD for hospitalized patients ($5,857 for preventable ADEs) (Bates et al. 1997). Drug-related morbidity (DRM) and mortality is estimated to cost the US healthcare system $177.4 billion US each year (Ernst and Grizzle 2001), and preventable drug-related morbidity and mortality in older adults costs the Canadian healthcare system $11 billion each year (Kidney and MacKinnon 2001).

Given the scope of the problem, it is understandable that public attention has been drawn to the issue of medication safety. Patients often express concern over the safety of the medication use system. Sixty-one percent of people surveyed by the American Society of Health-System Pharmacists (ASHP) said they were "very concerned" about "being given the wrong medicine" when asked about concerns related to receiving care in a hospital (ASHP 1999). In a sample of 920 employees and retirees of the University of Michigan, 18% reported having experienced a medication error at sometime during their lifetime (Nau and Erikson 2005). The results of the 2002 Commonwealth Fund Survey found that 20% of Canadians surveyed said a medical mistake had been made in their own care, while 11% said they had been given the wrong medication at one time or another (Schoen et al. 2003). Furthermore, 60% of those who had experienced a medical mistake believe it had a serious impact on their health (Blendon et al. 2003).

Despite the increase in research and increased public attention in medication safety, much confusion remains about this topic. With the rapid growth in the number of studies that have focused on methods to improve the medication use system, there is some confusion over how best to optimize medication safety, given the limited number of resources available to healthcare decision makers and professionals and the wide variety of possible intervention strategies proposed in the literature. The purpose of this paper is to review components of the medication use process and offer suggestions for transforming it into a safer system. Prevention strategies are suggested for improving medication use at each stage of the system.

The Medication Use Process

The Medication Use Process is a model that describes the typical course of action related to drug therapy in ambulatory care. It begins when a patient enters the healthcare system after recognizing some health-related problem. After assessing the patient's concern and forming a clinical impression, a treatment plan is developed and implemented in two steps. When the treatment plan involves medications, the medication is prescribed and dispensed with advice to the patient. Next, the patient consumes or administers the plan (medication) and typically exits the healthcare system (Hepler and Grainger-Rousseau 1995).

Because medication safety has become a significant concern of patients and healthcare professionals alike, it is important to highlight the connections between the medication use process and the five stages — ordering, transcription and verification, dispensing, medication administration, and consumption — of the delivery of medicines.

Ordering cannot occur until after the patient has entered the healthcare system and the physician or other healthcare provider has adequately assessed the patient. Once this has occurred, the healthcare provider is able to develop a therapeutic plan and can subsequently order any needed medications by writing a prescription for the patient. The remaining stages in the delivery of medications all coincide with implementation of the therapeutic plan. Transcription, verification and dispensing of the medication from the pharmacy occur during the first stage of plan implementation; administration and consumption of the medication occur during the final stage of plan administration.

Before any improvements related to medication safety can be suggested, it is important to understand where in the delivery of medications problems occur. Leape et al. (1995) performed a systems analysis of ADEs among a sample of hospitalized patients and found that the majority of events occurred during the ordering and administration stages (39% and 38% respectively). Twelve percent of events occurred during the transcription and verification stage, and 11% of events occurred during the pharmacy dispensing stage. Lack of knowledge about the drug and lack of information about the patient were the two most common attributable causes to ADEs identified in this study. Bates et al. (1995b), in their analysis of the incidence of both actual and potential ADEs, found similar results. Of the actual ADEs that were considered preventable, 49% occurred during the ordering stage, 11% occurred during the transcription stage, 14% occurred during the dispensing stage and 26% occurred during the administration stage. While room for improvement obviously exists at every stage in the delivery of medications, perhaps the most significant effects would be felt if resources were focused at improving processes used during the ordering and administration stages.

Perhaps the most rudimentary way to improve medication safety is to transform the medication use *process* into a medication use *system*. The fundamental component lacking from the process, as described previously, is a feedback loop between the last stage of plan implementation (consuming the medication) and the first stage of plan implementation (developing the therapeutic plan). The addition of a feedback loop at this stage of the process allows for ongoing monitoring of patient care and progress rather than simply allowing the patient to exit the healthcare system after receiving needed care. While the rate of ADEs in inpatient settings is shocking, evidence exists to suggest the rate of adverse events is four times higher out in the community (Gandhi et al. 2003). Therefore, a feedback loop that encourages patient monitoring turns the *process* into a *system* and is the first step in improving medication safety.

Strategies to Improve the Medication Use System

While transforming the medication use process into a system is the first step, there are many opportunities to enhance safety in all stages in the medication use system. The overall goal of

doing so is to optimize patient outcomes. There are strategies that can be used at each step in the delivery of medications, as well as strategies that focus on system-wide changes.

Ordering

Given the high proportion of injuries that occur at this stage in the process, much work has focused on the development of prevention strategies. In general, ordering is more likely to be appropriate if there is a clear therapeutic plan with objectives that are understood by the physician, the patient and the pharmacist (Hepler and Grainger-Rousseau 1995; MacKinnon 2002a).

One of the most frequently recommended approaches to preventing problems associated with this stage is computerized physician order entry (COPE) (Bates et al. 1995a; Cullen et al. 2000; Gurwitz and Rochon 2002; Conference Proceedings 1995; Anderson and Webster 2001; Bobb et al. 2004). The structured, ordered input that allows the physician to select from a menu of options is designed to reduce dosage errors by only offering those that are appropriate. The program can be linked to guidelines for the use of drugs and can provide prompts to check on such things as drug allergies or potential drug-drug interactions. Moreover, this technology eliminates the need for transcription, thus reducing the possibility of errors at this stage in the medication use process. Despite these advantages, widespread adoption will be limited by the cost of implementation and the willingness of physicians and/or organizations to adopt this technology. There is also evidence to suggest that the introduction of the technology introduces new opportunities for error. In their review of the CPOE system at a tertiary-care teaching hospital, Koppel et al. (2005a) identified 22 types of medication error risks that were facilitated by the use of CPOE (e.g., delay in information on drug allergies). The authors acknowledge that there have been technological advances to the system since the data were collected, but they emphasize that users must continually seek to improve the system (Koppel et al., 2005b). Although computerized order entry will not eliminate all errors, and may even result in different types of errors, the current evidence indicates that it can reduce the rates of medication errors (Kaushal et al. 2003; Oren et al. 2003). Oren et al. (2003) caution that in addition to their contribution to error reduction, technological advances should also be evaluated in terms of their appropriate application and impact on patient outcomes.

Another technological approach to improving the process at the ordering stage involves the use of computerized pharmacy systems (Bates 1996). The systems are designed to alert the pharmacist to potential problems associated with a prescription, although it does not obviate the need for the pharmacist to have direct contact with either the physician and/or the patient to discuss the best prescribing solution. In healthcare facilities without this technology, this task can be performed by manual review of orders by the pharmacist. It is important that the electronic system flags (e.g., to warn of drug-drug interactions) are appropriately sensitive and clinically important, otherwise there is a risk that the flags will be ignored (Kaushal et al. 2003), thus limiting the effectiveness of the intervention (Galanter et al. 2005). Clinical decision support technologies are most effective when integrated with CPOE systems and clinician workflow (Galanter et al. 2005; Garg et al. 2005).

Academic detailing refers to targeted physician education, usually conducted by a pharmacist. The thrust of this approach is to change physician-prescribing practices by providing objective information on specific medications. This can be used in conjunction with computer physician order entry, as the system flags can reinforce information provided in the academic detailing, to reduce problems at the ordering stage of medication delivery (Bates 1996).

Transcription & Verification

The use of physician order entry eliminates this stage of the process; however, it is not available to all facilities and providers. Ragan et al. (2005) report that only 7% of US hospitals have adopted the technology, so it is also necessary to consider simpler, nontechnological approaches to reducing problems at this stage. The age-old recommendation of writing legibly for written orders and speaking clearly for verbal orders is still applicable (Conference Proceedings 1995). As well, ensuring sufficient and well-trained personnel in a work environment that minimizes distraction will provide optimal conditions for minimizing problems at the transcription and verification stage of the process (Zellmer 1993). Another simple and economical approach is the avoidance of abbreviations or the use of standard abbreviations (Conference Proceedings 1995; Bates 1996).

Dispensing

Several advances have successfully been applied at this stage of the medication use process. Perhaps most notable is the use of the unit dose. Medications are dispensed in either a single unit or a unit dose in a ready to administer format. Usually no more than 24 hours of medication are dispensed at one time. Several studies have demonstrated that the use of the unit dose system reduced medication error, and in one study it did so by more than 80% (Simborg and Derewicz 1975; O'Brodovich and Rappaport 1991). Nurses have indicated a strong preference for the system, as it also results in some time saving for drug administration (O'Brodovich and Rappaport 1991; Gaucher and Greer 1992).

Pharmacy control systems play a role in the prevention of medication misadventures (Conference Proceedings 1995). Automated dispensing systems ensure that medications are only given to patients who should receive them, and the system

maintains a record of what has been given, to whom and when it was given. These systems are linked with inventory and reduce the potential for error (Conference Proceedings 1995; Bates 1996; Oren 2003). The packaging and labeling of products are other important elements that can be modified to reduce error (Conference Proceedings 1995). One of the major impediments to the use of automated dispensing systems is the cost.

A nontechnological approach to minimizing problems associated with dispensing medications is for the pharmacist to exercise care in making calculations and have a second person check the accuracy of the calculations. A work environment that has limited distractions and adequate lighting and space can also contribute to the prevention of calculation errors (Conference Proceedings 1995).

… including providers, patients, leaders, purchasers, industry and regulatory bodies, professional bodies, licensing and accreditation bodies …

Administration

This stage of the process represents one of the most high-risk activities for nurses in healthcare facilities (Anderson and Webster 2001; Preston 2004). As in other steps in the process, the work environment and availability of adequate personnel are important factors in the safety of the system (Zellmer 1993; Conference Proceedings 1995). Technological approaches such as unit dosing and bar coding medications can also reduce the potential for error (Conference Proceedings 1995; Bates 1996; Oren 2003). Bar coding technology has also demonstrated time-savings in work processes and fewer system errors (Oren 2003; Ragan 2005). In preliminary estimates following the introduction of bar coding at Brigham and Women's Hospital in Boston, drug errors have been reduced by 50 percent, or approximately 20 adverse drug events per day (Wright 2005). There are several factors that limit the adoption of bar coding technology, including cost and potential changes to work-flow patterns. There remain inconsistencies in industry standards for packaging and coding of products (Oren 2003; Ragan 2005). However, it is anticipated that the problem will be alleviated in the United States, at least, with the introduction of FDA regulations requiring the inclusion of bar codes on most prescription drugs (Ragan 2005).

Consumption

One of the most critical strategies to ensure that patients are using medications as prescribed is by ensuring that they have adequate education from the pharmacist (Conference Proceedings 1995). This is enhanced when there is a collaborative relationship between the prescriber and the pharmacist, as well as direct access to the pharmacist by the patient (Gurwitz and Rochon 2002). Also, ongoing communication with patients once they leave the healthcare facility, whether it is a hospital, physician's office, or outpatient clinic, is essential to prevent problems with medication use from happening out in the community. The introduction of medication reconciliation processes has been promoted as a mechanism to prevent medication errors that occur at transitions of care (Barnsteiner 2005).

System-Wide Approaches

In addition to the specific strategies described previously, broader, system-level approaches to improving safety have been widely recommended (Baker et al. 2004; Hepler and Strand 1990; Hepler and Grainger-Rousseau 1995; Cullen et al. 2000; Gurwitz and Rochon 2002; Conference Proceedings 1995; Anderson and Webster 2001; Bates 1996; Leape et al. 2002; MacKinnon 2002b). The healthcare system is comprised of a multitude of individuals. Cohen (2002) makes a cogent argument that all members of the system, including providers, patients, leaders, purchasers, industry and regulatory bodies, professional bodies, licensing and accreditation bodies share accountability for safety. In addition, the academic institutions that train healthcare professionals also need to assume part of the shared accountability and to teach about patient safety.

The routine addition of ongoing monitoring to the medication use process through the provision of pharmaceutical care is a fundamental element in optimizing patient outcomes (Hepler and Grainger-Rousseau 1995; MacKinnon 2002 a; Conference Proceedings 1995). However, there are currently few financial incentives for pharmacists to do this. Routine monitoring can be more readily achieved through ongoing collaboration amongst a multidisciplinary team of healthcare providers, including physicians, pharmacists and nurses (Hepler and Grainer-Rousseau 1995; Gurwitz and Rochon 2002). This approach can lead to the provision of care that is less fragmented, particularly at the transitions from one setting to another (MacKinnon 2002a). This so-called "seamless care" greatly enhances the quality of care, and ultimately health outcomes for patients. Pharmacists have a significant role to play in the process. Several authors have suggested that pharmacists need to become more visible members of the healthcare team (Zellmer 1993; Hepler and Grainger-Rousseau 1995; Conference Proceedings 1995; Cohen 2002). Another strategy related to ongoing monitoring is the development of reporting systems. The reports can be used to understand those factors that contribute to adverse events so that specific interventions can be put in place to prevent them from occurring again (Conference Proceedings 1995; Anderson and Webster 2001).

Attention must also be given to the work environment in healthcare (Zellmer 1993; Conference Proceedings 1995). There have been severe fiscal restraints throughout the healthcare system in the last decade or longer. Inadequate personnel and insufficient time for training have the potential to weaken system efficiency, thus contributing to the potential for adverse events. The success of other interventions will be limited if these factors are ignored.

A plethora of technological advances have demonstrated that there is potential to improve safety in all steps in the system. While not all of these technologies are in use throughout the system, nor have they all been comprehensively evaluated, they nonetheless offer direction for future development and implementation.

Decision Criteria for Allocating Resources

Resources in healthcare are focused on the provision of diagnostic and therapeutic care for patients. Difficult decisions must be made about how to allocate increasingly scarce resources. And while most would agree that improving patient safety is a laudable goal, there may be less agreement on where to find the resources to achieve this. Runyan (1998) suggests a number of decision criteria that can be applied in the decision-making process for injury prevention that can also be applied in the context of patient safety. The criteria include whether or not the intervention works (effectiveness) or is feasible to implement, as well as its cost. Decision-makers also need to consider if the strategy can be implemented in an equitable manner. For example, only some hospitals within a jurisdiction may be able to afford the expense of the physician computer order entry system. Consideration must also be given to the preferences of stakeholders and whether or not use of the strategy will have an impact on their freedom. Using the same example, some physicians may not want to use computer order entry because they may perceive it as limiting their freedom to prescribe the way they would like to. These criteria can be systematically applied to the decision-making process and they make the values that have guided the process more transparent (Conference Proceedings 1995; Anderson and Webster 2001; Runyan 1998).

Conclusions

The medication use system is highly complex. It faces increasing challenges with an aging population, direct-to-consumer advertising, the introduction of new drugs, technologies and over-the-counter products (Cohen 2002). There is a growing understanding of the problem. However, judging from the limited actions of patients, providers and decision-makers, more needs to be done to raise awareness of the magnitude of the problem and its costs.

There are many approaches to the problem, but there seems to be consensus that a systems approach will be far more effective than trying to change the behaviour of individuals. The greatest potential for change within the medication use system is to ensure that each patient has a clear therapeutic plan that is understood by the patient, pharmacist and physician. Finally, there should be a commitment and mechanisms in place for ongoing monitoring of the patient.

References

American Society of Health-System Pharmacists (ASHP). 1999. "Patient Concerns National Survey." Bethseda, MD: American Society of Health-System Pharmacists. http://www.ashp.org/pr/survey.cfm

Anderson D.J. and C.S. Webster. 2001. "A Systems Approach to the Reduction of Medication Error on the Hospital Ward." *J. Adv. Nurs. 35: 34–41.*

Baker G.R., P.G. Norton, V. Flintoft , R. Blais, A. Brown and J. Cox et al. 2004. "The Canadian Adverse Events Study: The Incidence of Adverse Events Among Hospital Patients in Canada." *CMAJ* 170: 1678–86.

Barnsteiner J.H. 2005. "Medication Reconciliation: Transfer of Medication Information Across Settings — Keeping It Free From Error." *AJN March* (Suppl.): 31–36.

Bates D.W., D.L. Boyle, M.B. Vander Vliet, J. Schneider and L.L. Leape. 1995. "Relationship Between Medication Errors and Adverse Drug Events." *J. Gen. Intern. Med.* 10: 199–205.

Bates D.W., D.J. Cullen, N. Laird, L.A. Petersen, S.D. Small and D. Servi et al. 1995. "Incidence of Adverse Drug Events and Potential Adverse Drug Events: Implications for Prevention. ADE Prevention Study Group." *JAMA* 274: 29–34.

Bates D.W. 1996. "Medication Errors: How Common Are They and What Can Be Done to Prevent Them?" *Drug Safety* 15: 303–10.

Bates D.W., N. Spell, D.J. Cullen, E. Burdick, N. Laird and L.A. Petersen et al. 1997. "The Costs of Adverse Drug Events in Hospitalized Patients. Adverse Drug Events Prevention Study Group." *JAMA* 277: 307–11.

Blendon R.J., C. Schoen , C. DesRoches, R. Osborn and K. Zapert. 2003. "Common Concerns Amid Diverse Systems: Health Care Experiences in Five Countries." *Health Aff.* 22: 106–21.

Bobb A., K. Gleason, M. Husch, J. Feinglass, P.R. Yarnold and G.A. Noskin. 2004. "The Epidemiology of Prescribing Errors: The Potential Impact of Computerized Prescriber Order Entry." *Arch. Intern. Med.* 164: 785–92.

Cohen M.R. "Prescription for Safety in Health Care." 2002. *Am. J. Health System Pharm.* 59: 1511–17.

Conference Proceedings. 1995. "Understanding and Preventing Drug Misadventures." *Am. J. Health System Pharm.* 52: 369–73.

Cullen D.J., D.W. Bates and L.L. Leape. 2000. "Prevention of Adverse Drug Events: A Decade of Progress in Patient Safety." *J. Clin. Anesthesia* 12: 600–14.

Ernst F.R. and A.J. Grizzle. 2001. "Drug-related Morbidity and Mortality: Updating the Cost-of-illness Model." 2001. *J. Am. Pharm. Assoc.* 41: 192–9.

Forster A.J., H.D. Clark, A. Menard, N. Dupuis, R. Chernish and N. Chandok et al. 2004. "Adverse Events Among Medical Patients After Discharge from Hospital." *CMAJ* 170: 345–49.

Galanter W.L., R.J. Didomenico and A Polikaitis. 2005. "A Trial of Automated Decision Support Alerts for Contraindicated Medications

Using Computerized Physician Order Entry." *J. Am. Med. Inform. Assoc*. 123: 269–74.

Gandhi T.K., S.N. Weingart, J. Borus , A.C. Seger, J. Peterson and E. Burdick et al. 2003. "Adverse Drug Events in Ambulatory Care." *N. Engl. J. Med.* 348: 1556–64.

Garg A.X., N.K.J. Adhikari, H. McDonald, M.P. Rosas-Arellano, P.J. Devereaux and J. Beyene et al. 2005. "Effects of Computerized Clinical Decision Support Systems on Practitioner Performance and Patient Outcomes: A Systematic Review." *JAMA* 293: 1223–38.

Gaucher M. and M. Greer. 1992. "A Nursing Evaluation of Unit Dose and Computerized Medication Administration Records." 1992. *Can. J. Hosp. Pharm*.;45: 145–50.

Gurwitz J.H. and P. Rochon. 2002. "Improving the Quality of Medication Use in Elderly Patients: A Not-so-simple Prescription." *Arch. Intern. Med.* 162: 1670–72.

Hepler C.D. and L.M. Strand. 1990. "Opportunities and Responsibilities in Pharmaceutical Care." 1990. *Am. J. Hosp. Pharm*. 47: 533–43.

Hepler C.D. and T.J. Grainger-Rousseau. 1995. "Pharmaceutical Care Versus Traditional Treatment: Is There a Difference?" *Drugs* 49: 1–10.

Kaushal R., K.G. Shojania and D.W. Bates. 2003. "Effects of Computerized Physician Order Entry and Clinical Decision Support Systems on Medication Safety: A Systematic Review." *Arch. Intern. Med.* 163: 1409–16.

Kidney T. and N.J. MacKinnon. 2001. "Preventable Drug-related Morbidity and Mortality in Older Adults: A Canadian Cost-of-illness Model." 2001. *Geriatrics Today* 4: 120.

Koppel R., J.P. Metlay, A. Cohen, B. Abaluck, A.R. Localia, S.E. Kimmel and B.L. Strom. 2005. "Role of Computerized Physician Order Entry Systems in Facilitating Medication Errors." *JAMA* 293: 1197–1203.

Koppel R., J.P. Metlay, A. Cohen, B. Abaluck, A.R. Localia, S.E. Kimmel and B.L. Strom. 2005. "Computerized Physician Order Entry Systems and Medication Errors." (Reply) *JAMA* 294: 180–81.

Lazarou J., B.H. Pomeranz and P.N. Corey. 1998. "Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-Analysis of Prospective Studies." *JAMA* 279: 1200–5.

Leape L.L., D.W. Bates, D.J. Cullen, J.W. Cooper, H.J. Demonaco and T. Gallivan et al. 1995. "Systems Analysis of Adverse Drug Events." ADE Prevention Study Group. *JAMA* 274: 35–43.

Leape L.L., D.M. Berwick and D.W. Bates. 2002. "What Practices Will Most Improve Safety?: Evidence-based Medicine Meets Patient Safety." *JAMA* 288: 501–7.

30. MacKinnon N.J. 2005. "Improving the Management of Medication Use in Older Adults." *Geriatrics Today* 5: 63–5.

MacKinnon N.J. 2002. "Early Warning: How Vigilant Pharmacists Can Prevent Drug-related Morbidity in Seniors." *Pharm. Pract.* 18: 40–4.

Michel P., J. L. Quenon, A. M. de Sarasqueta and O. Scemama. 2004. "Comparison of Three Methods for Estimating Rates of Adverse Events and Rates of Preventable Adverse Events in Acute Care Hospitals." *BMJ* 328: 199.

Nau D.P. and S.R. Erikson. 2005. "Medication Safety: Patients' Experiences, Beliefs, and Behaviours." *J. Am. Pharm. Assoc.* 45: 452–57.

Nickerson A., N.J. MacKinnon, N. Roberts and L. Saulnier. (In press.) "Drug-therapy Problems, Inconsistencies and Omissions Identified During a Medication Reconciliation and Seamless Care Service." *Healthcare Quarterly.*

O'Brodovich M. and P. Rappaport. 1991. "A Study Pre and Post Unit Dose Conversion in a Pediatric Hospital." *Can. J Hosp. Pharm*. 44: 5–15.

Oren E., E.R. Shaffer and B.J. Guglielmo. 2003. "Impact of Emerging Technologies on Medication Errors and Adverse Drug Events." *Am. J. Health-Syst. Pharm*. 60: 1447–58.

Preston R.M. 2004. "Drug Errors and Patient Safety: The Need for a Change in Practice." Br. J. Nurs, 13: 72–8.

Ragan R., J. Bond, K. Major, T. Kingsford, L. Eidem and J.C. Garrelts. 2005. "Improved Control of Medication Use with an Integrated Bar-code-packaging and Distribution System." *Am. J. Health-Syst. Pharm.* 62: 1075–79.

Runyan C.W. 1998. "Using the Haddon Matrix: Introducing the Third Dimension." *Inj. Prev.* 4: 302–7.

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

Simborg D.W. and H.J. Derewicz. 1975. "A Highly Automated Hospital Medication System: Five Years' Experience and Evaluation." *Ann. Intern. Med.* 83: 342–46.

Strand L.M., R.J. Cipolle, P.C. Morley, R. Ramsey, G.D. Lamsam. 1990. "Drug-related Problems: Their Structure and Function." *DICP Ann. Pharmacother* 24: 1093–97.

Wright A.A. and I.T. Katz. 2005. "Bar Coding for Patient Safety." *NEJM* 5(353): 329–31.

Zellmer W.A. 1993. "Medication Error Versus Medication Misadventure — What's in a Name?" *Am. J. Hosp. Pharm*. 50: 315–18.

About the Authors

Stacy Ackroyd-Stolarz is a PhD student in the Interdisciplinary PhD program and a lecturer in the Department of Emergency Medicine at Dalhousie University. Her research interests include the contribution of prescription medications to the risk of fall-related injuries in older adults.

Nicole Hartnell is a PhD candidate in the Interdisciplinary PhD program at Dalhousie University. Mrs. Hartnell's research interests are centered on medication error reporting.

Neil J. MacKinnon is the Associate Director for Research and Associate Professor in the College of Pharmacy at Dalhousie University. He has led several studies on medication safety and edited a book published in 2003 by the Canadian Pharmacists Association on seamless care.

The authors have no declared conflicts of interest.

Corresponding Author: Stacy Ackroyd-Stolarz, MSc, Interdisciplinary PhD Student, Dalhousie University, Department of Emergency Medicine, 351 Bethune Building, VG Site, 1278 Tower Road, Halifax, NS B3H 2Y9, Phone: (902) 473-3565, Fax: (902) 494-1625, E-mail: Stacy.Ackroyd@dal.ca

Drug-Therapy Problems, Inconsistencies and Omissions Identified During a Medication Reconciliation and Seamless Care Service

Ann Nickerson, Neil J. MacKinnon, Nancy Roberts and Lauza Saulnier

Abstract

Seamless care is the desirable continuity of care delivered to a patient in the healthcare system across the spectrum of caregivers and their environments. Medication Reconciliation is one component of seamless pharmaceutical care. A randomized controlled trial, carried out over nine months with a six-month follow-up period, investigated the impact of a pharmacist-directed seamless care service. Intervention patients admitted to one of two general medicine units were subjected to a comprehensive seamless care discharge process as they were discharged from a regional, academically affiliated hospital in Moncton, NB. The number, type and potential clinical impact of drug-therapy problems for seamless monitoring (DTPsm) and drug-therapy inconsistencies and omissions (DTIOs) in hospital discharge medications were measured. A total of 253 patients, with 134 patients in the intervention group and 119 in the control group, completed the study. An average of 3.59 DTPsm per intervention patient, with 72.1% of these being scored as having a significant or very significant clinical impact level, were communicated to community pharmacists. Ninety-nine DTIOs were identified and resolved in intervention patients before discharge. A retrospective medical chart review demonstrated that the intervention resolved almost all DTIOs. In conclusion, a pharmacist-directed seamless care service had a significant impact on drug-related clinical outcomes and processes of care.

Introduction

In recent years, the average hospital length-of-stay has been shortened and, consequently, patients are being discharged into the community setting and long-term care facilities with a higher level of acuity. Regrettably, in most healthcare models, an effective means of communicating patients' drug therapies upon discharge from the hospital to the community setting has not been established across the continuum of care. This is a critical omission, as during hospitalization drugs may be added or discontinued from a patient's drug regime or dosing may be altered. It has been documented that following hospitalization, up to 40% of medications used at admission are not continued at discharge and up to 45% of medications prescribed at discharge are medications first prescribed to the patient during their hospitalization (Beers et al. 1989). To address deficiencies in these areas, cooperative systems are needed *between* settings (e.g., community and hospital care).

Although the exact terminology may vary, seamless care is a concept that has been widely viewed as being a fundamental component in the optimal delivery of healthcare services. In the profession of pharmacy, *seamless care* has been defined as "... the desirable continuity of care delivered to a patient in the health care system across the spectrum of caregivers and their environments. Pharmacy care is carried out without interrup-

tion such that when one pharmacist ceases to be responsible for the patient's care, another pharmacist or healthcare professional accepts responsibility for the patient's care" (Canadian Society of Hospital Pharmacists and Canadian Pharmacists Association 1998). Seamless care has been argued to be one of the seven most important strategies to improve the medication-use system (MacKinnon 2001). The Canadian Society of Hospital Pharmacists (CSHP) and Canadian Pharmacists Association (CPhA) formed a joint task force on seamless care, and two national workshops were held in 1998 and 2000. In 2003, a "how-to" book on this subject, *Seamless Care: A Pharmacist's Guide to Providing Continuous Care Programs,* was published by CPhA (MacKinnon 2003). In 2004, CSHP released an official statement on seamless care (Canadian Society of Hospital Pharmacists 2004).

Recently, much activity has focused on *medication reconciliation,* a subset of seamless pharmaceutical care. These activities include the adoption of medication reconciliation services in the 2005 Canadian Council on Health Services Accreditation (CCHSA) patient safety goals (Canadian Council on Health Services Accreditation 2004) and in the *Safer Healthcare Now!* campaign of the Canadian Patient Safety Institute (CPSI) (Canadian Patient Safety Institute 2005). "Medication reconciliation is a process which ensures the collection and communication of accurate client/patient medication information. The ultimate goal of medication reconciliation is to facilitate continuity of pharmaceutical care for patients/clients at admission/beginning of service and or at discharge/transition/end of service (Canadian Council on Health Services Accreditation 2005). Medication reconciliation involves clarifying medications a patient is taking (including non-prescription medications) and comparing actual medications taken with records (Institute for Healthcare Improvement 2004). Omissions and inconsistencies found through medication reconciliation will be communicated to necessary healthcare professionals and result in fewer medication errors. Incorporating medication reconciliation into hospital practice is a crucial step towards improving the safety of the medication-use system at transitions of care.

While seamless care, including medication reconciliation, is widely accepted in healthcare at a conceptual level, implementation still has yet to occur in a majority of hospitals to date. Fortunately, this is starting to change with the activity surrounding medication reconciliation (Bussieres 2004). Still, at this time, there is little Canadian data to support the value of these services. The purpose of this study was to evaluate the impact of a pharmacist-directed seamless care service on drug-related clinical outcomes and processes of care.

Methods

Study Design

This study was a randomized controlled trial, carried out over nine months with a six-month follow-up period. The study was conducted at The Moncton Hospital, South-East Health Regional Health Authority, Moncton, NB. The Moncton Hospital is a 381-bed regional hospital that provides tertiary care services. Approval was granted by the hospital's research review committee prior to the start of the study.

Study Objectives

While the entire study measured the impact of this pharmacist-directed seamless care service on economic, clinical and humanistic outcomes and processes of care, this present paper focuses solely on drug-related clinical outcomes and processes of care. The randomized controlled study design was created to allow for comparison of the control and intervention groups on the economic and humanistic outcomes.

The specific study objectives were to determine: (1) frequency and potential clinical impact of drug-therapy problems for seamless monitoring (DTPsm) as identified by a seamless care pharmacist at the time of discharge and (2) frequency and potential clinical impact of drug therapy inconsistencies and omissions (DTIOs) in hospital discharge medication orders as identified by the seamless care pharmacist as part of the medication reconciliation process.

Study Population

Patients admitted to one of two family practice units from September 2000 to June 2001 were screened to participate in the study. The inclusion criteria were: family practice patient discharged from 3600 or 4200 (family practice patient units), discharged between 8h00 and 14h00, not discharged to another hospital, prescribed at least one prescription medication at discharge, completion of informed consent form, patient's community pharmacy had signed study participation agreement, and no previous enrollment in the study from a prior admission. Patients were excluded from the study if they were not able to answer the questions needed to complete the study (i.e., the surveys) or if they would not be available for follow-up after their discharge. Once consent was given and a patient was enrolled in the study, the patient was then randomized to the intervention or control group using computer generated random numbers produced by the hospital's Information Technology services. The physician and nursing staff were blinded to the patients' study group allocation to ensure that all patients received the same standard of care while hospitalized. The pharmacist was blinded to the allocation of the patients until the patient intervention at discharge took place.

Study Intervention

At the time of discharge, the patient care unit secretary contacted a designated pharmacy technician to determine if the patient was allocated to the intervention or control group.

Patients in the intervention group were subject to an intervention conducted by a clinical pharmacist (hereafter referred to as the seamless care pharmacist) at the time of discharge, whereas patients in the control group received the hospital's standard of care at discharge. The standard of care at this facility is for a nurse on the unit to perform the discharge counselling and manually transcribe the discharge notes from the patient's medical chart.

Within the intervention group, the seamless care pharmacist carried out the medication reconciliation process by reviewing discharge prescriptions (as written by a physician) and compared these with the Medication Administration Record (MAR) and the patient's medical chart to identify any discrepancies in the discharge orders. This pharmacist also reviewed the intervention patient's drug regime at discharge as part of a comprehensive pharmaceutical care work-up. The pharmacist also identified problems with drug therapy and communicated these to the patient's community pharmacy, hospital staff and family physician(s). Additionally, the seamless care pharmacist performed the medication discharge counselling to all intervention patients and provided them with a medication compliance chart

Drug-Therapy Problems for Seamless Monitoring (DTPsm)

A drug-therapy (related) problem (DTP) can be defined as an event or circumstance involving drug treatment that actually or potentially interferes with the patient experiencing an optimum outcome of medical care (Hepler and Strand 1990). The DTPs were classified into one of the categories previously established by Strand and colleagues (Strand et al. 1990). A research assistant entered all intervention patients' information into the Seamless Solutions Software® (Version 1.1, Seamless Solutions Corp., Winnipeg, Canada), and the data entry was verified by the seamless care pharmacist. Using the software, the pharmacist generated a list of the DTPs for each patient. To facilitate the community pharmacist in monitoring the patient's progress, each DTP was individually supplemented with additional relevant information such as laboratory findings, diagnosis and general patient notes. This provided the community pharmacist with a more complete picture of the patient's drug therapy and medical conditions. With this additional information provided to the community pharmacist for follow-up, the DTP was termed a *Drug Therapy Problem for Seamless Monitoring* (DTPsm) to better reflect its true composition. The complete list of DTPsm was generated for each patient and faxed to their community pharmacist and copied to the family physician at the time of discharge.

All of the DTPsm were scored for their potential clinical impact according to the Intervention Ranking system (Hatoum et al. 1988). Other researchers have used this scale to evaluate the clinical impact of pharmacists' interventions (Wernick et al. 1996). The Intervention Ranking system has six categories to rank the potential impact of the pharmacist's intervention. The scale is Likert-type and ranges from 1 (*adverse significance*) to 6 (*extremely significant*). The seamless care pharmacist and a second clinical pharmacist independently ranked the DTPsm – the former at the time of discharge and the latter after the patient was discharged. Consensus was reached through discussion when any difference in assignment arose.

Drug-Therapy Inconsistencies and Omissions (DTIOs) at the Time of Discharge

The seamless care pharmacist also carried out a medication reconciliation process by reviewing the intervention patient's discharge medication list as prepared by the physician and/or hardcopies of discharge prescriptions and comparing these with the hospital's computerized MAR for the day of discharge, and progress and consultation notes. Variations between the discharge medication list and the MAR and patient's medical chart were identified and recorded as either a drug-therapy inconsistency or omission. An inconsistency was defined as an alteration in a drug order component occurring between the MAR and discharge medication list. An omission was defined as a deletion of a drug order component occurring between the MAR and the discharge medication list. All variations were further classified into sub-groupings according to the nature of the variation. The sub-groupings are: dose, drug, duration, frequency, and legal. These sub-groupings were chosen based on a previous pilot project (Breau and Nickerson 1998). All DTIOs were completely resolved by the seamless care pharmacist in consultation with the patient's discharge physician before the patient left the hospital. The physician's opinion was considered the gold standard by which it was determined whether a DTIO had actually occurred. Any communication between the seamless care pharmacist and the patient's discharge physician was documented on the patient's medical chart. Each DTIO was also ranked for its potential clinical impact with the same methods (or tool) used for DTPsm.

DTIOs in Intervention and Control Patients – Retrospective Chart Review

The seamless care pharmacist performed a retrospective review of the control patients' (n=119) hospital discharge medication lists and hospital medical charts. The purpose of reviewing the control patients' files retrospectively was to determine their rates of DTIOs and to compare this with the rate in the intervention group. This was done retrospectively as it was viewed that a prospective identification of DTIOs in the control patients that would not be resolved would be unethical. In the retrospective review, the discharge medication list was compared with the patient's medical chart and the MAR at the time of discharge.

Discrepancies between the chart/MAR and the discharge medication list were identified and recorded as either an inconsistency or an omission. DTIOs for this review were also defined in the same manner as for the prospective identification of DTIOs.

A second clinical pharmacist performed a retrospective chart review of the intervention patients. This was done to serve as a validity check that the seamless care pharmacist had properly resolved the DTIOs that were identified and that no DTIOs were missed during the study intervention phase. This process was performed in the same manner as the retrospective chart review of the control patients described above. Since this was a very time-intensive process, it was felt that every sixth chart would be reviewed (n=28), and if many problems were identified with the seamless care pharmacist's interventions, then all the remaining charts would be reviewed.

Statistical Analysis

The intervention patients' drug-related information was entered into Seamless Solutions Software®. All additional data for both the intervention and control patients were compiled in a spreadsheet using Microsoft Windows Excel 2000 (Microsoft Corporation, Redmond, WA). Data analysis was performed using SPSS Version 9.0 (SPSS Inc., Chicago, IL) and JMP Version 4.0 (SAS Institute Inc., Cary, NC). To determine statistical significance, statistical evaluation was performed with mean variables and chi-square tests. A p value of less than 0.05 was considered significant.

Results

Over the nine-month enrollment period, 944 patients were screened for the study, with a total of 253 patients meeting the inclusion criteria and completing the study. One hundred thirty-four patients were randomized to the intervention group and 119 to the control group. The demographic characteristics of the two groups are contained in **Table 1**. Even though the two groups were randomized, the intervention group had a statistically significant greater number of home medication changes, and their mean age, number of medications upon admission and number of co-morbidi-

Table 1. Demographic Characteristics of the Intervention and Control Patients

CHARACTERISTIC	INTERVENTION (N=134)	CONTROL (N=119)	STATISTICS +
Gender Male Female	 42 (31%) 92 (69%)	 38 (32%) 81 (68%)	 NS NS
Mean age (years)	67.3	61.8	P=0.064
Mean hospital length-of-stay (days)	8.05	8.03	NS
Mean number of prescriptions at hospital admission	6.94	6.03	P=0.066
Mean number of prescriptions at hospital discharge	7.88	7.07	NS
Mean number of home medication changes	0.73	0.48	P=0.02
Mean number of co-morbidities	3.45	2.92	P=0.056

+ Chi-square tests

Table 2. Drug-Therapy Problems for Seamless Monitoring (DTPsm) Identified in Intervention Patients

TYPE OF DRUG -THERAPY PROBLEMS FOR SEAMLESS MONITORING	NUMBER OF EVENTS	PERCENTAGE OF ALL EVENTS
Needs additional drug therapy	160	33.3
Compliance (Not receiving drug)	103	21.4
Unnecessary drug therapy	59	12.3
Dosage too low	56	11.6
Wrong drug	37	7.7
Dosage too high	36	7.5
Adverse drug reaction	30	6.2

Table 3. DTPsm and the Potential Clinical Impact of the Pharmacist's Intervention

POTENTIAL CLINICAL IMPACT	NUMBER OF DTPSM IDENTIFIED	PERCENTAGE OF ALL DTPSM
Adverse significance	0	0
Not significant	3	0.6
Somewhat significant	131	27.2
Significant	272	56.6
Very significant	75	15.6
Extremely significant	0	0

ties were marginally significantly greater. No patients were lost in the six-month follow up, and all patients were included in the analysis.

Table 4. Drug-Therapy Inconsistencies and Omissions (DTIOs) at the Time of Discharge in Intervention Patients

NUMBER OF DRUG-THERAPY OMISSIONS & INCONSISTENCIES (DTIOS)	NUMBER OF PATIENTS	PERCENTAGE OF ALL PATIENTS
0	81	60.4
1	28	20.9
2	12	9.0
3	8	9.0
4	3	2.2
5	1	0.7
6	1	0.7

Table 5. Types of DTIOs Identified and Resolved at the Time of Discharge in Intervention Patients

INCONSISTENCIES				
	DRUG*	DOSE†	FREQUENCY‡	DURATION OF THERAPY§
Total Number Of Events	29	11	5	0
Total Number Of Patients	24	8	3	0
OMISSIONS				
	DRUG"	DOSE¶	FREQUENCY**	LEGAL††
Total Number Of Events	34	7	1	12
Total Number Of Patients	20	6	1	7

*Example: A patient was receiving metoprolol 100 mg once daily in hospital, but the discharge prescription is for atenolol 100 mg once daily.
†Example: A patient was receiving hydrochlorothiazide 25 mg once daily in hospital, but the discharge medication list reads hydrochlorothiazide 12.5 mg once daily.
‡Example: Rofecoxib 25 mg was dosed once daily on MAR, but the discharge medication list indicated twice daily dosing of the same strength.
§Example: The physician orders amoxicillin for 10 days, but the discharge prescription is only for seven days.
"Example: A hypertensive patient with fluid retention is receiving continuing therapy with furosemide, but the discharge medication list does not contain a prescription for it.
¶Example: A patient's discharge prescription reads omeprazole once daily, but does not indicate its strength.
**Example: A patient's discharge prescription reads ibuprofen 400 mg, but does not include any instructions on how or when to take the medication.
††Example: The doctor's signature may be missing, a part of a patient's name or any other component of a prescription that would render it invalid in the province of filling.

Drug Therapy Problems for Seamless Monitoring (DTPsm)

Within the intervention group (n=134), there were 481 DTPsm identified and communicated to the respective community pharmacists. Of the 134 intervention patients, only five did not have any identifiable DTPsm. The average number of DTPsm per intervention patient was 3.59 (S.D.=2.25). The most frequently identified DTPsm was *needs additional drug therapy* and it accounted for a third of all DTPsm (**Table 2**). Of the 481 DTPsm identified, only three were deemed *not significant* in terms of their potential clinical impact. The majority (83.8%) of the DTPsm identified by the seamless care pharmacist were *somewhat significant* or *significant*, with the *significant* category accounting for 56.6% of all events (**Table 3**). The average Intervention Ranking score per pharmacist intervention was 4.16 (S.D.=0.38).

Drug-Therapy Inconsistencies and Omissions (DTIOs) at the time of discharge

It was determined that 53/134 (39.6%) of the intervention patients had a DTIO at the time of discharge (**Table 4**). Ninety-nine DTIOs were identified and resolved before discharge, an average of 0.74 DTIOs per intervention patient (SD=1.18). A greater number of omissions (54) were identified compared to inconsistencies (45). A detailed breakdown of the resolved inconsistencies and omissions into sub-categories is provided in **Table 5**. An average potential clinical impact score for each patient with one or more inconsistencies was 4.33 (S.D.=0.69), whereas the average score for omissions was 4.35 (S.D.=0.60). **Table 6** depicts the breakdown of resolved inconsistencies and omissions by their potential clinical impact category and score. Ninety of the 99 DTIOs had an Intervention Ranking of *significant* or *very significant.*

Unresolved DTIOs – Retrospective Chart Review of Intervention and Control Patients

In the retrospective medical chart review, it was found that 67/119 (56.3%) of the control patients had a DTIO. There were 19 patients that had an inconsistency and 59 patients that had an omission and 11 patients had both types of errors (**Table 7**). In the validation check of the seamless care pharmacist's interventions,

only 1 of the 28 (3.6%) randomly selected medical charts of the intervention patients was found to still contain an unresolved DTIO (Table 7). Therefore, further charts were not reviewed, as it appeared the seamless care pharmacist resolved almost all of the DTIOs.

Discussion

By having a pharmacist accept responsibility to facilitate the continuity of pharmaceutical care for patients at hospital discharge, an improvement in the medication-use system was identified and the potential for preventable drug-related morbidities was decreased. In evaluating the results of a pharmacist-directed seamless care service, the pharmacist played a valuable role at the time of discharge in identifying potential and actual DTPsm and resolving DTIOs in hospital discharge medications.

The seamless care pharmacist was able to identify an average of 3.59 DTPsm per intervention patient at discharge. These were either resolved *or* they were potential drug-therapy problems that were communicated to the community pharmacist for follow-up. These numbers allude to the complexity of in-patient medication-use systems and the need for ongoing monitoring of patients post-discharge by their community pharmacist. Hepler and Strand have emphasized that identifying and resolving drug-therapy problems and ongoing monitoring is an integral part of providing pharmaceutical care (Hepler and Strand 1990). As patients move between sites of care, it may become more difficult to monitor the drug-therapy problems identified at the time of discharge and perform proper follow-up procedures. Communicating the patient's DRPs between sites of care, as was done in this study, allows all members of the patient's healthcare team to continually monitor patient progress, modify drug regimes as necessary and perform follow-up consultations, thereby preventing future drug-related morbidities. In our case, the community pharmacists were further aided by the additional information contained in the DTPsm such

Table 6. Drug-Therapy Inconsistencies and Omissions (DTIOs) and Potential Clinical Impact Score

POTENTIAL CLINICAL IMPACT CATEGORY	POTENTIAL CLINICAL IMPACT SCORE	NUMBER OF DTIO	PERCENTAGE OF ALL DTIO
Adverse significance	1	0	0
Not significant	2	0	0
Somewhat significant	3	9	9.1
Significant	4	48	48.5
Very significant	5	42	2.4
Extremely significant	6	0	0

Table 7. Retrospective Chart Review: Unresolved DTIOs in Control and Intervention

OMISSIONS				
GROUP	DRUG	DOSE	FREQUENCY	LEGAL
Control (n=119)	Number of patients 52	Number of patients 10	Number of patients 3	Number of patients 0
	Actual number of events 249	Actual number of events 31	Actual number of events 11	Actual number of events 0
Intervention[1] (n=28)	Number of patients 0	Number of patients 0	Number of patients 0	Number of patients 0
	Actual number of events 0	Actual number of events 0	Actual number of events 0	Actual number of events 0
INCONSISTENCIES				
GROUP	DRUG	DOSE	FREQUENCY	LEGAL
Control (n=119)	Number of patients 12	Number of patients 6	Number of patients 3	Number of patients 0
	Actual number of events 22	Actual number of events 6	Actual number of events 6	Actual number of events 0
Intervention[1] (n=28)	Number of patients 0	Number of patients 1	Number of patients 0	Number of patients 0
	Actual number of events 0	Actual number of events 1	Actual number of events 0	Actual number of events 0

[1] Every sixth chart of the intervention patients was reviewed

as laboratory findings, diagnostic information and by having access to the intended medication regime at discharge. The current standard of care does not allow the community pharmacist access to this information. By providing the community pharmacist with this information, they have a more complete clinical picture and are positioned to uncover future potential drug-therapy problems.

Discrepancies between the prescriptions written at discharge and the patient's hospital medications are cause for concern. The retrospective medical chart reviews revealed that 67/119 (56.3%) of the control patients were discharged from the hospital with an inconsistency or omission in the printed medication discharge list, and that the seamless care pharmacist resolved virtually all DTIOs in the intervention patients. The number of discrepancies identified in this study is larger than results reported in previous studies. A 60-day pilot study determined that 5.8% of study patients' discharge prescriptions contained an error, as identified by a clinical pharmacist (Schumock et al. 1994). Wernick and colleagues (1996) conducted a six-week study which evaluated the frequency and types of variances that occurred in patients' discharge prescriptions. Their study reported that 11.9% of the participating patients' discharge prescriptions contained a variance that required an intervention, and, using the same Intervention Ranking system (Hatoum et al. 1988), 48.6% of pharmacist interventions were categorized as *significant* (Wernick et al. 1996). As discussed by others (Schumock et al. 1994; Wernick et al. 1996), comparing rates of prescription discrepancies between studies can be difficult when each study does not use the same definition of discrepancy and the same identification methods. Although the discrepancies identified in this paper are similar in nature to those identified in the previously mentioned studies, they are not classified in exactly the same manner.

> … it is clear from the results of this present study that a comprehensive seamless pharmaceutical care program – not solely medication reconciliation – is required to fully optimize the patient's medication regime.

Several barriers will have to be overcome to establish pharmacist-directed seamless care services as a standard of care that patients can expect to receive when they are discharged from a hospital. A service such as this requires significant human and financial resources from the hospital pharmacy department. This can be difficult to justify, given that the benefits of these programs occur outside the walls of the hospital. These programs will require additional resources in community pharmacies as well. In order for community pharmacists to optimally incorporate the information provided by their hospital colleagues in their practices, they will need to allocate time to perform comprehensive pharmaceutical care work-ups and on-going monitoring. The financial incentives for community pharmacists to participate in these programs are few. Still, despite these barriers, all pharmacists should strive to provide this level of seamless care. A motivation for hospital pharmacists is that the 2005 CCHSA patient safety goals require a hospital to incorporate medication reconciliation in their processes of care. While the inclusion of medication reconciliation into these goals is to be commended, it is clear from the results of this present study that a comprehensive seamless pharmaceutical care program – not solely medication reconciliation – is required to fully optimize the patient's medication regime. Almost five times as many DTPsm were identified and resolved through the pharmacist-directed seamless care service as the number of DTIOs identified and resolved through the medication reconciliation process at the time of discharge.

There are some limitations of this study that need to be considered. The seamless care intervention was carried out by one clinical pharmacist at one hospital site. A multi-pharmacist and multi-centre study would have been preferable to increase the generalizability of the results. This seamless care service only occurred in one direction – from the hospital to the community. In the future, other seamless care evaluations that bridge the gap in the opposite direction should be conducted. An additional limitation is the number of intervention patient medical charts reviewed in the retrospective chart review. As mentioned previously, every sixth intervention patient medical chart was reviewed as opposed to all charts. This was done to "spot-check" the seamless care pharmacist's work to ensure that all DTIOs were actually identified and resolved. In the 28 charts reviewed, only one inconsistency and no omissions were identified; thus, the researchers felt justified in reviewing only a portion of the intervention charts, as the rate of error for the seamless care pharmacist was so low – 1/28. Reviewing the medical charts for all intervention patients would have given a more complete picture but was not feasible due to pharmacist staff shortages at the Moncton Hospital.

Conclusion

The interventions performed as part of this pharmacist-directed seamless care service identified and resolved an average of 3.5 DTPsm per patient, and eliminated almost all discrepancies related to DTIOs. Overall, the majority of the issues identified by the seamless care pharmacist were viewed as being significant. This study identified the need to enhance the safety of the medication-use systems and care processes in hospitals that have not established pharmacist-directed seamless care services.

References

Beers M.H., J. Dang, J. Hasegawa and I.Y. Tamai. 1989. "Influence of Hospitalization on Drug Therapy in the Elderly." *J Am Geriatr Soc.* 37: 679–83.

Breau, D. and A. Nickerson. 1998. "Seamless Pharmaceutical Care – Linking the Moncton Hospital and the Greater Moncton Community." In *Proceedings of the Seamless Care Workshop*. Canadian Society of Hospital Pharmacists and Canadian Pharmacists Association. Ottawa, ON.

Bussieres, J.J. 2004. "Clinical Pharmacy Services." In *2003/04 Annual Report Hospital Pharmacy in Canada*. Toronto, ON: Eli Lilly Canada. Retrieved August 6, 2005. <http://www.lillyhospitalsurvey.ca/hpc2/content/2004_Report/2003_04_full.pdf>.

Canadian Council on Health Services Accreditation. 2004. "CCHSA Patient Safety Goals and Required Organizational Practices." Ottawa, ON. Retrieved August 6, 2005. <http://www.cchsa.ca/pdf/PSCommunique2.pdf>.

Canadian Council on Health Services Accreditation. 2005. "CCHSA Patient/Client Safety Goals & Required Organizational Practices. Frequently Asked Questions - Updated June 6, 2005." Ottawa, ON. Retrieved August 6, 2005. <http://www.cchsa.ca/pdf/patientsafety-FAQJune062005.pdf>.

Canadian Patient Safety Institute. 2005. "Safer Healthcare Now!" Edmonton, AB. Retrieved August 6, 2005. <http://www.cpsi-icsp.ca/news_eng/Final-Release-Eng-June28.pdf>.

Canadian Society of Hospital Pharmacists. 2004. Statement on Seamless Care. Ottawa, ON: Author.

Canadian Society of Hospital Pharmacists and Canadian Pharmacists Association. 1998. Proceedings of the Seamless Care Workshop. Ottawa, ON: Author.

Hatoum, H.T., R.A. Hutchinson, K.W. Witte and G.P. Newby. 1988. "Evaluation of the Contribution of Clinical Pharmacists: Inpatient Care and Cost Reduction." *DICP Ann Pharmacother* 22: 252–59.

Hepler, C.D. and L.M. Strand. 1990. "Opportunities and Responsibilities in Pharmaceutical Care." *Am J Hosp Pharm* 47: 533–43.

Institute for Healthcare Improvement. 2004. "Getting Started Kit: Prevent Adverse Drug Events (Medication Reconciliation) How-To Guide." Boston, MA. Retrieved August 6, 2005. <http://www.ihi.org/NR/rdonlyres/47D5AE1C-0B29-4A59-8D58-BABF8F4E829F/0/ADEHowtoGuideFINAL5_25.pdf>.

MacKinnon, N.J. 2001. "Seven Strategies to Strengthen Our Medication-Use System (editorial)." *Can J Hosp Pharm* 54: 72–74.

MacKinnon, N.J. ed. 2003. "Seamless Care: A Pharmacist's Guide to Providing Continuous Care Programs." Ottawa, ON: Canadian Pharmacists Association.

Schumock, G.T., A.J. Guenette, T.V. Keys and R.A. Hutchinson. 1994. "Prescribing Errors for Patients about to Be Discharged from a University Teaching Hospital." *Am J Hosp Pharm* 51: 2288, 2290.

Strand L.M., R.J. Cipolle, P.C. Morley, R. Ramsey and G.D. Lamsam. 1990. "Drug-Related Problems: Their Structure and Function." *DICP Ann Pharmacother* 24: 1093–97.

Wernick, A.., C.J. Possidente, E.G. Keller and G. Gilroy. 1996. "Enhancing Continuity of Care Through Pharmacist Review of Discharge Medications." *Hosp Pharm* 31: 672–76.

About the Authors

Ann Nickerson, B.Sc. (Pharm.), is a Clinical Pharmacist, South-East Regional Health Authority in Moncton, NB. She has spoken widely on medication reconciliation and seamless care and still provides these clinical services at The Moncton Hospital.

Neil J. MacKinnon, Ph.D., R.Ph., is the Associate Director for Research and Associate Professor in the College of Pharmacy at Dalhousie University. He has led several studies on medication safety and edited a book published in 2003 by the Canadian Pharmacists Association on seamless care.

Nancy Roberts, B.Sc. (Pharm.), is Vice-President, Planning and Professional Services, South-East Regional Health Authority in Moncton, NB. She is a past-president of the Canadian Society of Hospital Pharmacists (CSHP). She was a member of the joint CSHP/Canadian Pharmacists Association Task Force on Seamless Care.

Lauza Saulnier, B.Sc. (Pharm.), is Chief of Pharmacy Services, South-East Regional Health Authority in Moncton, NB. Lauza heads a pharmacy department, which has been a national leader in medication reconciliation and seamless care, having first participated in a pilot project in the late 1990s.

Corresponding Author: Dr. Neil MacKinnon, 5968 College St., Halifax, NS, Canada, B3H 3J5, Phone: (902) 494-6379, Fax: (902) 494-1396, E-mail: neil.mackinnon@dal.ca

The authors have no declared conflicts of interest.

Acknowledgments: Emily Black, Dianne Breau, Debbie Carson, Christopher Daley, Jennifer Dykeman, Heather Robertson, Margaret Willan and Lesley Zwicker.

Acknowledgement of financial support: Atlantic Blue Cross Care, Canadian Society of Hospital Pharmacists – New Brunswick Branch, Eli Lilly, Friends of The Moncton Hospital, Hoffman LaRoche, Medbuy Corporation, New Brunswick Pharmacists Association, Shoppers Drug Mart, South-East Regional Health Authority.

Acknowledgement of support in kind: Medicare/Prescription Drug Program, Department of Health and Wellness, NB.

Using Healthcare Failure Mode and Effect Analysis Tool to Review the Process of Ordering and Administrating Potassium Chloride and Potassium Phosphate

Rosmin Esmail, Cheryl Cummings, Deonne Dersch, Greg Duchscherer, Judy Glowa, Gail Liggett, Terrance Hulme and the Patient Safety and Adverse Events Team*
Calgary Health Region, Calgary, Alberta, Canada

Abstract

During the spring of 2004, in the Calgary Health Region (CHR) two critical incidents occurred involving patients receiving continuous renal replacement therapy (CRRT) in the intensive care unit (ICU). The outcome of these events resulted in the sudden death of both patients.

The Department of Critical Care Medicine's Patient Safety and Adverse Events Team (PSAT), utilized the Healthcare Failure Mode and Effect Analysis (HFMEA) tool to review the process and conditions surrounding the ordering and administration of potassium chloride (KCl) and potassium phosphate (KPO_4) in our ICUs.

The HFMEA tool and the multidisciplinary team structure provided a solid framework for systematic analysis and prioritization of areas for improvement regarding the use of intravenous, high-concentration KCL and KPO_4 in the ICU.

Introduction

For the Calgary Health Region (CHR), patient safety was brought to the forefront in the spring of 2004, when there were two critical incidents that resulted in the death of two patients receiving CRRT in two different ICUs of the CHR (ISMP alert March 25, 2004). Here is a brief description of the incidents from the *External Patient Safety Review* (June 2004):

> "An 83-year-old woman who was a patient in the cardiovascular care unit at the Foothills Medical Center (FMC) site of the CHR died suddenly in the presence of her physician and members of her family. She was alert and oriented at the time and her condition, while very serious, did not seem to indicate reasons for immediate concern. Her unexpected death was devastating for her family and extremely distressing for all those involved in her care. An ICU physician suspected the cause — the composition of dialysate solution being used to treat her kidney failure. This was quickly confirmed and 30 bags of the solution made in the same batch were removed from patient care areas, undoubtedly preventing the deaths of other patients. An analysis of the other bags from that batch as well as a systematic review of patient records identified a second patient whose death, one week earlier, was likely caused by the same set of circumstances. This was not suspected at the time of death due to the patient's serious condition."

Upon further investigation, it was determined that in February 2004, pharmacy technicians in the central production facility of the CHR pharmacy department prepared a dialysate solution for patients receiving CRRT. During the process, KCL

was inadvertently added to the dialysate bags instead of sodium chloride (NaCl) solution. It is believed that these incorrectly prepared solutions were used in the dialysis of the two patients who died (*External Patient Safety Review*, CHR June 2004).

The CHR publicly disclosed the facts and initiated an external patient safety review. The Department of Critical Care Medicine (DCCM) also undertook a review of the process for ordering and administering intravenous, high-concentration KCl and KPO_4, using the HFMEA tool developed by DeRosier, Joseph et al. (2002). The focus of this article is to describe the application of the tool with respect to reviewing the processes involved in ordering and administering intravenous, high-concentration KCl and KPO_4, thereby allowing the DCCM to proactively identify hazards that may exist and establish a safer process.

Background

The DCCM has been engaged in ongoing quality improvement and patient safety initiatives both formally and informally for over 10 years (Esmail et al. 2005). At present, the region includes three adult acute care teaching hospitals and one pediatric hospital: Foothills Medical Centre (FMC), Peter Lougheed Center (PLC), Rockyview General Hospital (RGH) and the Alberta Children's Hospital. The Department of Critical Care Medicine oversees four adult intensive care units:

- A 24-bed Multisystem ICU (FMC)
- A 14-bed Cardiovascular ICU (FMC)
- A 12-bed Multisystem ICUs (PLC)
- A 10-bed Multisystem ICUs (RGH)

HFMEA vs Failure Mode and Effect Analysis (FMEA)

In the past, medicine used a human error approach which identified the individual as the cause of the adverse event. We now recognize that errors are caused by system or process failures (McNally et al. 1997). FMEA was developed for use by the United States military and is utilized by the National Aeronautics and Space Administration (NASA), to predict and evaluate potential failures and unrecognized hazards and to proactively identify steps in a process that could help reduce or eliminate a failure from occurring (Reiling et al. 2003). FMEA focuses on the system within an environment and uses a multidisciplinary team to evaluate a process from a quality improvement perspective. The Joint Commission for Accreditation of Healthcare Organizations (JCAHO) in the US has recommended that healthcare institutions conduct proactive risk management activities that identify and predict system weaknesses and adopt changes to minimize patient harm (Adachi et al. 2001).

In 2001 the Veteran's Administration (VA) National Centre for Patient Safety (NCPS) specifically designed the HFMEA tool for risk assessment in the healthcare field. The HFMEA tool was formed by combining industry's FMEA model with the U.S. Food and Drug Administration's Hazard Analysis and Critical Control Point (HACCP) tool together with components from the VA's root cause analysis (RCA) process. HACCP was developed to protect food from chemical and biological contamination and physical hazards. The HACCP system uses seven steps: (1) conduct a hazard analysis, (2) identify critical control points, (3) establish critical limits, (4) establish monitoring procedures, (5) establish corrective actions, (6) establish verification procedures, and (7) establish record-keeping and documentation procedures (Center for Food Safety and Applied Nutrition, 1997). It uses questions to probe for food system vulnerabilities as well as a decision tree to identify critical control points. The decision tree concept was adapted by the VA for the HFMEA tool.

The HFMEA tool has been subsequently recognized in the White Paper prepared by the American Society for Healthcare Risk Management (ASHRM). In an effort to globally share the merits of this process, a video, instructional CD and worksheets on the use and application of HFMEA has been sent to every hospital CEO in the US to be shared with individuals and risk managers responsible for patient safety (American Society for Health Risk Management 2002).

HFMEA Tool

There are five steps in the HFMEA tool. Step one is to define the topic; step two is to assemble the team; step three requires the development of a process map for the topic and consecutively numbering each step and substeps of that process; step four is to conduct the hazard analysis. This step involves four processes: the identification of failure modes, identification of the causes of these failure modes, scoring each failure mode using the Hazard Scoring Matrix, and working through the Decision Tree Analysis. The final step is to develop actions and outcomes. The next section will describe how the DCCM's Patient Safety and Adverse Events team (PSAT) worked through each step of the HFMEA tool to review the process of ordering process of ordering intravenous, high-concentration KCl and KPO_4.

HFMEA — Step One

Step one is to define the HFMEA topic. The topic is usually a process that has high vulnerabilities and potential for impacting patient safety. It is important in a HFMEA analysis to define boundaries and limit the scope of the topic being reviewed.

Following the two previously mentioned critical incidents, two reviews were conducted in the CHR. The first was an internal review and was conducted by the Patient Safety Task Force, and the second was considered external and performed by the External Patient Safety Review Committee (June 2004).

During the same time, in response to the tragic events from March 2004, disparate and poorly coordinated changes in policy regarding the storage and use of highly concentrated potassium were initiated within the regional ICUs. The department's ICU executive council determined the need to undertake a review of the process for the general handling of intravenous, high-concentration KCl and KPO_4 prior to reviewing the process of preparing CRRT bags for dialysis. It was understood that some of the steps in this process would overlap with the CRRT process.

HFMEA — Step Two

Step two in the HFMEA tool is to assemble a team. The team should include six to eight multidisciplinary members who are involved in the process being analyzed and are to some degree considered "subject matter" experts.

The department's PSAT was assigned this task. The team was co-led by an intensivist and the department's quality improvement and patient safety consultant. The team was multidisciplinary, with two intensivists, three respiratory therapists, two nursing educators, two frontline nursing staff from each hospital site and two pharmacists. The team had been previously working on chart reviews of adverse events using the IHI trigger tool methodology (Rozich et al. 2003) and staff education with respect to incidents and incident reporting. The team met every other week over a two-month period (April and May 2004).

HFMEA — Step Three

Step three of the HFMEA tool requires the development of a process map for the topic and consecutively numbering each step and substeps of that process. If the process is too complex, a specific area within the overall process can be focused upon. The team identified 11 steps in the process of ordering and administering KCl and KPO_4 (**Figure 1**). After reviewing these 11 steps, the team focused on two critical steps: obtaining the drug (step #6) and mixing the drug (step #7) and then identified the substeps for each of these two HFMEA steps (**Figure 2**). Site visits to review where KCL and KPO_4 were stored and conversations with frontline staff in the units to verify the process were also conducted.

Figure 1 : Process for Ordering Potassium Chloride/Potassium Phosphate at the Foothills Medical Centre

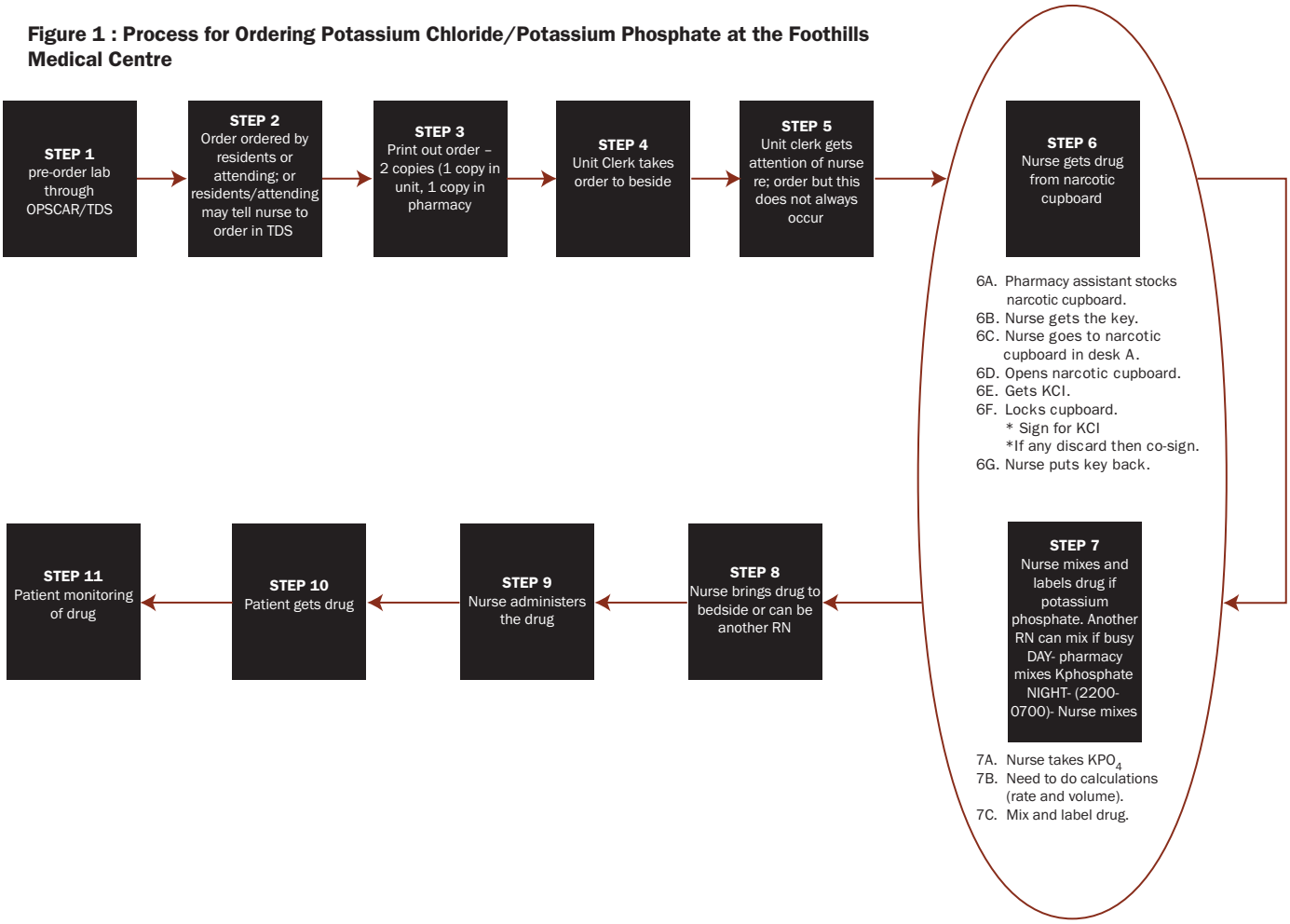
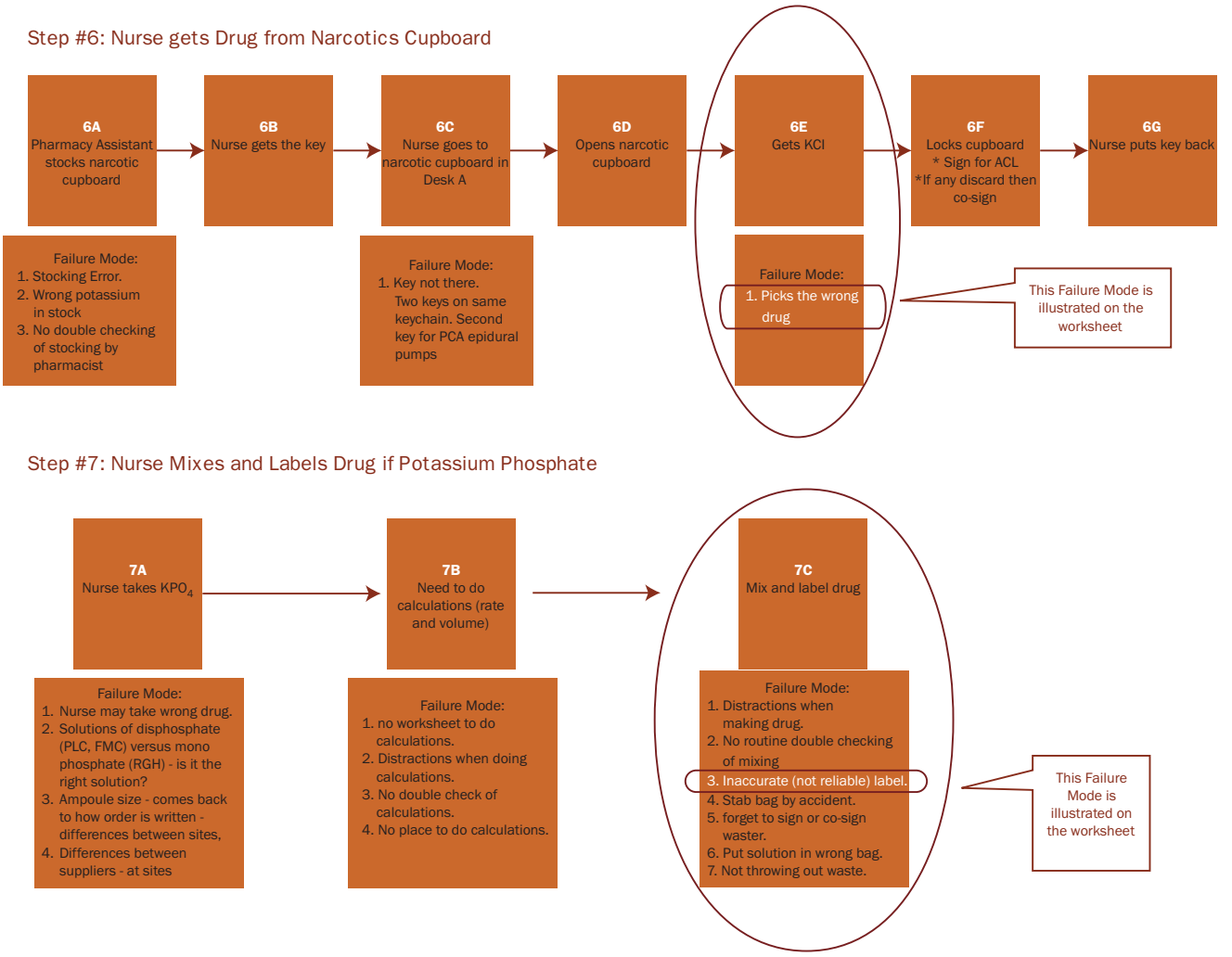


Figure 2: Failure Modes for Step 6 and 7



HFMEA —Step Four

In step four of the HFMEA tool, the area of focus is further narrowed using the following four processes: identification of failure modes, identification of the causes of these failure modes, scoring each failure mode using the Hazard Scoring Matrix, and working through the Decision Tree Analysis (DeRosier et al. 2002). The team identified the failure modes for steps #6 and #7 (**Figure 2**). The failure modes that received the highest hazards scores were: nurse selecting the wrong drug, distractions when mixing and inaccurate, or incomplete labels. Using the HFMEA decision tree analysis, the team worked through each hazard to determine if it needed further action.

HFMEA — Step Five

In step five of the HFMEA tool, actions are developed. Actions to address the identified hazards need to focus on root causes or contributing factors and need to be specific and concrete. Frontline staff involved directly in the process need to review them. Actions can then be tested prior to implementation using the Improvement Model methodology that includes testing changes using the Plan-Do-Study-Act (PDSA) cycle (Langley et al. 1996). Outcomes must be measurable, with a defined sampling strategy, set timeframe for measurement and with a realistic well-articulated goal.

Eleven recommendations were developed based on this analysis (**Appendix I**). These recommendations were placed into two categories, general and ICU-specific, and subsequently presented to the ICU executive council in July 2004. These recommendations addressed how KCl and KPO_4 are to be stored and who, where, and how the drugs are to be mixed. These recommendations also focused on the identification of look-alike and sound-alike products based on human factor

principles (Gosbee et al. 2002 and Wickens et al. 2004). Key recommendations were summarized into an action plan with delegated responsibility and timelines for implementation (**Figure 3**).

Implementation of the recommendations has proven to be more difficult than the HFMEA process itself. Once the recommendations were presented and approved at ICU executive council, those that were key ICU-specific recommendations were primarily delegated to pharmacy, unit patient care managers (PCMs) and unit directors and PSAT for implementation with specified timelines. For example, for recommendation #2, a "safety snippet" on the seven rights of drug administration was developed by a PSAT member and posted on the internal DCCM website to educate staff. Recommendations that had a broader regional impact were shared with the region's working group on high-risk medications who were developing a regional policy on KCl. The region is also in the process of developing standard labels for look-alike and sound-alike drugs.

Discussion

Team Lessons Learned

HFMEA was well recognized by the PSAT and it provided a solid framework for the step-by-step analysis of potassium ordering and administration. The team members were unaware of the numerous steps involved in administrating this medication and it became obvious that there were many opportunities for errors to occur. HFMEA enabled the team to prioritize the critical items of a complex process and took the subjectivity out of the analysis.

The multidisciplinary structure of PSAT allowed members to identify each step from their own professional practice perspective. The PSAT composition also generated diverse ideas when brainstorming actions and allowed for good discussion and deliberation, which ultimately promoted team building.

HFMEA was an easy tool to use by all members of the team. It made the approach to a very complicated process relatively straightforward. Using the HFMEA tool, the two leaders were able to focus the team on the specific components of the tool. The tool enabled the team to develop a structured outline of the goals that needed to be accomplished at each meeting. The team has also used this tool to analyze the hazards of the process for preparing CRRT bags for dialysis patients in the ICU.

Although the work of the PSAT was extremely valuable for the department, it was also time consuming. It would be appropriate to conduct a HFMEA analysis on one or two high-priority topics per year as has been recommended by the Joint Commission on Accreditation of Health Care Organizations in the United States (Adachi et al. 2001).

Figure 3: Worksheet for Failure Models 6E1 and 7C3

HPMEA Step 4 – Hazard Analysis									HPMEA – Identify Actions and Outcomes			
Failure Mode:	Potential Causes		Severity	Probability	Hazard Score	Single Point Weakness?	Existing Control Measure?	Proceed?	Action	Outcome Measure	Person/ Responsible	Follow-up Date
Picks the wrong drug	6E1	Nurse in a hurry, frustrated looking for key, chase after resident for verbal order and put in wrong box, inconsistent label from pharmacy (look-alike drug)	Major	Frequent	12	→	No	Yes	Recommendations #2, #3, #6 in Appendix 1	• number of staff educated on 7 rights • Sodium phosphate substituted for potassium phosphate • Improved labeling of look alike and sound alike drugs	Pharmacy, PCMs, unit directors, PSAT team	December, 2005
Inaccurate label (not reliable)	7C3	Distractions, doctor calls nurse, time constraints	Major	Occasional	9	→	No	Yes	Recommendation 8a in Appendix 1	# of inaccurate labels being filed in by staff	PCMs and unit directors	December 2005

Pharmacy Lessons Learned

The dialysate manufacturing error came as a harsh reminder to the CHR's pharmacy department of its need for structured policies and procedures for error avoidance. This error occurred despite existing safety procedures that including four double checks by pharmacists. The risks associated with intravenous potassium came to the forefront of the pharmacy department's focus and there was a heightened awareness of pharmacy's role in patient safety.

Since 2002, intravenous high concentration KCL vials have not been available in most patient care areas in the CHR. Premixed KCL bags are available and any special bags not commercially available are to be mixed in the pharmacy department. These policies are based on the ISMP Canada recommendations (2002) and also reiterated in the PSAT recommendations. Prior to the incidents, intravenous potassium vials were available in the night dispensary for use while the pharmacy was closed; these have now been replaced by premixed bags. The only vials of intravenous potassium available outside the pharmacy department include a small supply of KCl vials kept in narcotic cupboards of critical care and dialysis units. These vials are to be used for special CRRT solutions only.

Before the dialysate manufacturing error occurred, intravenous potassium vials were stored on the regular drug shelves within the pharmacy department. Since the error, all intravenous potassium vials are stored in a separate, locked area within the pharmacy. All intravenous potassium vials and minibags are now labelled with a warning sticker to further distinguish them, as per the recommendation from ISMP Canada (ISMP alert 2002).

Additionally, drug identification numbers have been added to the manufacturing worksheets used by pharmacy technicians in the sterile product preparation area. This adds redundancy through checking of the procedure for sterile products, including dialysate. Batches of dialysate are now quarantined until potassium levels in each batch are confirmed to be zero by laboratory testing.

By changing preparation, manufacturing, labelling and storage procedures for intravenous potassium products, the risk of error has been substantially reduced.

Conclusion

This article described the use of the HFMEA tool developed by the VA and its application in the process of ordering and administrating intravenous high-concentration KCL and KPO_4. Eleven recommendations resulted from this analysis. The ICU-specific recommendations that did not incur costs were implemented expeditiously. General recommendations, which were not under the purview of the DCCM, were shared with CHR's Regional Patient Safety Committee, which has since developed a regional policy on KCl.

In addition to this work, the knowledge and understanding gained from the application of the HFMEA tool by DCCM's PSAT will be shared with the Regional Patient Safety Transport working group reviewing patient transport between hospitals. This group has been formed based on recommendations from the External Patient Safety Review (June 2004). The Quality, Safety & Health Information Portfolio of the region is also in the process of determining the use or modification of this tool to proactively identify hazards in the system.

More importantly, the two critical incidents served as triggers that brought patient safety to the forefront for the CHR and the DCCM. Numerous changes and initiatives based on the recommendations from the internal and external reviews have been initiated or are underway with an attempt to transform the culture of the organization to one with a much greater awareness of hazard identification, incident and near miss reporting and patient safety.

References

Adachi, W. and A. E. Lodolce. 2005. "Use of Failure Mode and Effects Analysis in Improving the Safety of I.V. Drug Administration." *American Journal of Health- System Pharmacy* 62: 917–20.

American Society for Healthcare Risk Management. 2002. White paper: *Strategies and Tips for Maximizing Failure Mode Effect Analysis in Your Organization* American Hospital Association.

Calgary Health Region. 2004. *External Patient Safety Review.*

Center for Food Safety and Applied Nutrition, Advisory Committee on Microbiological Criteria for Foods. 1997. *Hazard Analysis and Critical Control Point Principles and Application Guidelines.* U.S. Food and Drug Administration. U.S. Dept of Agriculture. Retrieved August 5, 2005. <http://www.cfsan.fda.gov/~comm/nacmcfp.html>

DeRosier, J., E. Stalhandske, J. P. Bagian and T. Nudell. 2002. "Using Health Care Failure Mode and Effect Analysis™: The VA National Centre for Patient Safety's Prospective Risk Analysis System." *Journal on Quality Improvement* 28(5): 248–67.

Esmail, R., A. Kirby, T. Inkson and P. J. E. Boiteau. 2005. "Quality Improvement in the ICU. A Canadian Perspective." *Journal of Critical Care* 20:74–6.

Gosbee, J. 2002. "Human Factors Engineering and Patient Safety." *Quality and Safety in Healthcare* 11: 352s–54.

Institute for Safe Medication Practices Canada. 2004. *ISMP Canada Safety Bulletin* 4(3):1–2.

Langley, J. G., K. M. Nolan, T. W. Nolan, C. L. Norman, L. P. Provost. 1996. *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance.* New York (NY): Jossey-Bass.

McNally, M. K., M. A. Page and V. B. Sunderland. 1997. "Failure-mode and effects Analysis in Improving a Drug Distribution System." *American Journal Health-System Pharmacy* 54: 171–7.

Reiling, G. J, B. L. Knutzen and M. Stoecklein. 2003. FMEA – the Cure for Medical Errors. *Quality Progress* 36(8): 67–71.

Rozich, D J., C. R. Haradon, R. K. Resar. 2003. "Adverse Drug Event Trigger Tool: A Practical Methodology for Measuring Medication Related Harm." *Quality and Safety in Healthcare* 12: 194–200.

Wickens, D. C., J. D. Lee, Y. Liu, S. E. G. Becker. 2004. *An Introduction to Human Factors Engineering.* Upper Saddle River, New Jersey: Pearson Prentice Hall.

About the Authors

Rosmin Esmail, MSc, is the Quality Improvement and Patient Safety Consultant for the DCCM, CHR.

Cheryl Cummings, RN, is an ICU nurse at the Peter Lougheed Hospital, CHR

Deonne Dersch, RPh, is a pharmacist at the Foothills Medical Center, CHR

Greg Duchscherer, RRT, is a clinical development specialist, CHR

Judy Glowa, RN, BN, is an ICU Clinical Nurse Educator at the Foothills Medical Center, CHR

Gail Liggett, RN, BN, is an ICU/CCU Clinical Nurse Educator at the Peter Lougheed Hospital, CHR

Dr. Terrance Hulme, MD, FRCPC, is an intensivist at the Rockyview Hospital, CHR

Corresponding Author: Rosmin Esmail, Email: rosmin.esmail@calgaryhealthregion.ca

Acknowledgment

*Special thanks to the contribution of the other members of the Patient Safety and Adverse Events Team. They are Dr. Paul Boiteau, Colin Dececco, Judy Duffett-Martin, Alyce Kolody, Bobbi Sheppy, Arkadi Shuman, Teresa Thurber, Doug Vanstaalduine, and Peter Wiesner.

Appendix I: Recommendations

General/ICU

1. Use premixed solutions for high-risk drugs as much as possible.
   (a) Pharmacy premixes the high-risk medications.
   (b) Unusual or nonstandard doses not be mixed or administered, further, minimizing the need to mix potassium solutions.

General/ICU

2. Education, to re-emphasize the 5 (7) RIGHTS of drug administration: Right patient, right drug, right dose, right route, and right time, and,
   Right reason and right documentation.
   (a) Encourage a culture of double-checking of orders with physicians, when high-risk drugs are ordered.
   (b) Promote the identification of high-risk drugs.

General

3. Concentrated potassium solutions (high-concentrated vials) are removed from ward stock and the night pharmacy.
   (a) Sodium phosphate is substituted for potassium phosphate.
   (b) Monobasic potassium phosphate solution, when needed, is the only solution used.

ICU

   (c) With respect to CRRT, concentrated solutions are CRRT-specific or patient-specific medications. Only a small supply (4–6 vials) is available, after pharmacy has closed, for CRRT use only.

ICU

4a. Better identification and storage of the various minibags, with large colour-coded labels used.
   (i) Storage and medication areas are reorganized to separate bins, make them more distinct and placed at an appropriate and safe working level.
   (ii) The bins for the respective potassium concentrations are colour coded (i.e., with auxiliary fluorescent labels).
   (iii) Minibags be labelled and distributed from pharmacy.
   (iv) Pharmacy participates in this reorganization and takes ownership of the long-term organization of medication areas.
   (v) Have a magnifying glass available in all medication areas.

ICU

4b. Reduce the range of premixed potassium solutions available.
   (i) Restrict access and use of 40-mmol KCL minibags to only ICU patients, whose potassium is being replaced, per ICU potassium protocol. Provided that recommendation 4a is implemented.
   (ii) Use multiples of premixed bags for patients whose potassium is not being replaced per protocol.
   (iii) Goal should be to standardize the ordering of potassium with universal doses or protocol, concentrations and set infusion rates.

General/ICU

4c. If possible, use oral potassium supplements in lieu of intravenous solutions.

ICU

5a. In the FMC site, the "A" medication area is moved away from the unit clerk's desk. At the RGH site, medication area moved or renovated to decrease noise and distractions.

General/ICU

5b. Educate and encourage a *do not disturb* policy when medications are being mixed.

General/ICU

6. Look-alike and sound-alike drugs are highlighted better.
   (a) Use the same warning labels, consistently, throughout the region.
   (b) "Medication alert" labels be replaced with more specific labels stating either look- alike, sound-alike, different doses or routes.

ICU

7. When boluses of potassium are being given the orders and medication be double-checked and charted in QS. This should include patients receiving boluses of 40 mmols or greater or when the ICU K protocol is used.

General/ICU

8a. When medications are mixed in the ICU or on the ward, proper labelling is to include patient name, drug, concentration, date/time and who mixed the medication.

ICU

8b. A standardized protocol is developed and implemented for the administration and monitoring of potassium replacement in severe life threatening hypokalemia.

General/ICU

9a. Clear and simple instructions for mixing a solution are included in the region's intravenous therapy manual.
   (i) Goal is to minimize calculations and errors.
   (ii) Consideration is given to use of calculation grids in the instruction manuals.
   (iii) Revise the pharmacy information section on the internal ICU website, making information more easily available.

General

10. Consider using satellite pharmacies in areas where high-risk drugs are used.

ICU

9b. Use a "keypad box" for the narcotics key at the FMC site. (Currently used at the PLC and RGH.)

General

11. Immediate changes to the TDS order sets are made.
   (a) Reduce the options; i.e., solutions, concentrations, volumes and rates available for ordering potassium.
   (b) Promote the cultural changes necessary to reduce the use of verbal orders for all high-risk drugs. General/ICU
   (c) Introduce barriers when ordering potassium to prevent duplicated or multiple potassium orders for an individual patient.
   (d) Implement KCL protocols with appropriate inclusion and exclusion criteria, time limits or termination points are developed for non-ICU patients. Include in the protocol links to serum creatinine and previous potassium doses (similar to current Coumadin order sets in TDS).
   (e) Tables showing estimated potassium deficits and rate of replacement are included in the protocols.

Inappropriate Prescribing Practices: The Challenge and Opportunity for Patient Safety

Laurel K. Taylor, Yuko Kawasumi, Gillian Bartlett and Robyn Tamblyn

Abstract

Adverse clinical events related to inappropriate prescribing practices are an important threat to patient safety. Avoidance of inappropriate prescribing in community settings, where the majority of prescriptions are written, offers a major area of opportunity to improve quality of care and outcomes. Electronic medication order entry systems, with automated clinical risk screening and online alerting capabilities, appear as particularly promising enabling tools in such settings. The Medical Office of the Twenty First Century (MOXXI-III) research group is currently utilizing such a system that integrates identification of dosing errors, adverse drug interactions, drug-disease and allergy contraindications and potential toxicity or contraindications based on patient age.

This paper characterizes the spectrum of alerts in an urban community of care involving 28 physicians and 32 pharmacies. Over a consecutive nine-month period, alerts were generated in 29% of 22,419 prescriptions, resulting in revised prescriptions in 14% of the alert cases. Drug-disease contraindications were the most common driver of alerts, accounting for 41% of the total and resulting in revised prescriptions in 14% of cases. In contrast, potential dosing errors generated only 8% of all alerts, but resulted in revised prescriptions 23% of the time. Overall, online evidence-based screening and alerting around prescription of medications in a community setting demands confirmation in prescribers' clinical decision making in almost one-third of prescriptions and leads to changed decisions in up to one-quarter of some prescribing categories. Its ultimate determination of clinical relevance to patient safety may, however, have to await more detailed examination of physician response to alerts and patient outcomes as a primary measure of utility.

Patient safety is an increasingly recognized challenge and opportunity for stakeholders in improving health care delivery. It involves many issues, including delayed diagnosis and treatment, as well as inappropriate undertreatment and overtreatment. The common denominators, however, are that care and outcomes could be better, and there is a role for patients, providers and policy makers in making improvements.

The Challenge

Adverse events related to medication use are a leading cause of patient morbidity and mortality in North America (Lazarou et al. 1998). There are numerous contributing causes of the overall adverse event rates, including errors in dispensing, monitoring and adherence to medications (Avery et al. 2002). They may drive up to a quarter of all hospital admissions (Grymonpre et al. 1988; Hurwitz 1969; Ives et al. 1987; May et al. 1977), and this problem will likely be magnified by the increasing prevalence of chronic comorbidities in an increasingly aged population who also live in a culture of widespread over-the-counter medication use and acceptance of polypharmacy.

Changing the prescribing behaviour of physicians, particularly for complex aspects of care, can be a formidable challenge. Proven tools to facilitate recognition and closure of care gaps are few and even fewer offer a real time capability for matching problem identification to corrective action.

Recent work suggests that electronic prescription order entry systems with automated evidence-based risk-screening and alerting capabilities offer promise as tools in decreasing inappropriate prescribing patterns and related adverse clinical events (Bates et al. 1999; Bates et al. 2001; Bates et al. 2003; Bates and Gawande 2003; Kaushal and Bates 2002). At least theoretically, physicians consider an alerting system a worthwhile ingredient to improve prescribing safety (Ashworth 2002). However, despite the potential advantages offered by such tools, their effective acceptance and utilization has been slow (Aydin and Rice 1991; Bates and Gawande 2003; Tamblyn et al. 2003). Studies to assess why this is so have indicated several potential causes, including variable technical performance and the "back box" nature of some tools, which make it difficult to obtain reliable data to allow cause and effect analyses (Hazlet et al. 2001; Oren et al. 2003). Perhaps more importantly, there is also a physician perception of narrow clinical applicability, or inadequate general clinical relevance, of the parameters screened and alerts generated by these tools (Gurwitz et al. 2003; Hsieh et al. 2004; Monane et al. 1998).

One practical manifestation of this sense of clinical irrelevance is that physicians' frequently override, or ignore, drug alerts (Glassman et al. 2002; Magnus et al. 2002). This may also suggest an element of alert fatigue or information overload, further encouraging physicians to view alerts as a burden or hindrance to improving practice quality rather than as a decision support tool to improve quality of prescribing. If we are going to optimize the use of these systems to optimize patient safety, we need to understand four fundamental issues: the alerts these systems are producing, their clinical relevance, the physicians' response, and the reasons the physicians are responding in this manner. It is only with this information that we can improve the utility of these decision aids to reduce drug-related morbidity.

At this point, the purpose of this research was identify what alerts physicians are seeing in outpatient settings, to and to build a better understanding of their perceptions of the value of alert systems. We took advantage of a community-based trial to conduct a novel investigation of the type of drug-related alerts in primary care.

The Opportunity

The Medical Office of the Twenty First Century (MOXXI-III) is a group of academic and community-based health care stakeholders interested in improving care and outcomes for patients. As part of the research program, this partnership has developed a comprehensive, evidence-based and integrated drug management system designed to reduce prescription errors. Briefly, the system provides an electronic prescription, drug and disease management system for primary care physicians, community-based pharmacists and their patients. It is unique in several ways. It has the ability to identify dosing errors, drug interactions and duplications, as well as possible drug-disease contraindications, drug-allergy reactions, potential toxicity and contraindications due to patient age. The system also electronically documents the clinical rationale used by the physician in prescribing decisions at the point-of-care, including starting, stopping and renewing medications and response to drug alerts.

Participating physicians utilize a personal digital assistant (PDA) that includes a dynamic prescription pad that displays treatment indications and allows participating pharmacies to electronically retrieve the prescription. The content for the electronic prescription drug alerts was provided by Vigilance Santé Inc. via their Rx Vigilance therapeutic advisor. A drug profiler on the PDA allows the physician to view a graphic representation of each patient's prescription medication(s) for the prior 12 months, including drugs prescribed by other physicians via access to linked data from the provincial health database. The PDA alert system also flags drug interactions, therapeutic duplications, contraindications for specific allergies or diseases and verifies drug dosage against the base of continually updated evidence for these variables. A specific message is automatically generated on the PDA providing a summary of the situation and allowing the physician to respond in an autonomous manner. The physician's response to the alert is also captured in the system.

The MOXXI approach to assessing prescription-associated errors has been undergoing pilot testing in representative communities of care. One project was carried out in the West Island area of Montreal and involved 28 community physicians, 32 community pharmacies and approximately 12,500 patients between June 2003 and February 2004. The primary purpose was to gain an overview of the prevalence of prescribing problems, by type of prescribing error and disease and therapeutic category, in a large community care setting. A subsid-

iary purpose was to develop a sense of the clinical relevance of such data, particularly as it was used by physicians to alter their decision making. The early findings of this project are summarized below.

Where We Are Now

During a nine-month period, a total of 6,428 alerts were generated by 22,419 prescriptions, an overall alert rate of 29%. The overall revision rate (prescriptions revised on the basis of alert information received) on the alerted prescriptions was 14%. Six categories of potential error or inappropriateness accounted for 99% of the alerts. They were: drug-disease contraindication; drug duplication; drug-drug interaction; toxicity; dosing error; and age-related contraindications, displayed in **Table 1**. Drug-disease contraindications generated the greatest number of alerts; dosing errors, the least. However, dosing errors drove the highest rate of prescription revisions, 23%. Interestingly, age-related alerts were both infrequent and low drivers of revision.

The most prevalent drug classes associated with alert generation for each of the prescribing error categories are displayed in **Table 2**. Antidepressants were the most frequently involved class of drugs, accounting for 13% of all alerts and making the top three list of prevalence in five of the six alert categories (Table 2). A close second was the nonsteroidal anti-inflammatory drug class (NSAIDs), underlying 12% of all alerts and making the top three list for three alert categories.

In the drug-disease contraindication alert category, the top three medication classes (NSAIDs, thyroid replacements and antidepressants) generated 47% of all the alerts. Thirty percent of the alerts were triggered by a contraindication due to the presence of asthma, while 66% were associated with underlying hypertension. The presence of cardiovascular disorders was associated with 99% of the alerts for thyroid replacement therapy. Likewise, 82% of the warning messages that physicians received for antidepressant medication flagged a possible contraindication due to the presence of a cardiovascular disorder.

HMG-CoA reductase inhibitors led the drug-drug interaction category of alerts, the majority flagged because of concern over concomitant use with calcium channel blockers (47%). In the case of beta-blockers, 17% of the drug-drug interaction alerts involved potentially negative interaction with an antidepressant medication, while 14% involved an alpha or beta agonist. Insulin was implicated in 29% of the interactions with an NSAID, with sulfonylurea agents involved in 26%.

Potential toxicity was principally associated with antidepressant therapy, alerts warning of potential arrhythmias in 69% of the cases and of sedation in 31%. ACE inhibitors were associated with the potential for hyperkalemia in all cases, while benzodiazepines generated a warning of potential sedation in all cases. Antidepressants and benzodiazepines accounted for 58% of potentially inappropriate prescriptions among the older age patients.

Table 1. Prescription Alerts Generated and Revised, by Prescribing Error Category

Alert Category	Alerts Generated (n)	Alerts Revised	
		(n)	(%)
Drug Disease Contraindiction	2644	376	14
Drug-Drug Interactions	1522	207	14
Potential Toxicity	1022	137	13
Drug Duplication	731	120	16
Contraindicated for Patient Age	249	21	8
Potential Dosing Error	221	50	23
Other	39	8	21
Total	**6428**	**919**	**14**

Table 2. Most Prevalent Therapeutic Classes, by Alert Category

Alert Category	Top Three Therapeutic Medication Classes	Alerts Generated	
		(n)	(%)
Drug-Disease Contraindication	Antidepressants	225	9
	NSAIDs	192	7
	Thyroid Replacements	122	5
Drug-Drug Interactions	Beta-Blockers	81	5
	HMG CoA Reductase Inhibitors	77	5
	NSAIDs	65	4
Potential Toxicity	Antidepressants	314	31
	ACE Inhibitors	150	15
	Benzodiazepines	96	9
Drug Duplication	Antidepressants	136	19
	NSAIDs	128	18
	HMG CoA Reductase Inhibitors	56	8
Contraindicated for Patient Age	Antidepressants	13	5
	Benzodiazepines	6	2
	Thyroid Replacements	5	2
Potential Dosing Error	Antidepressants	33	15
	Restricted Medications*	24	11
	Thyroid Replacements	21	10

* Medication requiring physician pre-authorization

Potential dosing errors resulted in messages that alerted the prescribing physician that an initially prescribed medication dose was either too high or too low. All alerts associated with antidepressants and thyroid agents suggested too-high doses, while medications that required prior authorization by the prescribing physician warned of doses being too low.

The View Going Forward

In summary, automated online medication screening and risk alerting appears to have significant potential to reduce inappropriate prescribing practices and improve patient outcomes.

The MOXXI III evidence-based system used in the community based general practice setting demanded confirmation in prescribers' clinical decision making for almost one-third of prescriptions and led to changes in ultimate prescribing decisions about 14% of the time, overall, but up to one-quarter of the cases in some prescribing categories; for example, dosing level.

A potential weakness of all current alert systems, however, is that they address only part of the problems facing the prescribing physician in the real-world primary care setting. Each patient presents a unique set of clinical conditions and risks that the physician must incorporate into treatment decisions. For example, antidepressants are among the most frequently dispensed drugs in Canada and the most common alert-generating medication. As well, they are among the four most frequently involved classes of medication implicated in adverse drug events in malpractice claims (Rothschild et al. 2002). Risk of adverse events from antidepressants increases as patient's age and the number of comorbid diseases and associated coprescriptions increase. But in an individual patient all of these factors may be counterbalanced by some other risk-reducing factor, like the patient whose genetically determined drug metabolism is more rapid. Current automatic alert systems are not refined enough to take these patient-specific characteristics into account. If the failure to account for these clinical conditions produces many false positive alerts, physicians will be overloaded with information and be unlikely to respond to true high-risk safety situations. This issue is not easily addressed. Current systems make an effort to reduce false positives by instituting modifiable severity alert levels, as is the case with the MOXXI system. However, these classifications are based on theoretical risk, low-levels of empirical evidence, and fail to consider patient-specific risk profiles.

Thus, what these systems don't do is identify and relay information that allows the physician to assess the balanced level of total risk, and they cannot, at the present time, remove the need for, and value of, clinical judgment. Finding the best criteria for alert threshold that provides a high degree of certainty that a positive alert is truly positive in the sense it truly identifies risk requiring action will require more study and investigation in multiple clinical settings. Nonetheless, the MOXXI III results suggest that the system, even with its current sensitivity and positive predictive value characteristics, may be seen as providing a measure of clinically relevant assistance for prescription decision making and lend itself to widespread adoption in general practice settings with modifications based on further analysis.

Its ultimate determination of clinical relevance to patient safety may, however, have to await the results of other studies, particularly randomized clinical trials, with patient outcomes as the primary measure.

References

Ashworth, M. 2002. "Re: GPs' Views on Computerized Drug Interaction Alerts." *J.Clin. Pharm. Ther.* 27(5): 311–312.

Avery, A. J., A. Sheikh, B. Hurwitz, L. Smeaton, Y. F. Chen, R. Howard, J. Cantrill and S. Royal. 2002. "Safer Medicines Management in Primary Care." *Br. J. Gen. Pract. 52 Suppl.* S17–S22.

Aydin, C. E. and R. E. Rice. 1991. "Social Worlds, Individual-Differences, and Implementation - Predicting Attitudes Toward A Medical Information System." *Information & Management* 20(2): 119–136.

Bates, D. W., M. Cohen, L. L. Leape, J. M. Overhage, M. M. Shabot and T. Sheridan. 2001. "Reducing the Frequency of Errors in Medicine Using Information Technology." *J. Am. Med. Inform. Assoc.* 8(4): 299–308.

Bates, D. W., R. S. Evans, H. Murff, P. D. Stetson, L. Pizziferri and G. Hripcsak. 2003. "Detecting Adverse Events Using Information Technology." *J. Am. Med. Inform. Assoc.* 10(2): 115–128.

Bates, D. W. and A. A. Gawande. 2003. "Improving Safety With Information Technology." *N. Engl. J. Med.* 348(25): 2526–2534.

Bates, D. W., J. M. Teich, J. Lee, D. Seger, G. J. Kuperman, N. Ma'Luf, D. Boyle and L. Leape. 1999. "The Impact of Computerized Physician Order Entry on Medication Error Prevention." *J. Am. Med. Inform. Assoc.* 6(4): 313–321.

Glassman, P. A., B. Simon, P. Belperio and A. Lanto. 2002. "Improving Recognition of Drug Interactions: Benefits and Barriers to Using Automated Drug Alerts." *Med. Care* 40(12): 1161–1171.

Grymonpre, R. E., P. A. Mitenko, D. S. Sitar, F. Y. Aoki and P. R. Montgomery. 1988. "Drug-Associated Hospital Admissions in Older Medical Patients." *Journal of the American Geriatrics Society* 361092–1098.

Gurwitz, J. H., T. S. Field, L. R. Harrold, J. Rothschild, K. Debellis, A. C. Seger, C. Cadoret, L. S. Fish, L. Garber, M. Kelleher and D. W. Bates. 2003. "Incidence and Preventability of Adverse Drug Events Among Older Persons in the Ambulatory Setting." *JAMA* 289(9): 1107–1116.

Hazlet, T. K., T. A. Lee, P. D. Hansten and J. R. Horn. 2001. "Performance of Community Pharmacy Drug Interaction Software." *J. Am. Pharm. Assoc.* (Wash.) 41(2): 200–204.

Hsieh, T. C., G. J. Kuperman, T. Jaggi, P. Hojnowski-Diaz, J. Fiskio, D. H. Williams, D. W. Bates and T. K. Gandhi. 2004. "Characteristics and Consequences of Drug Allergy Alert Overrides in a Computerized Physician Order Entry System." *J. Am. Med. Inform. Assoc.* 11(6): 482–491.

Hurwitz, N. 1969. "Predisposing Factors in Adverse Reactions to Drugs." *British Medical Journal:* 1536–539.

Ives, T. J., E. J. Bentz and R. E. Gwyther. 1987. "Drug-Related Admissions to a Family Medicine Inpatient Service." A*rch. Intern. Med* 147(6): 1117–1120.

Kaushal, R. and D. W. Bates. 2002. "Information Technology and Medication Safety: What Is the Benefit?" *Qual. Saf Health Care* 11(3): 261–265.

Lazarou, J., B. H. Pomeranz and P. N. Corey. 1998. "Incidence of Adverse Drug Reactions in Hospitalized Patients: a Meta-Analysis of Prospective Studies." *JAMA* 279(15): 1200–1205.

Magnus, D., S. Rodgers and A. J. Avery. 2002. "GPs' Views on Computerized Drug Interaction Alerts: Questionnaire Survey." *J. Clin. Pharm. Ther.* 27(5): 377–382.

May, F. E., R. B. Stewart and L. E. Cluff. 1977. "Drug Interactions and Multiple Drug Administration." *Clinical Pharmacology and Therapeutics:* 22322.

Monane, M., D. M. Matthias, B. A. Nagle and M. A. Kelly. 1998. "Improving Prescribing Patterns for the Elderly Through an Online Drug Utilization Review Intervention: a System Linking the Physician, Pharmacist, and Computer." *JAMA* 280(14): 1249–1252.

Oren, E., E. R. Shaffer and B. J. Guglielmo. 2003. "Impact of Emerging Technologies on Medication Errors and Adverse Drug Events." *Am. J. Health Syst. Pharm.* 60(14): 1447–1458.

Rothschild, J. M., F. A. Federico, T. K. Gandhi, R. Kaushal, D. H. Williams and D. W. Bates. 2002. "Analysis of Medication-Related Malpractice Claims: Causes, Preventability, and Costs." *Arch. Intern. Med.* 162(21): 2414–2420.

Tamblyn, R., A. Huang, R. Perreault, A. Jacques, D. Roy, J. Hanley, P. McLeod and R. Laprise. 2003. "The Medical Office of the 21st Century (MOXXI): Effectiveness of Computerized Decision-Making Support in Reducing Inappropriate Prescribing in Primary Care." *CMAJ.* 169(6): 549–556.

About the Authors

Laurel K. Taylor, PhD, is a Postdoctoral Fellow in the Department of Medicine, McGill University, QC.

Yuko Kawasumi, MSc, is a PhD Candidate in the Department of Epidemiology and Biostatistics, McGill University, QC.

Gillian Bartlett, PhD, is an Assistant Professor in the Department of Medicine and an FRSQ funded Chercheur-Boursier.

Robyn Tamblyn, PhD, is a Professor in the Department of Medicine and the Department of Epidemiology and Biostatistics at McGill University, Faculty of Medicine. She is a Canadian Institutes of Health Research (CIHR) scientist and a McGill University William-Dawson scholar. She also holds a position as Medical Scientist at the McGill University Health Center Research Institute.

Corresponding Author: Laurel K. Taylor, PhD, Clinical and Health Informatics Research Group, McGill University, 1140 Pine Avenue West, Montreal, Quebec, H3A 1A3, Canada., Tel: (514) 934-1934 ext. 32968; Fax: (514) 843-1551; Email: laurel.taylor@mcgill.ca

Acknowledgment

The authors gratefully acknowledge the MOXXI-III project team for their assistance and support. This project is supported by Canadian Institutes of Health Research (CIHR), Canada Health and the Canada Health Infostructure Partnerships Program (CHIPP).

Safer Care – Measuring to Manage and Improve

Kira Leeb, Jennifer Zelmer, Greg Webster and Indra Pulcins

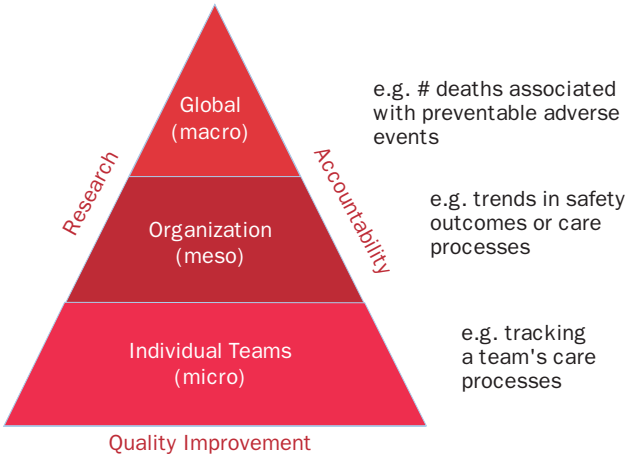
As early as the 17th century BC, Hammurabi's Code acknowledged that harm might result from medical care. Interest in measuring patient safety to support quality improvement emerged more recently, but is by no means new. Around 1910, for example, Ernest Codman advocated a focus on "end results," taking comprehensive measurements during and following care in order to help prevent undesirable outcomes. Similarly, Florence Nightingale documented survival rates for surgical patients during the Crimean War.

Fast-forward to today and patient safety is on the agenda worldwide. In Canada the first nationwide study of adverse events in hospitals was published in 2004 (Baker et al. 2004). Healthcare providers, the new Canadian Patient Safety Institute, provincial institutes and task forces, and many others are working to respond to the results of the study.

While medical practice has changed since the days of Ernest Codman, what has not changed is the focus on having good information to guide quality improvement efforts. Measures are required at a variety of levels (see **Figure 1**). For instance, broad-based global metrics provide information about the prevalence of adverse events and their impact on patients. Healthcare organizations often seek to track patient safety outcomes for their patients, as well as related processes of care. Individual quality improvement teams also require detailed information to monitor their progress in specific areas. This information may be collected as part of rapid cycle improvement or other change processes and will evolve over time depending on the focus of quality improvement efforts.

Figure 1: Measuring for Safety

Understanding the state of patient safety is an important step towards achieving safer care. A century ago, this information was rarely available, with scattered tracking primarily by individual care providers interested in safer care. Today, information is available from a broader range of standard and special purpose sources. Information collected from an organizational perspective (e.g., at the level of a hospital) helps to identify where problems may exist and tracks improvements in care. Information from the global perspective provides a population-based measure of patient safety, a first step in enabling jurisdictions to compare their results over time and with others.



From the Global Perspective

In 2004 approximately one in four (23%) Canadian adults 15 years and older said that they or a member of their family had experienced an adverse event related to their medical care (Canadian Institute for Health Information 2004). That translates to about 5.2 million people across the country. Almost a third (30%) said that the most recent event happened within the last year.

In hospitals, the largest study in Canada of adverse events found that between 9,250 and 23,750 medical and surgical adult patients with overnight hospital stays in 2000–2001 experienced a preventable adverse event and later died (Baker et al. 2004). Interestingly, the public tends to estimate much lower numbers of deaths. In 2003–2004 the Canadian Institute for Health Information (CIHI) commissioned a telephone survey of just over 4,200 adults across the country. Only 7% of respondents thought that 10,000 or more Canadians die in hospital each year from preventable adverse events (Canadian Institute for Health Information 2005a). Another 21% said that they did not know how many people died annually. Similarly, most respondents to a 2000 survey in the U.S. believed that fewer in-hospital deaths due to preventable errors occurred than estimated by authors of a landmark study by the Institute of Medicine (Blendon et al. 2002).

While many studies provide overall estimates of adverse event rates, more detailed research demonstrates that the frequency of specific types of adverse events varies widely. For example, adverse events related to medications are much more common than those related to infected blood transfusions (see **Table 1**). Emerging data also suggest that rates may vary significantly from one part of the country to another. Regional in-hospital hip fracture rates, for instance, ranged from 0.5 to 3.4 per 1,000 seniors admitted to Canadian acute care hospitals in 2001–2002 to 2003–2004 (excludes Quebec and Manitoba) (Canadian Institute for Health Information 2005b).

Table 1: How Often Various Types of Adverse Events Occur

Event Type	Rate
Reporting having been given the wrong medication or the wrong dose by a doctor, hospital or pharmacist in the past 2 years**	1 in 9 adults with health problems
Contracting a healthcare-related infection while in an acute care hospital****	1 in 9 adults 1 in 11 children
Experiencing an adverse event in an acute care hospital*	1 in 13 adult medical/ surgical patients
Reporting an adverse event in the past year for oneself or a family member***	1 in 16 adults
Third/fourth-degree tears during childbirth	1 in 20 mothers who deliver vaginally in hospital
Birth trauma (e.g. bone, scalp or spinal cord injury at birth)§	1 in 81 newborns
Death associated with a "preventable" adverse event in an acute care hospital*	1 in 152 adult medical/ surgical patients
Adverse transfusion reactions§	1 in 299 patients who receive a transfusion in hospital
In-hospital hip fractures§	1 in 1,250 hospitalized seniors
Foreign object left in after procedure§	1 in 6,667 medical/ surgical patients
Hepatitis B infected blood [a]	1 in 72,046 units of transfused blood
Hepatitis C infected blood [a]	1 in 2,857,143 units of transfused blood
HIV-infected blood [a]	1 in 10,000,000 units of transfused blood

Sources:

* G. R. Baker et al., "The Incidence of Adverse Events in Canadian Hospitals," *Canadian Medical Association Journal,* 170,11 (2004):1678–1686.

** From: R. J. Blendon, C. Schoen, C. DesRoches, R. Osborn, K. Zapert, "Common Concerns Amid Diverse Systems: Health Care Experiences in Five Countries," *Health Affairs* 22, 3 (2003):106–121.

*** Canadian Institute for Health Information (survey conducted by The Berger Population Health Monitor) (Toronto: CIHI, 2004); includes adults 15 years of age and older.

****From Canadian Nosocomial Infection Surveillance Program and the Canadian Hospital Epidemiology Committee of Health Canada.

§ Discharge Abstract Database for 2001–2002 to 2003–2004, CIHI

[a] From: J. A. Chiavetta, M. Escobar, A. Newman, Y. He, P. Driezen, S. Deeks, D. Hone, S. O'Brien, G. Sher, "Incidence and Estimated Rates of Residual Risk for HIV, Hepatitis C, Hepatitis B and Human T-cell Lymphotropic Viruses in Blood Donors in Canada, 1990–2000," *Canadian Medical Association Journal* 169, 8 (2003): pp. 767–773. Estimates based on units of donated blood. Excludes Quebec.

Note: The figures above are based on point estimates of adverse event rates. See the original references for more information on confidence intervals around these estimates.

A View from the Organizational Perspective

Knowing the extent to which adverse events occur within a population provides a baseline from which to start to measure change. However, individual health care organizations may also use more detailed qualitative and quantitative measures to track their progress towards safer care and to identify opportunities for quality improvement.

One option is to compare outcomes with other similar healthcare providers. The majority of hospital executives in all five countries surveyed by the Commonwealth Fund in 2003 felt that this approach would be somewhat or very effective in improving quality of care (see **Figure 2**) (Blendon et al. 2004). Compared with other countries, Canadian hospital executives were among the most supportive of disclosing quality information, such as the rates of nosocomial infections and medical errors, to the public.

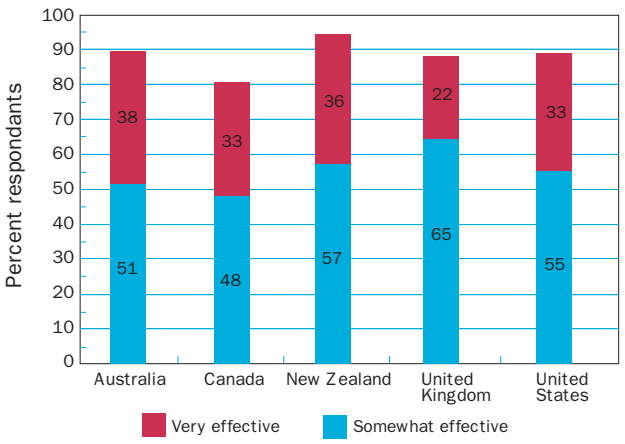
Already, a number of initiatives are underway that build on these premises. For example, a number of health regions and hospitals across the country participate in the CIHI/Hay Group Benchmarking Comparison of Canadian Hospitals. In recent years, this project has included a range of patient safety indicators. At a regional level, comparable data on selected outcomes of care (e.g., 30-day in-hospital acute myocardial infarction mortality) and patient safety (e.g., in-hospital hip fracture rates) are produced through the CIHI/Statistics Canada Health Indicators Project. There are also several provincial initiatives and efforts to provide comparable information for different specialty areas.

Additional initiatives are also emerging. For example "*Safer Healthcare Now*!", a grassroots patient safety campaign aimed at reducing preventable complications and deaths, is testing the use of intervention-specific process and outcome measures, as well as broad-based safety indicators. Originally developed in the United Kingdom, Hospital Standardized Mortality Ratios (HSMRs) compare observed versus expected deaths on a hospital-specific basis, adjusted for the age, sex, diagnoses, and admission status of its patients (Jarman et al. 2005). The Institute for Healthcare Improvement in the United States is now using this measure to track the success of its 100,000 Lives patient safety campaign, and it will be a core measure for the Canadian *Safer Healthcare Now*! campaign.

HSMRs provide a baseline from which hospitals can track and compare their results over time. In 2000, for example, the Walsall Hospitals NHS Trust in England had 1,080 deaths compared with the 830 that would be expected based on the patient mix that they cared for (Jarman et al. 2005). This translates into an HSMR or 130, the highest level of any hospital in the country at the time. Through a series of concerted improvements, over a four-year period they reduced their HSMR to 93. That represents a reduction of 295 observed compared with expected deaths per year.

Figure 2: Outcome Comparisons and Improving the Quality of Care

In 2003 hospital executives from five countries were asked how effective they thought having outcome comparisons with other hospitals would be in improving quality of care. Over 80% in each country, including Canada, felt they would be either a somewhat or very effective means mechanism for quality improvement.



Source: Blendon R.J., C. Schoen, C. M. DesRoches, R. Osborn, K. Zapert, and E. Raleigh. 2004. "Confronting Competing Demands To Improve Quality: A Five-Country Hospital Survey." *Health Affairs*, 23(3):119–35.

From the Team Perspective

Measurement is at the heart of many quality improvement efforts. For example, Plan, Do, Study, Act (PDSA) cycles are being used by healthcare teams across Canada and around the world. This approach uses pragmatic data collection and measurement activities to inform and support incremental changes in the process of care. For the local teams leading these initiatives, measurement is not the goal; rather it is a tool that facilitates progress towards the goal. Unlike measurement for research, data used by quality improvement teams often involves smaller samples and less complex collection methods (Institute for Healthcare Improvement 2005).

In some cases, teams may be able to build on shared approaches to data collection and analysis. For example, The

Guidelines Applied in Practice (GAP), endorsed by the American Heart Association and widely accepted internationally, outlines five specific practices at time of discharge that have been shown to reduce mortality in patients with heart disease (Parsons et al. 2002). Application of GAP-related improvements is one of six strategies in *Safer Healthcare Now!* The campaign intends to provide tools that can be used by individual teams to track their progress over time.

Conclusions

According to the World Health Organization (WHO), adverse events represent "a challenge to quality of care, a significant avoidable cause of human suffering, and a high toll in financial loss and opportunity cost to health services" (WHO 2002). To address this challenge, WHO, in conjunction with its partners, launched the World Alliance for Patient Safety in October 2004 to reduce the number of preventable illnesses, injuries, and deaths patients experience during their care.

In Canada and elsewhere, in order to know whether progress is being made and where further opportunities for improvement might exist, high-quality information is required at multiple levels. At a macro level, we need to know how many Canadians experience preventable adverse events, as well as how the situation is changing over time. As Ernst Codman pointed out almost a century ago, health regions and healthcare providers also need more detailed information to understand the progress of their quality improvement initiatives and patient outcomes following care. And finally, healthcare teams can test rapid improvement strategies by collecting and rapidly responding to data that tracks the results of their efforts.

References

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

Blendon, R. J., C. M. DesRoches, M. Brodie, J. M. Benson, A. B. Rosen, E. Schneider, D. E. Altman, K. Zapert, M. J. Herrmann, and A. E. Steffenson. 2002. "Views of Practicing Physicians and the Public on Medical Errors." *New England Journal of Medicine* 347(24): 1933–40.

Blendon R.J., C. Schoen, C. M. DesRoches, R. Osborn, K. Zapert, and E. Raleigh. 2004. "Confronting Competing Demands To Improve Quality: A Five-Country Hospital Survey." *Health Affairs* 23(3): 119–35.

Canadian Institute for Health Information (CIHI). 2004. Health Care in Canada, 2004. Ottawa.

Canadian Institute for Health Information (CIHI). 2005a. "The Berger Population Health Monitor." Ottawa. (Unpublished, 2004.)

Canadian Institute for Health Information (CIHI). 2005b. *Health Indicators,* 2005. Ottawa.

Institute for Healthcare Improvement. 2005. Measures. http://www.ihi.org/IHI/Topics/Improvement/ImprovementMethods/Measures/.

Jarman B., A. Bottle, P. Aylin, and M. Browne. 2005. "Monitoring changes in hospital standardized mortality rations." *British Medical Journal* 330: 329.

Parsons L.S., C.V. Pollack, K. Newby, and K.A. Littrell. 2002. "Death rates lower in hospitals that follow heart attack guidelines." *American Heart Association's Scientific Sessions* 2002: Abstract 3557.

World Health Organization. 2002. "Quality of Care: Patient Safety." *Report by the Secretariat to the Fifty-Fifth World Health Assembly.* Geneva.

About the Authors

Kira Leeb, MA, Manager, Health Services Research, has managed the production of CIHI's annual report on the health of Canada's healthcare system and has led the production of more focused reports or research on Canada's healthcare system.

Jennifer Zelmer, PhD, is Vice-President, Research and Analysis. In this role, Dr. Zelmer leads an integrated program of health services and population health-related analytical and research initiatives.

Greg Webster, MSc, Director, Research and Indicator Development. In this role, Mr. Webster is responsible for providing vision, leadership and direction in fostering CIHI's relationships with the health services research community, in developing comparative health indicators and in enhancing CIHI's analytical capacity.

Indra Pulcins, PhD, Manager, Health Indicators. Dr. Pulcins conducts health services research and is responsible for the development of health indicators at CIHI, with a particular focus on outcomes and patient safety.

Corresponding Author: Greg Webster, Director, Research and Indicator Development, Canadian Institute for Health Information (CIHI), 90 Eglinton Avenue East, Suite 300, Toronto, Ontario M4P 2Y3, Phone: (416) 481-1616 Ext. 3508, Fax: (416) 481-2950, e-mail: gwebster@cihi.ca, web-site: www.cihi.ca

The Development of the Canadian Paediatric Trigger Tool for Identifying Potential Adverse Events

Anne Matlow, Virginia Flintoft, Elaine Orrbine, Barbara Brady-Fryer, Catherine M. G. Cronin, Cheri Nijssen-Jordan, Mark Fleming, Mary-Ann Hiltz, Michele Lahey, Margaret Zimmerman and G. Ross Baker

Introduction

Research on adverse events (AEs) has highlighted the need to improve patient safety. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada (CAES) reported that 7.5% of the annual medical and surgical, adult hospital admissions in Canada are associated with an AE, and close to 2.8% may be preventable (Baker et al. 2004). These data are consistent with the results obtained by many of the international studies that used the same methodology: retrospective chart review using a trigger tool (Brennan et al. 1991; Leape et al. 1991; Wilson et al. 1995; Thomas et al. 2000; Davis et al. 2001; Vincent et al. 2001; Davis et al. 2002; Davis et al. 2003). The CAES focused on patients 19 years of age and older. The rate of AEs in Canadian children remains unknown.

The Canadian Association of Paediatric Health Centres (CAPHC) is a national, not-for-profit, organization whose members are multidisciplinary health professionals who provide care for children, youth and families within community, regional and tertiary/quaternary healthcare facilities, rehabilitation centres and community home care services. At the 2004 Canadian Association of Paediatric Hospitals (CAPHC) annual conference, patient safety priorities and recommendations for CAPHC's Patient Safety Collaborative were identified and developed by a multi-stakeholder National Patient Safety Group. A key recommendation of the workshop was for CAPHC to take the lead in developing a paediatric trigger tool to assess the incidence of AE in paediatric populations.

In this article, we will provide background information on the use of trigger tools to detect AEs, and then describe the process used for developing a Canadian paediatric trigger tool and testing its feasibility and validity. Development of this trigger tool is one component of a long-term initiative that will contain several phases and responses to the issue of paediatric patient safety. We believe this project will lead to specific recommendations for improved data collection and event monitoring and will provide a baseline for further intervention studies to reduce AEs in Canadian paediatric acute care hospitals.

What Are Trigger Tools?

The term trigger tool was first coined by Classen et al. (1991) to describe a method used to detect potential adverse drug events (ADEs). The impetus for developing this computer-based system was the desire to establish a methodology that would be less labour intensive and more effective than the traditional chart review. In Classen's system, customized software linked to the patient's electronic medical record, which already had an interface with the hospital pharmacy system, was used to identify sentinel signals or triggers (e.g., certain drugs, antidotes, abnormal laboratory values and abrupt stop orders) suggestive of medication-related medical error and ADEs. These triggers

were able to prompt a more detailed review of the chart, possibly in real-time, thereby allowing the possibility of intervention. Chart reviewers (e.g., nurses, MDs and pharmacists) with knowledge and understanding of the medical milieu were trained to distinguish use of the drug in response to an ADE from its use for another reason, and thus could more accurately estimate the number of ADEs.

The concept of using triggers or clues to detect AEs has not been restricted to detection of ADEs alone. Using retrospective chart review, numerous studies have applied screening criteria to identify potential AEs. Such methodology forms the basis for studies published in the United States, United Kingdom, Australia, New Zealand and Canada on the incidence of AEs in hospitalized adults (Brennan et al. 1991; Leape et al. 1991; Wilson et al. 1995; Thomas et al. 2000; Davis et al. 2001; Vincent et al. 2001; Davis et al. 2002; Davis et al. 2003). More recently, the Institute for Healthcare Improvement (IHI) has developed a Global Trigger Tool for measuring AEs, which they define as "injury or harm related to (or from) the delivery of care" (Rozich et al. 2003). There remains no published report, however, on the use of a trigger tool to detect AEs in hospitalized children.

… it is reasonable to expect that unique triggers may be required to detect AEs in paediatrics.

Why a Trigger Tool for Paediatrics?

Research conducted in the US has shown that children experience a substantial number of potentially preventable patient safety problems. Using an administrative database, Miller et al. (2003) reported incidence rates of patient safety events from 0.2 (foreign body left during procedure) to 154 (birth trauma) per 10,000 discharge records, and noted that children who experienced patient safety problems whilst in hospital were 2 to 18 times at greater risk of death than children who did not experience patient safety problems. In another study, Slonim et al. (2003) reported the rate of US hospital-related medical errors to range from 1.81 to 2.96 per 100 discharges. Unique paediatric in-patient issues, such as strangulation by IV tubing, have been described (Garros et al. 2003), and AEs arising during the course of paediatric emergency care have been reported (Kozer et al. 2002; Goldmann and Kavshal 2002).

Patient factors such as developmental change, dependency on adults, different disease epidemiology and demographic characteristics (the four Ds) and healthcare provider factors can each contribute, alone or in combination to vulnerabilities in paediatric care (Miller et al. 2004). Therefore, it is reasonable to expect that unique triggers may be required to detect AEs in paediatrics, since wellness and disease may manifest differently across the spectrum from infancy through adolescence, and differ again from presentation in adults.

Development of the Trigger Tool: Establishing Objectives

In January 2005, CAPHC's "Trigger Tool Design Group" (TTDG) was formed, consisting of a team of paediatric clinicians and administrators, human factors scientists, health information professionals, stakeholders and two members of the CAES study team, all authors on this report. The TTDG was challenged with the task of developing a Canadian paediatric trigger tool for potential AEs. The objectives in developing the tool were to:

1. Develop a valid and reliable tool that could be used to identify and quantify the number of AEs in paediatric acute care;
2. Compare the incidence of AEs in hospitalized children to that previously reported in adults;
3. Act as a launching pad for quality improvement activities toward the prevention of AEs in paediatrics.

Establishing a Framework for the Trigger Tool Project

With funding from the Health Care Strategies and Policy Contribution Programs, Health Canada, the TTDG began its work. Following a number of preliminary teleconferences, a face-to-face meeting was convened in February 2005 in order to propose a framework for the initiative. Given the broad content expertise and experience with trigger tool methodology within the TTDG, the following road map was developed:

- Evaluate existing trigger tools and customize one to meet our paediatric needs.
- Model the CAPHC Paediatric Trigger Tool Project on the CAES to enable comparison of AE rates.
- Develop a procedure manual and toolkit for use with the trigger tool.
- Pilot the newly developed paediatric tool at several facilities in Canada in order to
  (1) establish the feasibility of using the newly formed tool, and
  (2) validate the customized tool.
- Establish and train physician/pharmacist/nurse teams from several Canadian paediatric health sciences centres to determine whether a "trigger" was indeed evidence of an AE.

- And, ultimately, implement a pan-Canadian project designed to determine the rate of AEs in the paediatric acute care setting.

Developing the Tool

Five trigger tools were identified through a detailed literature review and personal communication with international groups [Child Healthcare Accountability Initiative (CHAI) and the Vermont Oxford Neonatal Network (VONN)] investigating the role of trigger tools in paediatrics. Tools identified as appropriate for further consideration included:

- The Canadian Adverse Events Study screening criteria
- The CHAI medication trigger tool
- The Global Trigger Tool: Institute for Healthcare Improvement (IHI)
- The VONN neonatal trigger tool (personal communication Dr. Paul Sharek)
- The Calgary Trigger tool

The IHI Global Trigger Tool was selected as the foundation upon which to build the CAPHC trigger tool because it was comprehensive and modular. In order to focus on in-patient paediatric care, four of the original six modules (care, medication, surgical and intensive care) were included, and a new one, laboratory tests, was created. A key consideration was to ensure that all triggers would be collapsible into the CAES framework to enable us to fulfil our objective of comparing the incidence of AEs in hospitalized Canadian children to that reported by Baker et al. (2004) in the CAES. Therefore, an EXCEL spreadsheet was created wherein each of the other four trigger tools (CAES, CHAI, Calgary, VONN) were lined up against the modified Global Trigger Tool, and individual triggers from the four tools were cross-referenced to those of the Global Trigger Tool. Common triggers were identified, and through this process of reconciliation and consolidation, a preliminary new tool containing 94 triggers was established.

On review of this preliminary tool, specialists in human factors science determined that a 94-trigger tool substantially exceeded an acceptable and manageable size for application in a clinical chart audit. As a result, representatives from the Canadian and US paediatric patient safety community have been invited to join the TTDG to evaluate and reduce the preliminary trigger tool with a goal of achieving a more workable 40 triggers. The revised trigger tool will be finalized in Fall 2005.

Feasibility Testing and Validation of the Tool

Two further steps are proposed prior to actual implementation of the new Pediatric trigger Tool. Initially, the feasibility of using the new tool will be tested in each of three types of paediatric hospitals – stand-alone, hospital-within-a-hospital and a general hospital providing paediatric in-patient services to ensure that our study plan is practical. Subsequently, we will validate the new tool by a two-phase process: having a physician review the charts (Phase 2), triggered by a nurse review (Phase 1) to ensure that triggers are indeed identifying AEs in the paediatric population.

Future Application

Once established and validated, the Paediatric Trigger Tool will have several applications. First and foremost, it will enable delineation of the incidence of AEs in paediatric acute care across Canada. The cross-referencing of the Paediatric Trigger Tool to other tools, specifically the CEAS tool, will make it possible to compare the incidence of AEs in Canadian children to that in adults, and to track the incidence of AEs over time. From a logistics point of view, the tool will be compatible with portable electronic devices, facilitating real time audit and database updates where applied.

A key objective of this initiative is to create a tool that will generate data that can be viewed both from a national and a local hospital perspective, and to launch quality improvement activities to prevent AEs in paediatric care. As part of the ultimate implementation and analysis of results, it is envisioned that each individual hospital would be given access both to their own breakdown of AEs, and to that of the nation-wide survey, both stratified anonymously by site and aggregated. Not only would these data identify issues and quantify rates, they would also identify target rates that could subsequently be used for benchmarking and identification of best practices. Through subsequent quality improvement initiatives, safer paediatric care would be generated.

A fundamental vision of CAPHC is to improve the safety of healthcare for all infants, children and youth across the continuum of care. By making the finalized Paediatric Trigger Tool readily available to all paediatric facilities across the country, we feel that we will be able to generate meaningful qualitative and quantitative data that can be applied to achieve safer paediatric healthcare.

References

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

Brennan, T.A., L.L. Leape, N.M. Laird, L. Hebert, A.R. Localio, A.G. Lawthers et al. 1991. "Incidence of Adverse Events and Negligence in Hospitalized Patients. Results of the Harvard Medical Practice Study I." *N Engl J Med* 324(6): 370–77.

Classen, D.C., S.L. Pestotnik, R.S. Evans and J.P. Burke. 1991. "Computerized Surveillance of Adverse Drug Events in Hospitalized Patients." *JAMA* 266(20): 2847–51.

Davis, P., R. Lay-Yee, R. Briant, S. Schug, A. Scott and S. Johnson et al. 2001. "Adverse Events in New Zealand Public Hospitals: Principal Findings from a National Survey." Wellington, NZ: Ministry of Health.

Davis, P., R. Lay-Yee, R. Briant, W. Ali, A. Scott and S. Schug. 2002. "Adverse Events in New Zealand Public Hospitals I: Occurrence and Impact." *N Z Med J* 115(1167): U271.

Davis, P., R. Lay-Yee, R. Briant, W. Ali, A. Scott, S. Schug. 2003. "Adverse Events in New Zealand Public Hospitals II: Preventability and Clinical Context." N Z Med J 116(1183): U624.

Garros, D., J. King, B. Brady-Fryer and T.P. Klassen. 2003. "Strangulation with Intravenous Tubing: A Previously Undescribed Adverse Advent in Children." *Pediatrics* 111: e732–e734.

Goldmann, D. and R. Kaushal. 2002, Oct. "Time to Tackle the Tough Issues in Patient Safety." *Pediatrics* 110(4): 823–26.

Kozer, E., D. Scolnik, A. Macpherson, T. Keays, K. Shi, T. Luk and G. Koren. 2002, Oct. "Variables Associated with Medication Errors in Paediatric Emergency Medicine." *Pediatrics* 110(4): 737–42.

Leape, L.L., T.A. Brennan, N. Laird, A.G. Lawthers, A.R. Localio and B.A. Barnes et al. 1991. "The Nature of Adverse Events in Hospitalized Patients. Results of the Harvard Medical Practice Study II." *N Engl J Med* 324(6): 377–84.

Miller, M.R., A. Elixhauser and C. Zhan. 2003. "Patient Safety Event During Pediatric Hospitalizations." *Pediatrics* 111(6): 1358–66.

Miller, M.R., P.J. Pronovost and H.R. Burstin. 2004. "Pediatric Patient Safety in the Ambulatory Setting." *Ambulatory Pediatrics* 4: 47–54.

Rozich, J.D., C.R. Haraden and R.K. Resar. 2003. "Adverse Drug Event Trigger Tool: A Practical Methodology for Measuring Medication Harm." *Qual Saf Health Care* 12: 194–200.

Slonim, A.D., B.J. LaFleur, W. Ahmed and J.G. Joseph. 2003. "Hospital-Reported Medical Errors in Children." *Pediatrics* 111(3): 617–21.

Thomas, E.J., D.M. Studdert, H.R. Burstin, E.J. Orav, T. Zeena, E.J. Williams et al. 2000. "Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado." *Med Care* 38(3): 261–71.

Vincent, C., G. Neale and M. Woloshynowych. 2001. "Adverse Events in British Hospitals: Preliminary Retrospective Record Review." [published erratum in BMJ 322: 1395]. *BMJ* 322(7285): 517–19.

Wilson, R.M., W.B. Runciman, R.W. Gibberd, B.T. Harrison, L. Newby and J.D. Hamilton. 1995. "The Quality in Australian Health Care Study." *Med J Aust 163* (9): 458–76.

www.ihi.org (accessed June 30, 2005)

About the Authors

Anne Matlow, Hospital for Sick Children, University of Toronto, Canada

Virginia Flintoft, Department of Health Policy, Management and Evaluation, University of Toronto

Elaine Orrbine, Canadian Association of Pediatric Health Centers

Barbara Brady-Fryer, Stollery Children's Hospital, Capital Health, Edmonton

Catherine M.G. Cronin, University of Manitoba, Winnipeg Regional Health Authority

Cheri Nijssen-Jordan, University of Calgary, Calgary Health Region

Mark Fleming, Saint Mary's University, Halifax, Nova Scotia

Mary-Ann Hiltz, CCHSA(c), IWK Health Centre, Halifax, Nova Scotia

Michele Lahey, Stollery Children's Hospital, Capital Health, Edmonton

Margaret Zimmerman, Policy and Partnerships Division, Marketed Health Products Directorate, Health Canada

G. Ross Baker, Department of Health Policy, Management and Evaluation, University of Toronto

Corresponding Author: Anne Matlow, MD FRCPC, Director, Infection Prevention & Control Programme, Physician Liaison, Patient Safety, The Hospital for Sick Children, 555 University Avenue, Toronto, ON M5G 1X8, Tel (416) 813-5996, Fax (416) 813-4992, Email: anne.matlow@sickkids.ca

The Human Factor: Unexpected Benefits of a CPOE and Electronic Medication Management Implementation at the University Health Network

Howard Abrams and Dafna Carr

Introduction

For the most part, literature and research around the benefits of computerized physician order entry (CPOE) and electronic medication management (EMM) have focused on the reduction of adverse events and medication errors. While these are major anticipated benefits relating to patient safety, the University Health Network (UHN) discovered that there are other unexpected benefits to be gained, related to human factors, from implementing CPOE and EMM. And they, too, can improve patient safety.

Definition of EMM

Throughout this article, EMM is the term used to describe the entire electronic medication process from the physician's order, to the pharmacist's review of the medication, to the nurse's documentation of medication administration and all the processes in between. **Figures 1** and **2** describe the medication management workflow pre- and post-implementation of CPOE and EMM at UHN.

UHN's Implementation of CPOE and EMM

UHN has been working on implementing electronic medication management (EMM) for a number of years. In its first phase, the project was primarily a technical endeavour, involving two vendors working to interface their products – in UHN's case, the hospital information system (HIS) where the medication order is placed had to interface with the pharmacy system where the medication product is reviewed, released and inventoried. This was no easy feat and took approximately 18 months including rigorous testing of interfaces. With testing complete, UHN piloted the solution for the first time in February 2003. The results of the pilot were mixed: the system design was usable, but the system performance was slow. In other words, while clinicians (physicians, nurses and pharmacists) were willing to use the system for electronic medication management, the system's speed and reliability could not support the clinical practice.

In June 2004, after additional technical work, increased consultation with clinicians, much improved system performance and more testing, on-line medication CPOE went live for all patients admitted to the General Internal Medicine units at the Toronto General Hospital. This was shortly followed by the implementation of the electronic Medication Administration Record (MAR). Roll-out of the complete EMM system has continued, and the schedule of implementation is shown in **Figure 3**.

The Effect of CPOE and EMM on Day-to-Day Activities

Imagine that one day medication orders are written on paper and the next day, all clinicians need to access the computer system

Figure 1. Workflow Prior to Implementation

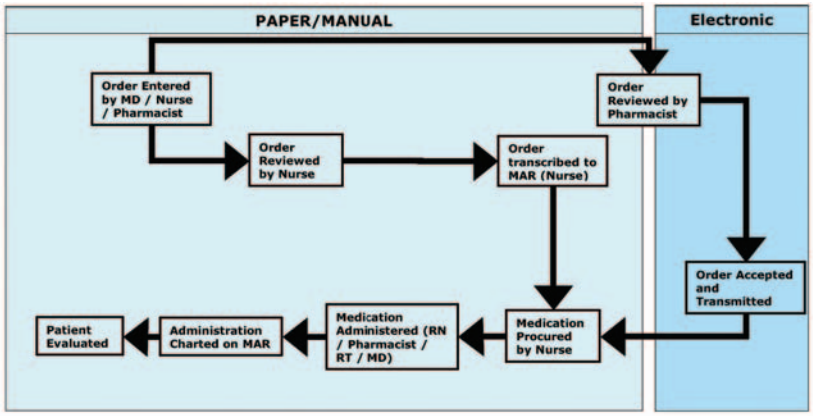
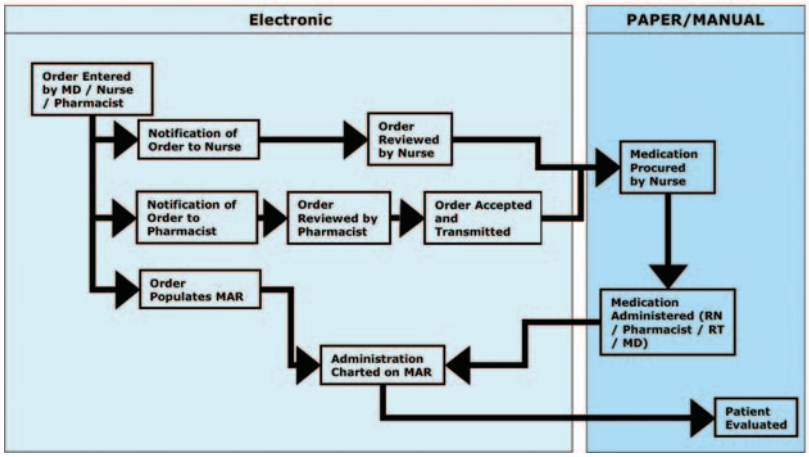


Figure 2. Workflow Post-Implementation



for any action related to medication management. Placing orders, reviewing orders and administering the medication are activities that cannot be done without accessing the computer. In addition, the system will not process the on-line medication order until all elements of the order have been entered (e.g., dose, route, etc.). And, a review of the patient's medications may need to take place in order to respond to a drug/allergy alert. In short, transforming the paper medication process into an electronic process is very complex and affects the workflow of all clinicians on the unit.

Although there are too many changes to describe here, reviewing a sample of activities is helpful in getting an appreciation of the changes a clinician will experience with the implementation.

1. *Medication orders are entered electronically.* Paper orders are no longer processed.
2. *Medication information is available online in one location in the electronic chart.* Clinicians need only look at the medication history tab in the patient's electronic chart to review the patient's current medications. They will no longer need to find the paper chart or review the numerous pieces of paper making up the patient's medication history. Duplicate order alerts are automatic as are drug/allergy alerts.
3. *Medication administration information is located in the electronic MAR and can be accessed from any computer in the hospital.* Finding the paper MAR, which is often with the nurse administering the medication, in the medication room or with the pharmacist, is no longer required.
4. *Physicians are checking their electronic inbox to review all results.* All action items are located in one area of the electronic chart, eliminating the chances of a paper result being missed.
5. *Attending physicians can review all orders placed by their team.* This provides rapid and complete information on their patient and an improved ability to supervise patient care.
6. P*hysicians can access the patient's electronic chart from any location in the hospital and from home.* The number of verbal or telephone orders is reduced, and the physician can review the patient's electronic chart prior to placing the order.
7. M*edical student orders are entered directly into the system and held until a physician reviews the order and electronically co-signs the order.* Teaching occurs at the point of computer access and less via review of the written order.
8. *Nursing staff check the electronic order notification board and/or their electronic inbox for new medication orders.* Information about the medication is stored in the electronic inbox and needs to be reviewed by the nursing staff before administration.
9. *Pharmacy staff no longer enters the physician's medication orders into the pharmacy system.* Medication orders are automatically interfaced to the Pharmacy system, and the pharmacists review the electronic medication orders.
10. *Patients receive their medications more rapidly.* The turnaround time between medication order entry and the delivery of the medication to the patient has been reduced.

11. *Reports are available to nurse managers that indicate the "missed doses" by shift.* A nurse manager can review the reports before end of shift and follow-up with nursing staff before the shift change.
12. *When a review or audit is required, information in the electronic chart can be easily reviewed or reported.*

The Human Reaction

With the introduction of EMM, business is not as usual. Human resistance to change and disruption of the status quo prompted the following types of reactions.

- We don't mind labs and radiology order entry, but don't mess with medication order entry!
- What's wrong with the way we do things today?
- Do I still need to tell the nurse?
- There is nowhere to hide.

We don't mind labs and radiology order entry, but don't mess with medication order entry!

In contrast to orders such as labs and radiology, there is a far greater sensitivity to medication ordering. First, the implication of ordering medications incorrectly is likely to be more serious than ordering the wrong lab test. Second, writing medication orders and personally signing them has been the medical tradition and represents a very personal act. Entering medication orders electronically may not initially reproduce that same sense of control and personal relationship with the patient. As a result of this, the addition of medications to the on-line menu is often received with trepidation, hesitation and concern.

Figure 3. Schedule of Implementation

Group	Services	Go-Live Date
1	General Internal Medicine, Gastrointestinal, Nephrology & Emergency	100%
2	Psychiatry (TGH) & Emergency Psychiatric Assessment (TWH)	100%
3	TWH General Internal Medicine, Family Medicine, Cardiology & Emergency	100%
4	Orthopedics, Rheumatology, General Surgery, Post-Anesthetic Care Unit (PACU), Pre-Admission	100%
5	TWH Neurology, Neurosurgery, Step-Down Unit, Interventional Radiolog	September 2005
6	TGH Cardiovascular Surgery, Cardiac Short Stay, Cardiology, CICU, Cardiovascular Pre-Admit, Cath Lab	September 2005
7	PMH – Clinics: Head & Neck, Breast, BMT, Gyn-Onc, G.I, Sarcoma Thoracic, Brain, GU	September 2005
8	TGH General Surgery, PACU, Gynecology Oncology, Urology, ENT/Plastics/Head & Neck, Thoracic/Respiratory	November 2005
9	TGH Transplant	January 2006
10	TGH & TWH Intensive Care Units	March 2006
11	PMH Inpatient Units	TBD
12	Other Areas: Infectious Disease, Endocrine, Palliative Care, etc.	TBD

What's wrong with the way we do things today?

Because medication errors are so difficult to identify in the paper environment, there is a sense that the current system isn't so bad. This mood is described well by Dr. Matthew Morgan in his paper, "In Pursuit of a Safe Canadian Healthcare System: What we do not look for, we will not see. What we do not measure, we will not investigate. What is perceived as unbroken, we will not fix" (2004). Unfortunately, recent studies have shown that adverse events from medical error are unacceptably high, and that the majority of these preventable events are due to medication error (Kohn et al. 1999).

Do I still need to tell the nurse?

Interestingly, the introduction of an electronic system can change the patterns of verbal communication. Initially, as clinicians get accustomed to the type and amount of information that is stored in the electronic chart, important verbal communication decreases due to the belief that the system has a mechanism for replacing that communication. Clinicians have to be reminded that verbal communication within the healthcare team remains just as important as it was prior to CPOE. In fact, during the implementation phase, communication needs to increase as clinical groups adapt to the new system.

There is nowhere to hide.

On-line information is far more powerful than information on disparate pieces of paper located around a unit. With the "flick" of a switch, information is collected in the electronic chart, presented and reported differently. This results in workflow and practice issues becoming more transparent.

This level of transparency is uncomfortable. It will result in the perception that an increase in errors has occurred. Whereas in the past, reporting or auditing errors was a cumbersome and lengthy process, electronic information is easier to review, report and present. Errors that have existed in the paper environment, possibly buried within the many layers of the patient's paper record, now appear to be more visible. Additionally, while

different workflows are tolerated in a paper environment, an electronic environment forces process review and adoption of a best practice standard.

The Unexpected Benefits and Increased Patient Safety

While the human factor will affect the implementation of EMM, overcoming these factors yields some unexpected benefits that go beyond medication error reduction, but that, nevertheless, yield increased patient safety benefits.

Better Understanding of Overall Workflow

Although there have been many advances in the area of medication therapy, there has been very little change in its method of delivery. The same workflow has been adhered to for many years. The introduction of EMM will force a review of the process as clinicians and informaticians work together to marry technology and workflow. This review results in the quick identification of ambiguous or inefficient workflow. EMM cannot support disparate workflows, and this results in the clarification and development of standards and possibly the introduction of new practice and policies.

At UHN, EMM implementation has forced a review of the verbal order policy, the hemodialysis workflow, the consultant order process and policy, and the allergy documentation process and policy.

Increased Communication

Implementing EMM must be done with all clinical disciplines at the table. While we expect that interdisciplinary communication occurs on a regular basis, in reality, the extremely busy pace of healthcare practice has limited this interchange. As EMM is implemented, the changes to workflow and process must be discussed by an interdisciplinary team. At UHN, this increased interaction between disciplines reinforces informal networks and encourages a better understanding of how the organization functions, resulting in a stronger healthcare team better able to rapidly troubleshoot issues.

Teambuilding

While teambuilding within the unit is a by-product of this implementation, teambuilding outside the walls of the unit is also a benefit. At UHN, each go-live requires the attention and dedication of many players. The information technology (IT) department works very closely with clinicians' pre- and post- go-live ensuring the system meets the practice and workflow needs of the clinicians. This intense collaboration puts the IT professional on the front line of patient care, literally side-by-side with the clinicians. There is a sharing of perspectives and an increase in mutual respect and understanding. IT is no longer seen as a remote department that interferes with patient care by forcing clinicians to change the way they've always done things. They are part of the healthcare team who need clinician feedback and involvement in order to provide the best electronic environment for clinicians to do their work.

Hospital administration and clinical leadership, via the use of a report card and meetings with the unit, also monitor carefully the rate of adoption and productivity of the units. Because the medication management process is so critical to the patient as well as to the overall workings of the organization, these many stakeholders work quickly and closely together to ensure the smoothest transition as possible to EMM.

Implementing EMM must be done with all clinical disciplines at the table.

Introduction of New Process and Structure for Issue Resolution

The speed at which issues need to be resolved, as well as their interdisciplinary nature, forces the development of a process and structure for issue resolution. While there are many formal and informal structures already existing in the hospital for issue resolution, it was found that they were unable to make timely decisions that represented the interdisciplinary nature of medication management. As a result, a leadership team with multidisciplinary representation was created for each unit. This team is accessible and able to make rapid and daily decisions that enable the unit to operate as seamlessly as possible. When the issue at hand will affect practice, policies and standards, this team takes the issues to the Electronic Health Record Clinical Advisory Committee and possibly to other committees.

Management and Leadership Engagement

While UHN has undergone many system implementations, EMM has been one of the longest and most difficult. The sensitivity around medication management and the attention around medication errors and adverse events have made adoption of EMM a closely scrutinized process. While this level of attention can be difficult to manage, it does offer the benefit of engaging administrators, managers and clinical leaders. This engagement means that issues such as practice, standards and policy changes are monitored and addressed promptly.

Conclusion

Many of the benefits listed in this paper are the subtle and unexpected by-products of CPOE and EMM implementation. Formal and informal interdisciplinary networks are strengthened, improving the functioning of a complex institution. Role and process clarification occurs, allowing the creation of best practices throughout the hospital. Previously hidden errors are brought to light. These unexpected benefits, primarily a result of human factors, provide important additional benefits to a CPOE and EMM implementation. These benefits go beyond medication error reduction and equally improve patient care.

References

Morgan, M.W. 2004. "In Pursuit of a Safe Canadian Healthcare System." *Healthcare Papers* 5(3): 10–26.

Kohn, L.T., J.M. Corrigan and M.S. Donaldson, eds. 1999. *To Err Is Human: Building a Safer Health System*. IOM Committee on Quality of Health Care in America. Washington, DC: National Academy Press.

About the Authors

Howard Abrams is the Director of the Medical Consultation Service, University Health Network (UHN) and Mount Sinai Hospital, and Director of the General Internal Medicine Clinical Teaching Units, Toronto General Hospital. He has lectured internationally in the fields of Clinical Epidemiology, Evidenced Based Medicine, and delivering information at the point-of-care.

Dafna Carr is a Project Director with the Shared Information Management Services (SIMS) at UHN.

Corresponding Author: Dafna Carr, dafna.carr@uhn.on.ca.

Identifying and Preventing Technology-Induced Error Using Simulations: Application of Usability Engineering Techniques

Elizabeth Borycki and Andre Kushniruk

Abstract

In this paper, we describe a framework for the analysis of technology-induced errors, extending approaches from the emerging area of usability engineering. The approach involves collection of a rich set of data consisting of audio and video recordings of interactions of healthcare workers with health information systems under simulated conditions. The application of the approach is discussed, along with methodological considerations and issues in conducting such studies. The steps involved in carrying out such studies are described along with a discussion of our current work. It is argued that health care information systems will need to undergo more rigorous evaluation under simulated conditions in order to detect and prevent technology-induced errors before they are deployed in real healthcare settings.

"Mistakes are a fact of life. It is the response to the error that counts." – Nikki Giovanni

Introduction

Medical errors are a significant cause of death and disability in North America (Baker et al. 2004a; Baker & Norton 2004b; Institute of Medicine 2000). Current Canadian estimates suggest approximately 185,000 hospital admissions are associated with an adverse event each year (Baker et al. 2004a: 1678). Similar studies have been conducted in other countries with analogous results (i.e., United States, Australia) (American Hospital Association, 1999; Wilson et al. 1999). In recent years, health information technology has been touted as being an effective method for reducing the overall incidence of medical error (Institute of Medicine, 2000). For example, a number of studies have shown that physician order entry, decision support and medication administration systems can decrease the number of certain types of medical errors (Bates et al. 1998). However, more recent research findings indicate such health information technologies may in fact increase rather than decrease the incidence of certain types of medical errors (Koppel et al. 2005; Kushniruk et al. 2004). This has led some researchers to suggest technology can introduce new types of medical errors arising from the technology itself or from the nature of the interaction between the technology and the clinician in real work contexts (technology-induced errors) (Ammenwerth & Shaw 2005; Horsky et al. 2005; Koppel et al. 2005; Kushniruk et al. 2004).

This new research has called into question previous work that has asserted the value of health information technologies in reducing medical error. It has also led to the development of new research aimed at examining technology-induced error in health informatics and has led to consideration of differing research methods and designs that could be used to study technology-induced error. In this paper, we will describe the use of research methods arising from the usability engineering literature and

their application in the study of technology-induced error for evaluating health information systems. We will begin by providing a discussion of the emergence of usability engineering as an approach that can be applied to the study of technology-induced error. Following this we will present a description of our methodology for evaluating health information systems based on this approach.

Origins of Usability's Importance in Health Informatics

The usability of healthcare information systems has emerged as a critical issue in health informatics. Usability can be defined as a measure of how efficient, effective, enjoyable and safe a computer system is to use (Preece et al. 1994). Many studies have documented the importance of usability in terms of its impact upon the adoption and appropriation of health information systems (physician order entry, clinical documentation) by health professionals (physicians and nurses) (Ash et al. 2003; Sicotte et al. 1998). Studies have underscored the fact that a system will not be used by health professionals in everyday practice unless the system is usable (Ash et al. 2003; Murff & Kannry 2002).

There are many documented cases of organizations that have implemented and deployed health information systems that were later "turned off," boycotted, or were not used to their fullest extent because of health profession dissatisfaction with the health information system (Galanter et al. 1999; Massaro 1993a; Massaro 1993b; Tjora 2000). Such research led to the exploration of the underlying causes for such health professional discontent where the usability of a health information system was concerned (Kushniruk et. al. 1996). Many of these works have attempted to identify and quantify the reasons for health professional dissatisfaction with such systems in hopes that they would lead to improvements in system design and improved success in terms of health professional adoption and appropriation of health information systems (Murff & Kannry 2002).

Application of Usability Techniques in Health Informatics

During the 1990s, methods for assessing usability emerging from the field of usability engineering began to be applied in the design of health information systems (Kushniruk et al. 1996). During this period, usability engineers began to concern themselves with making systems easier to use and learn by attempting to improve their safety, utility, effectiveness and efficiency. Early health information systems were very large, costly to develop and implement, and difficult to use (Shortliffe & Blois 2001). Researchers responded by attempting to understand those aspects of health information system design that make systems difficult to use in real world health care contexts (Tang & Patel 1994; Kushniruk et al. 1996). Although it has been found that there are a number of benefits associated with health information systems use (Bates et al. 1998), some investigators have found that system usability could have a significant and sometimes unintended impact on users' cognitive processes. For example, the particular layout and organization of information presented on a computer screen (i.e., in an electronic health record) to a user (a physician) can have significant impact on how the user interacts in real world work contexts with colleagues and patients. For example, Kushniruk et al. (1996) found that the use of some electronic health records could lead health professionals to become "screen-driven," basing their selection of diagnostic questions posed to patients on the way that information is presented to them by a particular computer system. In some cases, this led to suboptimal diagnostic performance by physicians. In a later study, the impact of the screen layout of information in electronic health records was found to have a profound impact on what data was actually recorded by physicians in doctor-patient interactions, particularly as compared to analysis of data collected by physicians using paper records (Patel et al. 2000). These research findings were used to provide feedback into the design and deployment of health information systems in a process of formative evaluation and iterative systems development, including the design and refinement of Columbia University's PatCIS patient information system and the MED vocabulary (Cimino, Patel & Kushniruk 2001). As a result of usability testing, it has been shown that user satisfaction and adoption of these systems can be improved (Kushniruk & Patel 2004). Such findings have also led to an industry tendency to evaluate a health information system's usability as part of the process of system selection and procurement by healthcare organizations (Ash et al. 2003).

In summary, new methods from the usability engineering literature, some pioneered in health informatics, have been applied to the improvement of user satisfaction with health information systems in order to make user interactions with a computer system more efficient, effective and enjoyable in hopes that it would improve the adoption and appropriation of the health information system (Kushniruk 2002).

Usability and its Application to the Study of Technology-Induced Error

With recent concerns raised over the potential negative impact of poorly designed information technology on facilitating medical errors (Horsky et al. 2005; Koppel 2005; Kushniruk et al. 2004), usability engineering methods (i.e., usability inspection and usability testing) have been applied in the assessment of health information system safety in order to identify and prevent costly medical errors that may arise from the use of health information systems (i.e., technology-induced error) before they are deployed in real world contexts. Specifically, such methods have begun to be applied to the assessment of the

impact of specific user interface features and design choices on medical error (Kushniruk et al. 2004).

There are two major methodological approaches, borrowed from the usability engineering literature, that can be used to evaluate technology-induced error in the health informatics. One approach is termed usability inspection, where systems and their user interfaces are systematically reviewed by analysts who apply design principles to assess their usability. In healthcare, such an approach has been applied by Zhang and colleagues (2003) to analyze the usability and error potential of devices such as infusion pumps. The other main approach is known as usability testing. Usability testing, unlike usability inspection, involves the recording and analysis of the actual process of use of healthcare systems by real users carrying out specific tasks using a computer system. Such an approach has the potential of allowing investigators to identify exactly where errors occur in the dynamic context of system use by representative users carrying out representative tasks for which the system was designed. The application of usability testing to the study of medical error has the potential to provide a powerful methodological approach for identifying technology-induced medical errors, relating usability problems to the occurrence of medical error, and predicting technology-induced medical error prior to system release (Kushniruk et al. 2005). Additionally, the approach is easily extensible to the study of a wide range of healthcare systems and can be carried out by typical healthcare organizations in a highly cost-effective manner given the steadily decreasing cost of basic computer and video equipment required. In the next section of this paper, we will describe how usability testing can be applied under simulated conditions which are representative of real world work situations to assess technology-induced error.

Towards a New Methodology for Analyzing Human Interaction with Health Information Systems to Identify and Prevent Medical Error

As described above, our approach to analysis of technology-induced error typically involves conducting simulations of real healthcare situations. There are a number of motivations for incorporating simulations as part of usability testing when studying technology-induced error: (a) simulations allow for detailed analysis of the process of use of a system prior to its release in hospitals and other organizations, and therefore can be used to predict and prevent technology-induced medical errors before a system is deployed (b) such an approach is of low risk to patients (i.e., no patients are receiving actual care in the evaluation) (Kushniruk et al. 2004; Kushniruk et al. 2005), and (c) such evaluation during any or all of the various stages of system development (from early system design to customization phases) could greatly reduce the risk of death and disability to patients once a health information system is deployed.

The advantage of using simulations is that they can effectively mimic real world situations involving patient care

Methods based on simulations have been used in health informatics to study human-computer interaction in a number of research domains including the study of usability, doctor-patient interactions involving technology, health professional decision making, testing of new devices and medical error (Kushniruk et al. 2004; Kushniruk 2001; Patel et al. 2000). The advantage of using simulations is that they can effectively mimic real world situations involving patient care (i.e., aspects of task urgency and complexity). There are a number of differing types of simulations, including computer-based simulations that attempt to mimic human behaviour (Gaba 2004) and simulations that are developed to test specific system components (Kushniruk et al. 2004). In our work, we utilize a category of simulations that involve real users interacting with systems in simulated environments as they perform realistic tasks, such as entering a medication order. Such simulations can be effectively used to develop, pilot test and evaluate systems across the continuum of the system development life cycle from requirements specification to customization. This may also include use of "standardized patients" who play the part of a patient when observing healthcare professionals using a system while interacting with a patient (as described by Kushniruk et al. 1996).

There are a number of steps that can be carried out in conducting simulation-based studies of technology-induced error in health care (as illustrated in **Figure 1** and described below). Although there may be some variation in the overall

Figure 1. Steps in the Usability-Based Assessment of Technology-Induced Error in Healthcare.

	Activities
Step One	Select representative users
Step Two	Select representative tasks
Step Three	Develop scenarios
Step Four	Select equipment and recording methods
Step Five	Collect video, computer screens and audio data
Step Six	Qualitatively code transcripts and quantify qualitative data

method employed, the development of simulations in our work has typically involved consideration of each of these steps to ensure the generalizability, applicability and value of the findings in informing health information systems development, design and implementation. Initially, the objective of the evaluation needs to be carefully considered prior to designing the study. (Objectives may include testing for technology-induced error arising from programming, assessing usability of the user interface, assessing changes in health professionals' workflow, etc.)

Our methodological approach involves techniques adapted from the area of usability engineering and also the application of simulation of real work contexts, as described in the steps below.

Step 1: User Selection

This crucial step involves the identification and selection of representative users for studying interaction with a particular health information system. Users should be representative of those individuals who will use the system. This may involve prescreening of health professionals in terms of their level of disciplinary, domain and technology expertise (Kushniruk & Patel 2004). It has been shown that as few as 10 users can provide significant feedback about the quality of a health information system, along with specific feedback to designers regarding improvements (Lewis 1994; Nielsen 1993).

Step 2: Task Selection

This stage involves the selection of representative tasks that the users (health professionals) are expected to undertake when using the system under study. A range of tasks could be selected. For example, in the study of errors induced by use of a medication order entry system, this may include presenting users (i.e., physicians) with written descriptions of patient cases (that might include, for example, a prescription list for the patient in the case). The actual patient cases can vary from routine to atypical. Some studies may also involve use of actors playing the role of a patient presenting with a medical problem (i.e., an extension of the standardized patient approach used for assessing residents' interviewing skills in medical education). Users in such studies (i.e., physicians) are observed as they interact with both the simulated patient and the computer system under study (as will be described in a subsequent step) in order to carry out a task. For example, the task in such studies might include instructing the users (i.e., physicians) to carry out an interview with the patient while using the system under study to arrive at a diagnosis and treatment plan (Kushniruk & Patel, 2004).

Step 3: Scenario Design

Scenarios used to drive usability testing can range from simple written medical case descriptions that are given to users to read, to more elaborate scripts to guide actors in playing roles in simulated doctor-patient interactions (Gaba 2004; Kushniruk et al. 2004). Attention should be paid to the attributes or qualitative dimensions of each scenario. Researchers should consider varying levels of scenario complexity, urgency and time constraints in scenario design (Kushniruk & Patel, 2004). Scenarios should also be representative of the range of situations encountered by users from the routine to the atypical to ensure the health information system's limits or boundaries are sufficiently tested (Kaner et al. 1999; Patton 2001).

Step 4: Equipment and Recording Methods

The complexity of the equipment required for simulations varies from low-fidelity to high-fidelity simulations (Gaba 2004; Kushniruk & Patel 2004). A low-fidelity simulation roughly approximates the nature of the real world situation that the simulation is supposed to represent. For example, a simple low-fidelity study may involve presenting physicians with a short written case description of a patient and asking them to enter prescription information about the patient into a physician order entry system while recording the interaction with simple video or audio devices. A high-fidelity simulation would reproduce more closely the real world situation being studied. For example, a simulation may involve actors playing the roles of patients and staff in a clinic in the study of how physicians use of a patient record system. Such a study may involve multiple recording devices to precisely document all user interactions (i.e., audio and video recording of all verbalizations, computer activities and the hospital room or clinic environment in order to document actions).

Step 5: Data Collection

As health professional users carry out the tasks created for the study (i.e., entering medications into a physician order entry system), the process of their interaction with the system under study is recorded in its entirety. We recommend that users' verbalizations be audio recorded. This may involve instructing users to "think aloud" while carrying out a task and tape recording their verbalizations (Ericsson & Simon 1993). Audio data is for the most part a primary source of data providing information about what is being focused on and considered by the users during simulations. Other forms of data can include computer screen recordings of users' interaction with a computer system (obtained by outputting the computer screens into a VCR, using a PC-video converter, or alternatively by using screen recording programs such as HyperCam). In addition, users' physical behaviours can be video recorded. Video data and computer screen recordings can provide additional insights and key findings when triangulated with audio data. Increasingly, the role of computer screen recordings and video data has been demonstrated to inform and contextualize information and can provide additional insights and understanding of underlying

cognitive processes and the effects of computerization upon them. For example, in a recent study examining the relationship between medical error and system usability by Kushniruk and colleagues (2004), video recordings of computer screens were collected in conjunction with audio data consisting of users' verbalizations as they interacted with the system under study. In this study, audio data indicated users believed they had entered the correct prescription when using an electronic prescribing program, while the corresponding video data and computer screen recordings revealed usability issues led users to unknowingly enter incorrect prescriptions. A more detailed description of the approaches, techniques and equipment for conducting such studies in a cost-effective manner is outlined in Kushniruk and Patel (2004).

… corresponding video data and computer screen recordings revealed usability issues led users to unknowingly enter incorrect prescriptions.

Step 6: Data Analysis

The data collected in step 5 (i.e., audio, video and computer screen recordings of users' interactions with a system) can be analyzed to identify: (a) usability problems, (b) medical errors and (c) the relationship between usability problems and medical errors. This typically involves having the audio portion of the data first transcribed in its entirety and then applying coding schemes to facilitate identification of aspects of the user's interaction with the system that are of interest to the investigators. We have employed a number of coding schemes for identifying usability problems, including application of categories for identifying user interface problems (data entry problems, display problems, navigational problems) and problems with the content of a system (information being out of date, defaults for medication dosage presented by the system being inappropriate). In addition, the actual occurrence of medical errors made by a health care professional (i.e., entering an incorrect medication) are also identified from analysis of the video and audio recordings of a user's interaction with the system under study.

An example of a coded transcript illustrating the relationship between usability problems and technology-induced medical error is given in **Table 1**. In the example, a physician user enters a medication into a medication order entry system. In Table 1 the audio portion of the subject's "thinking aloud" is given in the left-hand column. The corresponding human-computer interactions are recorded using video and are given in the second column. In this example, the user enters a medication (Tylenol), its dosage (two tablets) and frequency (q6h). The system responds with a menu that has defaulted to an inappropriate frequency. However, the user's final action is to submit the order and consequently the wrong frequency is entered into the system. This is indicated in the third column as a usability problem ("default frequency is inappropriate") and as a medical error shown in the fourth column ("wrong frequency recorded in system"). This approach can be used to identify the relationship between specific usability problems and medical errors.

Qualitative data (coded verbal transcripts and coded observations from video data or recorded computer screen information) can be converted into quantitative data by (Barbour 1998; Sandelowski 2000) tabulating the frequencies for each coded category (usability problems and medical error) in the transcribed data, and then inferential statistics can then be applied (Patel et al. 2000). For example, the

Table 1. An example of a coded segment illustrating a medical error related to a usability problem (i.e., an inappropriate default).

Audio	Video	Usability Problem	Medical Error
"I am entering an order for Tylenol number three q6h prn [i.e., every six hours as needed]. Okay, it looks fine and I'll enter the prescription now."	User Action: Clicks on Tylenol number three from drug drop- down menu list. User Action: Clicks on two tablets from the dose drop-down list. User Action: Clicks on q6h from the frequency drop-down list. System Response: Default of q4h reappears for frequency. User Action: Clicks OK for ordering prescription.	Default frequency is inappropriate After input of q6h (i.e., frequency every 6 hours), the default of q4h reappears (i.e., frequency of every 4 hours). However, the user does not notice the system's response (with the inappropriate frequency).	Wrong frequency recorded in system.

number of medication errors that occur when physicians use a medication order entry system during simulation testing can be quantified. Each category of usability problems identified in the users' interactions with the system (using the coding scheme) can also be quantified (problems related to specific issues such as appearance of inappropriate dosage defaults on a menu, navigational problems with the user interface, etc.) and related to the occurrence of actual medication errors (see Kushniruk et al. 2005).

Example: Use of Simulation in the Study of Technology-Induced Error

In our current work, we have found that simulation methods provide a powerful approach for the analysis of errors resulting from user interactions with healthcare information systems. For example, in a recent study we conducted involving a physician order entry system, a simulation was used where physicians' interaction with a prescribing program were video and audio recorded and then transcribed (Kushniruk et al. 2005). Specifically physicians were asked to "think aloud" as they entered prescriptions from written text into a handheld prescribing program. They were also given scenarios (in the form of short written cases) to respond to and enter prescriptions for. The transcriptions from these sessions were coded to identify usability problems using a theoretically based coding scheme (identification of navigational problems, display visibility problems, etc.) as well as being coded to identify actual medication errors (incorrect dosages entered into the system). The statistical correlation between the occurrence of coded usability problems and medication errors was calculated in order to determine the predictive power of the usability coding in identify potential occurrences of medication error. From this study, it was found that 100% of the actual errors in medication entry made by physician users during the simulation could be predicted by the occurrence of independently coded usability problems.

We are currently following up with naturalistic study to determine if the error rates observed in the laboratory are the same or different in the naturalistic (clinical) setting. One approach we are using here is application of a remote tracking system we have developed known as the "Virtual Usability Laboratory" (VUL), which allows for tracking of computer screens as users interact with a system under study (described in detail in Kushniruk & Ho 2004).

Conclusions

In this paper, we have described our work in the development, refinement and application of a new approach to the assessment of technology-induced errors based on the study of human interaction with a health information system under simulated conditions. The approach builds on previous work in the area of usability engineering (Kushniruk et al. 1996) and leads to a rich collection of qualitative as well as quantitative data. In addition, the approach can be used throughout the system development life cycle, from analysis of user needs (as a basis for system design) to assessment of the impact of health information systems upon technology-induced error. Results from such study can guide and provide focus for the improvement of health information systems before they are deployed in real world clinical settings.

There is a need to develop and employ new research methods that identify sources of technology-induced error before a system is deployed in an organization. Usability-based methods (involving simulations) allow one to determine the specific origin of errors while providing systems designers with feedback about how best to redesign a system to prevent technology-induced errors. Work on health information systems quality is needed to prevent errors before they occur; however, previous studies (Koppel and colleagues 2005) have focused on technology-induced error identified after the system under study has already been deployed in real work settings. There is a need to evaluate systems before they are used in real clinical situations and to develop best practices based on ongoing health information systems research throughout systems development to inform system designers and develop design standards that reduce the likelihood of technology-induced error, as has been done in other industries such as aviation. After all, what passenger or commercial pilot would fly in a plane that hasn't been properly tested for the presence of technology-induced errors?

References

American Hospital Association. 1999. *Hospital Statistics*. American Hospital Association, Chicago, IL.

Ammenwerth, E. and N.T. Shaw. 2004. "Bad Informatics Can Kill – Is Evaluation the Answer?" *Methods of Information Medicine* 44(1): 1–3.

Ash, J. S., P.Z. Stavri and G.J. Kuperman. 2003. "A Consensus Statement on Considerations for a Successful CPOE Implementation." *JAMIA* 10(3): 229–234.

Baker, G. R., P.G. Norton, V. Flintoft, R. Blais, A. Brown, J. Cox, E. Etchells, W.A. Ghali, P. Hébert, S.R. Majumdar, M. O'Beirne, L. Palacios-Derflingher, R.J. Reid, S. Sheps and R. Tamblyn. 2004a. "The Canadian Adverse Events Study: The Incidence of Adverse Events Among Hospital Patients in Canada." *Canadian Medical Association Journal* 70: 1678–1686.

Babour, R. 1998. "The Case of Combining Quantitative Approaches in Health Services Research." *Journal of Health Services Research Policy* 4(1): 39–43.

Baker, G. R. and P. Norton. 2004. "Addressing the Effects of Adverse Events: Study Provides Insights into Patient Safety at Canadian Hospitals." *Healthcare Quarterly* 7(4): 20–21.

Bates, D. W., L.L. Leape, D.J. Cullen, N. Laird, L.A. Petersen, J.M. Teich, E. Burdick, M. Hickey, S. Kleenfield, B. Shea, M.Vander Bliet and D.L Sager. 1998. "Effect of Computerized Physician Order Entry and a Team Intervention on Prevention of Serious Medication Errors," *JAMA* 280(15): 1311–16.

Cimino, J. J., V.L. Patel and A.W. Kushniruk. 2001. "Studying the Human-Computer-Terminology Interfact." *Journal of the American Medical Informatics Association* 8: 163–73.

Ericsson, K. A., H.A. Simon. 1993. Protocol Analysis: Verbal Reports as Data (2nd ed.). Cambridge, MA: MIT Press.

Gaba, D. 2004. "The Future Vision of Simulation in Health Care." *Quality and Safety in Health Care* 13(1) supplement: 12–20.

Galanter, W. L., R.J. Di Domenico and A. Polikaitis. 1999. "Preventing Exacerbation of an ADE with Automated Decision Support." *Journal of Healthcare Information Management* 16(4): 44–48.

Horsky, J., J. Zhang and V.L. Patel. 2005. "*To Err is Not Entirely Human: Complex Technology and User Cognition*." *Journal of Biomedical Informatics* (in press).

Institute of Medicine. 2000. *To Err is Human: Building a Safer Health Care System.* Washington. D.C.: National Academy Press.

Kaner, C., J. Falk and H.Q. Nguyen. 1999. *Testing computer software* (2nd ed.). New York, NY: Wiley & Sons.

Koppel, R., J.P. Metlay, A. Cohen, B. Abaluck, R. Localio, S.E. Kimmel and B.L. Strom. 2005. "Role of Computerized Physician Order Entry Systems in Facilitating Medication Errors." *JAMA* 293: 1197–03.

Kushniruk, A.W. 2001. "Analysis of Complex Decision-Making Processes in Health Care: Cognitive Approaches to Health Informatics." *Journal of Biomedical Informatics* 34(5): 365–76.

Kushniruk, A.W. 2002. "Evaluation in the Design of Health Information Systems: Application of Approaches Emerging from Usability Engineering." *Computers in Biology and Medicine* 32: 141–49.

Kushniruk, A. W. and F. Ho. 2004. "The Virtual Usability Laboratory." In the Proceedings of *E-Health* 2004. Victoria, BC. May 2004.

Kushniruk, A.W., D.R. Kaufman, V.L. Patel, Y. Levesque and P. Lottin. 1996. "Assessment of a Computerized Patient Record System: A Cognitive Approach to Evaluating an Emerging Medical Technology." *MD Computing* 13(5): 406–15.

Kushiniruk A., B. Triola, B. Stein, E. Borycki and J. Kannry. 2004. "The Relationship of Usability to Medical Error: An Evaluation of Errors Associated with Usability Poblem in the Use of a Handheld Application for Prescribing Medications. *Medinfo* 2004: 1073–76.

Kushniruk, A., B. Triola, E. Borycki, B. Stein and J. Kannry. 2005. "Technology Induced Error and Usability: The Relationship Between Usability Problems and Prescription Errors When Using a Handheld Application." *International Journal of Medical Informatics* 74(7–8): 519–26.

Kushniruk, A.W., D.R. Kaufman, V.L. Patel, Y, Levesque and P. Lottin. 1996. "Assessment of a Computerized Patient Record System: A Cognitive Approach to Evaluating Medical Technology." *MD Computing* 13(5): 406–15.

Kushniruk, A.W. and V.L. Patel. 2004. "Cognitive and Usability Engineering Approaches to the Evaluation of Healthcare Information Systems." *Journal of Biomedical Informatics* 37: 56–76.

Lewis, J. R. 1994. "Sample Sizes for Usability Studies: Additional Considerations." *Human Factor* 36(2): 368–78.

Lowery, J. C. and J.B. Martin. 2001. "Evaluation of Healthcare Software from a Usability Perspective." *Journal of Medical Systems* 14(1–2): 17–29.

Massaro, T. A. 1993a. "Introducing Physician Order Entry at a Major Academic Medical Centre: Impact on Organizational Culture and Behaviour." *Academic Medicine* 68(1): 25–29.

Massaro, T. A. 1993b. "Introducing Physician Order Entry at a Major Academic Centre: Impact on Medical Education." Academic Medicine 68(1): 25–29.

Murff, H. J. and J. Kannry, J. 2002. "Physician Satisfaction with Two Order Entry Systems." JAMIA 8(5): 499–509.

Nielsen, J. 1993. *Usability Engineering*. Boston, MA: Academic Press.

Patel V. L., A.W. Kushniruk, S. Yang and J.F. Yale. 2000. "Impact of a Computer-Based Patient Record System on Data Collection, Knowledge Organization and Reasoning." *Journal of the American Medical Informatics Association* 7(6): 569–85.

Patton, R. 2001. Software Testing. Indianapolis, IN: SAMS.

Preece, J., H. Sharp, D. Benyon, S. Holland and T. Carey. 1994. *Human-Computer Interaction*. Don Mills, ON: Addison-Wesley.

Shortliffe, E. H. and M.S. Blois, M. S. 2001. The Computer Meets Medicine and Biology: 3–40. In E. H. Shortliffe, L. E. Perreault, G. Wiederhold and L. M. Fagan (eds.). *Medical Informatics: Computer Applications in Health Care and Biomedicine* (2nd ed.). New York, NY: Springer Verlag.

Sandelowski, M. 2000. "Combining Qualitative and Quantitative Sampling, Data Collection and Analysis Techniques in Mixed-Method Studies." *Research in Nursing and Health* 23: 2046–55.

Sicotte, C., J.L. Denis, P. Lehoux and F. Champagne. 1998. "The Computer-Based Patient Record Challenges: Towards Timeless and Spaceless Medical Practice." *Journal of Medical Systems* 22(4): 237–56.

Tang, P. C. and V.L. Patel. 1994. "Major Issues in User Interface Design for Health Professional Workstations: Summary and Recommendations." *International Journal of Biomedical Computing* 34(1–4): 139–48.

Tjora, A. H. 2000. "The Technological Mediation of Nursing-Medical Boundary." *Sociology of Health and Illness* 22(6): 721–41.

Wilson, R. M., B.T. Harrison, R.W. Gibberd and J.D. Hamilton. 1999. "An Analysis of the Causes of Adverse Events from the Quality in Australian Health Care Study." *Medical Journal of Australia* 170(9): 411–15.

Zhang, J., V.L. Johnson, V.L. Patel, D. Paige and T. Kubose. 2003. Usability Heuristics to Evaluate Patient Safety of Medical Devices. *Journal of Biomedical Computing* 36(1/2): 23–24.

About the Authors

Andre Kushniruk School of Health Information Science, University of Victoria, Human and Social Development Building A202, 3800 Finnerty Road (Ring Road), Victoria, BC, Canada,V8P 5C2

Elizabeth Borycki School of Health Information Science, University of Victoria, Human and Social Development Building A202, 3800 Finnerty Road (Ring Road), Victoria, BC, Canada,V8P 5C2; School of Nursing, University of Victoria, Victoria, BC, Canada, V8P 5C2; Department of Health Policy, Management and Evaluation, University of Toronto, McMurrich Building, Queen's Park Circle, Toronto, ON, Canada

Corresponding Author: Elizabeth Borycki, Assistant Professor, School of Health Information Science, University of Victoria, Human and Social Development Building A202, 3800 Finnerty Road (Ring Road), Victoria, BC, Canada, V8P 5C2, Email address: emb@uvic.ca, Tel: (250) 721-8576, Fax: (250) 472-4751

HEALTHCARE QUARTERLY: Best practices, policy and innovations in the administration of healthcare. For administrators, academics, insurers, suppliers and policy leaders. *Edited by* Dr. Peggy Leatt, University of North Carolina, Chapel Hill ✦ CANADIAN JOURNAL OF NURSING LEADERSHIP covering politics, policy, theory and innovations that contribute to leadership in nursing administration, practice, teaching and research. Peer reviewed. *Edited by* Dr. Dorothy Pringle, University of Toronto, Toronto ✦ HEALTHCARE PAPERS: Review of new models in healthcare. Bridging the gap between the world of academia and the world of healthcare management and policy. Authors explore the potential of new ideas. *Edited by* Dr. Peggy Leatt, University of North Carolina, Chapel Hill. ✦ HEALTHCARE POLICY: Healthcare policy research and translation. Peer reviewed. For health system managers, practitioners, politicians and their administrators, and educators and academics. Authors come from a broad range of disciplines including social sciences, humanities, ethics, law, management sciences, and knowledge translation. *Edited by* Dr. Brian Hutchison, McMaster University, Hamilton. ✦ ELECTRONIC HEALTHCARE: Best practices, policy and innovations exploring e-models, e-practices and e-products for e-health. For administrators, academics, insurers, suppliers and policy pundits. *Edited by* Dr. Michael Guerriere, University of Toronto, Toronto and Denis Protti, University of Victoria, Victoria. ✦ LAW & GOVERNANCE: Within the framework of the law and the role of governance providing policies, programs, practices and opinions for the providers, administrators and insurers of healthcare services. *Editorial Chair.* Dr. Kevin Smith, McMaster University, Hamilton. ✦ HRRESOURCES: Cases, commentary and policy reviews for healthcare clinicians, human resources managers and the policy leaders, insurers, academics, administrators, boards and advisors of all healthcare organizations. *Editorial Chair.* Dr. Louise Lemieux-Charles, University of Toronto, Toronto. ✦ JOURNAL OF WORLD HEALTH & POPULATION: Best practices, policy and innovations in the administration of healthcare in developing communities and countries. For administrators, academics, researchers and policy leaders. Includes peer reviewed research papers. *Edited by* Dr. John Paul, University of North Carolina, Chapel Hill. ✦ LONGWOODS.COM: Enabling excellence in healthcare. Providing electronic access to news, information, career opportunities, conference schedules, research, case studies, policy reviews and commentary that cover politics, policy, theory, best practices and innovations in healthcare.

Reports of Preventable Medical Errors from the Alberta Patient Safety Survey 2004

Laura C. Vanderheyden, Herbert C. Northcott, Carol E. Adair, Charlene McBrien-Morrison, Lynn M. Meadows, Peter Norton and John Cowell

Abstract

The Health Quality Council of Alberta (HQCA) is charged with reporting to Albertans on the quality, safety and performance of the healthcare system. In 2004, the HQCA conducted a telephone survey (response rate: 55%) of 1,500 adult Albertans to assess their perceptions of and personal experiences with preventable medical errors (PMEs). A total of 559 (37.3%) respondents reported that they or a family member had ever experienced a PME. The most common PMEs were related to clinical performance (n=128), medication (n=123), diagnosis (n=121) and communication (n=73). Through this research, patients have provided an orientation to interventions to improve patient care and prevent medical errors.

Introduction

Patient safety, including the occurrence of medical errors or adverse events (AEs), is receiving increasing attention in Canada (Baker et al. 2004). Some AEs are unavoidable, some are potentially preventable (Baker et al. 2004) and the severity of others can be reduced (Baker and Norton 2004). AEs may result in a variety of undesirable consequences, including death, disability or other physical harm (Baker et al. 2004; Blendon et al. 2002; Kuzel et al. 2004), psychological harm (Kuzel et al. 2004), additional or prolonged treatment (Blendon et al. 2002), or an increased financial burden to the healthcare system (Baker et al. 2004).

Most AE research has focused on hospital patients with data drawn from hospital records. Through a review of hospital charts at Canadian acute care hospitals in 2000, the AE rate was estimated at 7.5%, over one-third (36.9%) of which were preventable (Baker et al. 2004). Similar results have been obtained in studies conducted in Britain (Vincent et al. 2001), New Zealand (Davis et al. 2001) and the United States (Tomas et al. 2000). In a study of the internal medicine service at one Canadian hospital, researchers interviewed patients discharged over a 14-week period and found that 23% reported an AE after discharge, half of which were preventable or ameliorable (Forster et al. 2004).

Community-based studies, including surveys of the general population, have been less common than those of hospital

While it is believed that none of the authors of this article are in any conflict of interest, this article is based on two reports prepared for the Health Quality Council of Alberta (HQCA). One report was prepared by Laura Vanderheyden and the other by Herbert Northcott. Both Laura Vanderheyden and Herbert Northcott prepared their reports while acting as paid consultants to the HQCA. In addition, Carol Adair's role in this research was as a paid consultant to the HQCA.

The Health Quality Council of Alberta is an arm's length organization empowered and funded by the Government of Alberta through the Minister of Health and Wellness to report directly to Albertans on the quality, safety and performance of the healthcare system.

patients (Baker and Norton 2004). In one Canadian survey in 2003, 24% of respondents reported that they or a family member had ever experienced a preventable AE, 52% of which had serious consequences (Canadian Institute for Health Information 2004). In a 2002 national survey of physicians and the public in the United States, 35% of physicians and 42% of the public reported that they or a family member had ever experienced a medical error (Blendon et al. 2002). This study focused on opinions about medical error and did not solicit information on respondents' experiences with medical error.

In response to the growing concern over medical errors, in 2003 the Canadian government created the Canadian Patient Safety Institute and in 2004 the Alberta government added patient safety to the mandate of the Health Quality Council of Alberta (HQCA: formerly the Health Services Utilization Commission established in 2001). The HQCA is charged with reporting to Albertans on the quality, safety and performance of the healthcare system. Accordingly, in 2003 the HQCA surveyed Albertans to assess their perceptions of and actual experiences with health services. Concern about medical errors emerged as the second most important factor associated with overall quality in the healthcare system, second only to accessibility (Health Services Utilization and Outcomes Commission 2003). Furthermore, 14% of those surveyed reported that they or a family member had experienced a medical error within the past year that resulted in serious harm, such as death, disability, or prolonged treatment. These results were corroborated by a 2004 survey in which 13% of those surveyed reported that they or a family member had experienced a medical error within the past year (HQCA 2004). In the spring of 2004, the HQCA sponsored a subsequent survey to further explore patient safety issues. This article reports findings from that survey, focusing on patients' experiences with preventable medical error (PME) and their descriptions of the most recent PME that they or a family member had experienced.

Methods

A representative sample of 1,500 adult Albertans (over 17 years of age) was surveyed. The sample was stratified by age, gender and regional health authority (RHA) and included 400 respondents each from the Calgary and Capital (Edmonton area) RHAs and 100 respondents from each of the remaining seven RHAs. The sample was weighted to represent the provincial population, given that the Calgary and Capital RHAs were under-sampled, while the smaller RHAs were over-sampled. The final sample provided estimates that are accurate to within plus or minus 2.5%, 19 times out of 20.

The Alberta Patient Safety Survey 2004 was administered by trained interviewers using a computer-assisted telephone interviewing system in April and May of 2004. Households were selected by random digit dialling and the individual in the household with the most recent birthday was selected for interview. The response rate w as 55%, calculated as total number of completed questionnaires over total completed plus refusals plus those who could not participate due to communication and language problems.

Concern about medical errors emerged as the second most important factor associated with overall quality in the healthcare system.

The questionnaire was adapted from a structured questionnaire developed and administered in the United States by Blendon et al. (2002). Items were modified to be appropriate to the Alberta healthcare system and open-ended items were added to solicit detail on experiences with PME. PMEs were defined as mistakes resulting in serious harm, such as death, disability or additional prolonged treatment that occurred while receiving medical care.

The questionnaire was pretested to ensure it could be appropriately administered by interviewers and questions were clear to respondents. Following the pretest, minor changes were made to refine the questionnaire. Closed-ended questions elicited perceptions of PMEs in general. In addition, respondents were asked if they or a family member had ever experienced a PME. Those who responded yes were asked to share the details of the most recent PME. Further closed-ended questions sought details regarding health consequences of the error, persons or institutions responsible and disclosure of the error. Open-ended questions were: What was the error? What do you think caused the error? How could the error have been prevented?

Responses to closed-ended questions are reported as frequency distributions. A content analysis (Crabtree and Miller 1999) was performed on the open-ended questions. The coding template that was applied to open-ended data began with three category headings: types of errors, perceived causes, and beliefs regarding prevention. Detailed subcategories were developed within these categories through several iterations of reading the data to ensure the analysis accurately reflected respondents' descriptions. Frequencies were calculated at the subcategory level and themes were identified (Crabtree and Miller 1999).

To assess reliability of the coding template, before data analysis began two coders (LV and CMM) independently applied the template to a random sample of the data. Results were compared and inter-rater reliability was assessed at 0.81 (81% agreement).

Table 1: Demographic Characteristics of Respondents to the Alberta Patient Safety Survey 2004

Demographic Characteristics	Respondents who Experienced PME		All Other Respondents	
	number	%	number	%
Total	559		941	
Female	320	57.3	438	46.5
Male	239	42.7	503	53.5
X2=15.7, df=1, p=.0001				
Age: 18 – 24 years	62	11.1	144	15.3
25 – 44 years	244	43.6	374	39.7
45 – 64 years	192	34.4	277	29.5
65 years +	60	10.8	146	15.5
X2=14.2, df=3, p=.003				
Income: < $30,000	90	16.1	158	16.8
$30,000–59,999	171	30.6	282	29.9
$60,000–99,999	135	24.1	251	26.7
$100,000 +	106	19.0	159	16.9
No response	57	10.1	91	9.6
X2=2.0, df=4, p=.73				

Results

A total of 37.3% (95% CI 34.8%-39.8%) of respondents reported that they or a family member had ever experienced a PME while receiving healthcare service within Alberta. Females were more likely than males (p=0.0001) and individuals aged 25 to 64 years were more likely than older or younger individuals (p=.003) to have experienced a PME (**Table 1**).

Of those who reported having experience with PME, over half (54.2%, n=302) said the most recent error had one or more serious health consequence, including significant loss of time at work, school or other important life activities (79.1%), severe pain (78.2%), temporary disability (64.3%), long-term disability (53.6%), death of a family member (35.7%) and other serious health consequences (40.7%). Other reported serious health consequences were grouped into five categories: 1. *physical* (e.g., loss of limb, brain damage); 2. *psychological* (e.g., depression, panic or anxiety; suicidal thoughts), 3. *treatment* (e.g., further, prolonged or subsequent treatment or hospitalization), 4. *financial* (e.g., lost income, unnecessary costs to the healthcare system) and 5. *social* (e.g., unable to meet family obligations, personal relationships affected).

Respondents were most likely to assign responsibility for the most recent PME to doctors (66.7% said doctors had a lot of responsibility) in comparison to nurses (21.6%), other health professionals (17.7%) or the institutions involved (29.5%). About one-third (31.9%) said they had been told an error had been made and 30.0% said the doctor or health professionals involved had apologized. Only 3.9% indicated they or their family member sued the health professional for malpractice.

Of those respondents who had experience with a PME, 79.1% (n=435) agreed to share the details about the most recent PME that occurred. The following results use the respondents' language as much as possible to reflect their personal account of the experience.

Reported Types of Medical Errors

Respondent descriptions of the types of PME (n=539; some narratives described more than one PME) they or a family member had experienced most recently were grouped into 12 categories with subcategories (**Table 2**). The most common categories of described PMEs were related to clinical performance (n=128, 23.7%), medication (n=123, 22.8%), diagnosis (n=121, 22.4%) and communication (n=73, 13.5%). In the clinical performance category, 54 narratives (42.2%) were related to the belief that a practitioner did not properly follow a procedure; for example, if a surgical incision was not properly cleaned. In the medication category, 53 narratives (43.1%) were related to receiving the wrong prescription. The diagnosis category was dominated by narratives related to misdiagnosis (n=72, 59.5%).

Perceived Causes of Medical Errors

Respondents' beliefs regarding the causes of the most recently experienced PME (n=596; some narratives identified more than one cause) were grouped into eight categories with subcategories (**Table 3**). The most frequently mentioned categories of perceived causes were: clinical performance (n=161, 27.0%), practitioner attitude (n=136, 22.8%), lack of communication (n=91, 15.3%) and practitioner education or knowledge (n=73, 12.2%). The clinical performance category included narratives describing perceived practitioner negligence or incompetence (n=36, 22.4%) and of perceptions that practitioners were not paying attention to their patients (n=33, 20.5%). One-quarter (n=35, 25.7%) of the narratives in the practitioner attitude category were regarding a perceived lack of caring by a practitioner towards their patient.

Beliefs Regarding How Medical Errors Could Have Been Prevented

Respondent beliefs regarding how the PME could have been prevented (n=920) were varied. Responses were grouped into categories and subcategories, but no primary category emerged as the most prevalent. Respondents were most likely to say that their PME could have been prevented if a practitioner had

Table 2: Reported Types of Medical Errors

Categories and Subcategories of Medical Error	Number of Reports	
	Categories	Sub-Categories
Clinical Performance	128 (23.7%	
Did not follow protocol or complete procedure properly		54
Procedure did not go as intended (i.e., mistake)		39
Did not look into problem thoroughly enough		14
Made incorrect decision regarding care		10
Improperly read test results or patient chart		6
Not prepared for patient or procedure		5
Medication	123 (22.8%)	
Wrong prescription given/received		53
Incorrect dose		24
Adverse reaction		13
Not given when needed		16
Drug interaction		9
Medicated too long		3
Unnecessary		3
Ingredients not listed properly		1
Wrong route of administration		1
Diagnosis	121 (22.4%)	
Misdiagnosis		72
Delayed Diagnosis		45
Inappropriate or unnecessary diagnostic tests		4
Communication	73 (13.5%)	
Did not listen to patient		18
Not enough or incorrect information given to patient		12
Mix up with patient charts or treatments		12
Different clinics, etc., did not communicate efficiently or effective		11
Did not read patient chart		7
Did not report or record patient complications or related events in patient chart		7
Did not read or follow instructions left by other practitioner		3
Did not ask relevant questions before administering treatment		3
Patient Management	34 (6.3%)	
Improper monitoring, supervision or follow up		16
Inappropriate care		15
Taken to wrong hospital/put in wrong ward		3
Time	21 (3.9%)	
Waited too long for treatment or testing	12	
Waited too long for emergency physician	4	
Did not take time to look into problem thoroughly enough	2	
Delay in receiving test results	2	
Not enough time in hospital	1	
Surgery	13 (2.4%)	
Complications	6	
Unnecessary	4	
Inappropriate	2	
Inadequate supplies	1	
Therapy	10 (1.9%)	
Wrong		3
Not received		3
Delayed		3
Unnecessary		1
Practitioner Attitude or Disposition	8 (1.5%)	
Rude		7
Did not want to perform procedure (too risky)		1
No improvement in condition	4 (0.7%)	
Inefficiency with time or resources	2 (0.4%)	
Lack of procedures	2 (0.4%)	
Total*	539	

*Some respondents indicated more than one category of error for the PME they most recently experienced.

completed further diagnostic tests or looked into a problem more thoroughly (n=97, 10.5%); a practitioner had followed a procedure correctly (n=84, 9.1%); a second opinion had been received or a procedure had been double checked (n=75, 8.2%); a practitioner had paid increased attention to or listened to a patient (n=62, 6.7%); there had been better communication between healthcare professionals (n=58, 6.3%); and a practitioner had cared more for a patient or their treatment (n=54, 5.9).

Themes

Four themes emerged from the detailed accounts of the most recent PME.

Communication. Some respondents felt they were not listened to or heard by their health professionals. They felt they did not have a voice and that their concerns, issues and opinions were not valued. They felt they did not have a say in their treatment decisions, but should have.

The healthcare system is stressed and overloaded. Many respondents indicated that the healthcare system is stressed and overloaded. This theme is evident in comments about health professionals being overworked, working shifts that are too long, not having a long enough break between shifts and having too many patients, as well as there not being enough hospitals, money and resources in the system.

Negative Practitioner Attitudes. The attitudes of individual practitioners were often seen as an immediate cause of an error and improving attitudes was seen as a strategy to improve the healthcare system and prevent future errors. While often discussed in relation to communication and an overloaded system, many respondents felt that their practitioner was arrogant, lazy, rushed, did not care about them or their concerns, was overconfident or did not have people skills.

Team-oriented Care. Many respondents stated that a team approach to healthcare would have prevented many errors. Respondents identified many situations where errors were perceived to have occurred as a result of poor communication and a lack of coordination and cooperation. For example, PMEs were perceived to have occurred as a result of inappropriate followup or because all necessary viewpoints, such as that of a pharmacist, a nutritionist and a general practitioner, were not considered.

Discussion

The Alberta Patient Safety Survey was the first in Canada to explore PMEs from the patient perspective. This research has produced preliminary taxonomies of errors reflecting patient views of types of error that occur, causes and strategies for prevention. Patients appear to blame individuals, versus the system, for errors and seem to be more concerned with the process by which errors occur versus the errors themselves. For example, patients appear to emphasize a practitioner who did not seem to care about them, rather than being misdiagnosed, and seem to blame the practitioner for the misdiagnosis versus a lack of clinical practice guidelines (a system problem), for example. This perspective contrasts with the medical error literature, which emphasizes system problems as the primary cause of errors (Leape et al. 2002). A likely reason for this difference in perspective is that a patient's experience with the system is often limited to contact with one practitioner and patients do not have the same level of understanding of the system as do practitioners and researchers. It is becoming apparent that medical errors are multifactorial and may be caused by one or many components in a complex web of events. Such an understanding of medical errors has long been recognized in the patient safety literature, but has not percolated into public understanding. Perhaps, as the healthcare system moves towards a more open and transparent environment around the disclosure of medical errors that result in patient harm, a shift in patient perspectives towards a more comprehensive understanding of medical errors may result.

Kuzel et al. (2004) have proposed a broad definition of medical errors: "all forms of improper, delayed or omitted care that unnecessarily injures patients by either worsening health outcomes or causing physical or emotional distress." This definition, although appropriately encompassing patient views as suggested by the current study, blurs the line between patient satisfaction and medical error — a line that hinges on what is accepted as legitimate harm. Research from a physician and administrator perspective typically recognizes physical harm, including death, and additional treatment as the only legitimate consequences of errors (Baker et al. 2004; Blendon et al. 2002; Kuzel et al. 2004). Patient-centred research suggests that psychological and social consequences (Berwick 2005; Kuzel et al. 2004) should also be recognized. The patient perspective broadens the definition of error, but identifies meaningful points of intervention to potentially reduce preventable harm and improve patient care.

The Alberta Patient Safety Survey 2004 has provided insight into how the adult public who have experienced PME perceive the healthcare system. Some feel the system is set up so they cannot be heard or listened to; it is inadequately funded; there is little encouragement for cooperation and consultation; and some feel that some practitioners have a negative attitude toward their jobs and patients. The language used by respondents to describe their experiences with PME was often harsh. Terms such as negligence, incompetence, arrogance and laziness were not uncommon. While these results are of concern, they must be taken in context. The opinions expressed in this study were provided while describing experienced PMEs, and therefore reflect only the views of individuals who are describing a negative experience with the system but who otherwise may

Table 3: Perceived Causes of Medical Errors

Categories and Subcategories of Perceived Cause	Number of Reports		Categories and Subcategories of Medical Error	Number of Reports	
	Categories	Sub-Categories		Categories	Sub-Categories
Clinical Performance	161 (27.0%)		Did not listen to or talk to patient/family		14
Negligence/incompetent		36	Did not provide patient with appropriate information		8
Not enough attention to patient or inattentive		33	Practitioner did not ask relevant questions		6
Outlined/standard procedure not followed		23	Did not record information properly		4
Human error, or mistake made while following correct procedure		21	Did not refer when necessary		3
Not thorough examination before diagnosis		16	Poor handwriting		2
Poor or incorrect decision regarding care		15	Did not have sufficient patient records		1
Misunderstanding/improper reading of test results or prescription		7	Pharmaceutical improperly labelled		1
Improper preparation for a procedure		7	Patient did not ask relevant questions		1
Did not consult necessary resources		2	Did not work with patient to find suitable treatment		1
Practitioner was not available when needed		1	Language barriers		1
Practitioner attitude/disposition	136 (22.8%		Practitioner Knowledge or Education	73 (12.2%	
Lack of caring/Uncaring		35	Lack of knowledge on patient condition or treatment		31
Too busy/rushing		27	Poor/insufficient training of practitioners		14
Assumption knows problem/overconfidence		21	Individual lack of experience		12
Fatigue/overwork		18	Individual lack of skill		11
Arrogance		16	Two (or more) diseases share the same symptoms		3
Practitioner was too old		5	Systemic lack of information on new drugs		2
Lazy		3	System	63 (10.6%)	
Optimism		3	Limited resources/cutbacks		25
Discrimination		2	Professionals have too many patients		18
Personal concerns		2	Poor supervision of practitioners or students		7
No people skills		2	Lack of procedures		5
Practitioner was under the influence of alcohol		1	Cost-focused versus patient-focused		5
Concerned regarding risk factors		1	Does not hold physicians accountable		2
Lack of Communication	91 (15.3%)		Pressure to not prescribe antibiotics		1
Same institution – between professionals		20	Time	56 (9.4%)	
Different institutions – between professionals		15	Not enough time with doctor		13
Did not read patient chart		14	Delay in referral (e.g., specialist, surgery, testing)		13
			Not enough time spent diagnosing a patient (incl. diagnostic tests)		12

Categories and Subcategories of Medical Error	Number of Reports	
	Categories	Sub-Categories
Delay in receiving treatment/procedure/diagnosis		7
Not enough time spent on a procedure		7
Not enough time for proper monitoring or followup		2
Drs not taking time to discuss patient amongst each other		1
Not enough time for doctor-patient followup		1
Treatment or Diagnostic Procedure	13 (2.2%)	
Difficult in nature		7
Equipment/supply error		4
Rare disease/condition		1
Two or more drugs share a similar name		1
Patient Characteristics or Behaviour	3 (0.5%)	
Patient did not follow recommended treatment		1
High-risk patient		1
Patient did not take enough responsibility		1
Total*	596	

*Some respondents indicated more than one cause for the PME they most recently experienced.

be satisfied with their healthcare. Nevertheless, patients have provided some general orientation to prevention strategies that can be explored by healthcare administrators and decision-makers to increase patient confidence and to potentially prevent medical errors. Patient-practitioner communication is of central importance. From a patient perspective, practitioners who care about their job and their patients, who listen to and respect their patients and who take the time to provide information and respond to patient concerns are more likely to prevent an error from occurring. Further, patients appear to be responding to government and media messages regarding the ideal of an integrated healthcare system, where physicians, nurses, pharmacists and other community-based practitioners work together to provide patient-focused care. From a patient perspective, improved coordination and cooperation of various providers across the healthcare system could improve patient care and reduce PMEs.

From a patient perspective, improved coordination and cooperation of various providers across the healthcare system could improve patient care and reduce PMEs.

The Alberta Patient Safety Survey 2004 had several potential limitations. First, it is increasingly difficult to get high response rates in telephone surveys given that more people are screening incoming calls and are opting for cell phones in place of landlines. As a result, there may be bias in selection of the sample. A telephone survey was the preferred design, however, as complete information, which is more probable with telephone surveys versus postal surveys, for example, as the goal. Second, respondents were asked to describe PMEs that either they or a family member had experienced at any point during their lives in Alberta, which casts a broad net. Responses therefore may not be entirely representative of the current situation or reflective of the range of errors that may occur. Finally, beyond the three open-ended interview questions, interviewers were not instructed to probe for further details or clarification of respondents' descriptions. The resultant narratives were necessarily succinct. Although lacking in depth, the large sample allowed for PMEs to be explored in breadth.

A similar survey within other Canadian province's healthcare systems may be informative to assist geographical comparisons of patient satisfaction and patient experiences with medical errors. Such comparisons would promote communication between provinces and allow various provinces to learn from one another's best practices and experiences. Several lessons were learned from the Alberta Patient Safety Survey 2004 that may be of use to administrators and researchers in other jurisdictions who may want to conduct a similar survey. First, the addition of a cognitive testing component to the pretest phase would be of great value. The topic of PMEs is emotionally charged and thus open to multiple interpretations. A cognitive testing component would allow issues around question clarity to emerge through probing pretest respondents' understanding of questions and their thinking as they provide responses. Second, fixed choice responses to open-ended questions could be expanded to reflect patient experiences and perspectives. For example, it is clear that patients perceive a broader range of consequences to medical

errors than prolonged treatment, disability and death. The addition of emotional and social consequences (depression, anxiety, loss of income, having relationships affected) as fixed responses would assist in a more thorough exploration of PMEs from a patient perspective. Finally, a less structured interview format with some or different respondents would assist in the exploration of PMEs with greater depth and clarity. There is a trend towards combining qualitative and quantitative research methods to enhance validity and theoretical insights (Polit and Hungler 1999). In addition to the structured survey, a series of individual and semistructured in-depth interviews with respondents who have experienced a PME would add context to the study of PMEs and would provide insight into the depth of the complex experience of a PME.

No one perspective — be it the perspective of healthcare administrators, practitioners or patients — can adequately express the complexity and depth of PMEs. Instead, a combination of perspectives is needed before PMEs may be comprehensively understood and before meaningful patient safety initiatives may be advanced. The patient perspective is traditionally overlooked or only modestly considered in patient safety research, yet must be considered if the ultimate goal of patient confidence and patient safety is to be realized.

References

Baker, G.R., P.G. Norton, V. Flintoft, R. Blais, A. Brown and J. Cox et al. 2004. "The Canadian Adverse Events Study: The Incidence of Adverse Events Among Hospital Patients in Canada." *Canadian Medical Association Journal* 170(11): 1678–86.

Baker, G.R. and P.G. Norton. 2004. "Adverse Events and Patient Safety in Canadian Health Care." *Canadian Medical Association Journal* 170(3): 353–54.

Berwick, D. 2005. "My Right Knee." *Annals of Internal Medicine* 142: 121–25.

Blendon, R.J., C.M. DesRoches, M. Brodie, J.M. Benson, A.B. Rosen and, E. Schneider et al. "Views of the Practicing Physicians and the Public on Medical Errors." *New England Journal of Medicine* 347(24): 1933–1940.

Canadian Institute for Health Information. 2004. Health Care in Canada. Ottawa: Canadian Institute for Health Information. Retrieved 22 June 2005 from www.cihi.ca.

Crabtree, B.F. and W.L. 1999. *Doing Qualitative Research.* Thousand Oaks, CA: Sage Publications.

Davis, P., R. Lay-Yee, S. Schug, R. Briant, A. Scott and S. Johnson et al. "Adverse Events Regional Feasibility Study: Indicative Findings." *New Zealand Medical Journal* 114 (1131): 203–5.

Forster, A.J., H.D. Clark, A. Menard, N. Dupuis, R. Chernish and N. Chandok et al. "Adverse Events Among Medical Patients after Discharge from Hospital." *Canadian Medical Association Journa*l 170(3): 345–349.

Health Services Utilization and Outcomes Commission. 2003. Health Services Satisfaction: Survey of Albertans. Calgary, Alta. Health Services Utilization and Outcomes Commission.

Health Quality Council of Alberta. 2004. *Satisfaction with Health Care Services: A Survey of Albertans 2004*. Calgary, Alta. Health Quality Council of Alberta. Retrieved 12 May 2005 from www.hqca.ca.

Kuzel, A.J., S.H. Woolf, V.J. Gilchrist, J.D. EngelD, T.A. LaVeist and C. Vincent et al. 2004. "Patient Reports of Preventable Problems and Harms in Primary Health Care." *Annals of Family Medicine* 2(4): 333–40.

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

Polit, D.F. and B.P. Hungler. 1999. *Nursing Research: Principles and Methods.* Philadelphia, PA: Lippincott-Raven.

Thomas, E.J., D.M. Studdert, H.R. Burstin, E.J. Orav, T. Zeena and E.J. Williams et al. "Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado." *Medical Care* 38(3): 261–71.

Vincent, C., G. Neale and M. Woloshynowych. 2001. "Adverse Events in British Hospitals: Preliminary Retrospective Record Review." *British Medical Journal* 322: 517–19.

About the Authors

Laura C. Vanderheyden, Consultant, Health Quality Council of Alberta, Department of Community Health Sciences, University of Calgary

Herbert C. Northcott, Professor, Department of Sociology, University of Alberta

Carol E. Adair, Associate Professor, Departments of Community Health Sciences and Psychiatry, University of Calgary

Charlene McBrien-Morrison, Research and Evaluation Manager, Health Quality Council of Alberta

Lynn M. Meadows, Associate Professor and Shoppers Drug Mart Professor in Women's Health, Departments of Community Health Sciences and Medicine, University of Calgary

Peter Norton, Professor and Department Head, Department of Medicine, University of Calgary

John Cowell, Chief Executive Officer, Health Quality Council of Alberta

Corresponding Author: John Cowell, Health Quality Council of Alberta, Phone: (403) 297-8162, Fax: (403) 297-8258, Email: john.cowell@hqca.ca.

Acknowledgements

The Alberta Patient Safety Survey 2004 was administered by the Population Research Laboratory at the University of Alberta. Dr. Raewyn Basset served as a consultant to the project providing her expertise in formatting, importing and running reports in QSR N6 on the atypical qualitative dataset.

Attribution

From Inquest to Insight

Valdine Berry, Linda Smyrski and Laurie A. Thompson

Background

In March 1995, The Chief Medical Examiner, Province of Manitoba, ordered an inquest into the deaths of 12 children who died in 1994 while undergoing or shortly after having undergone cardiac surgery at Health Sciences Centre in Winnipeg, Manitoba, Canada. The inquest spanned over five years, and resulted in almost 50,000 pages of transcript, including the testimony of more than 80 witnesses (Sinclair 2000).

Justice Sinclair found that the Pediatric Cardiac Program did not provide the standard of care that it was mandated to provide, as he determined that at least five of the deaths were preventable.

In response to the 516-page report issued by Judge Murray Sinclair, the former Minister of Health, the Honourable Dave Chomiak, established a Review and Implementation Committee to review the recommendations from the inquest and determine (1) what actions had already been taken to address the recommendations, (2) what future actions should be taken and (3) the implications of the recommendations for the broader health system. A learning process began, which would have a ripple effect throughout the Manitoba health system for years to come.

The Review and Implementation Committee, chaired by Professor Paul Thomas, issued a report in May, 2001, entitled *Report of the Review and Implementation Committee for the Report of the Manitoba Pediatric Cardiac Surgery Inquest* containing 53 recommendations which sought to "identify institutional arrangements and procedures that would provide Manitobans with a stronger guarantee of competent, safe and ethical healthcare in the future" (Manitoba Health 2001).

Milestones...

It is the goal of all Manitoba's healthcare community to be leaders in providing quality care and promoting patient safety. In the keynote speech at a November 2003 Provincial Patient Safety Conference, former Minister Chomiak committed Manitoba Health to a collaborative approach directed toward continuous improvement in patient safety and quality of care throughout Manitoba.

A key component in improving quality of care and patient safety is moving to a culture that views quality of care and patient safety as a systems issue that requires evaluation, inter-disciplinary cooperation and commitment to change, as opposed to a culture of individual blame.

In the journey *From Inquest to Insight,* Manitoba's approach to patient safety is beginning to result in health system changes that promote a culture of non-blame and will, ultimately, result in the prevention and reduction of critical incidents*.

Recommendations from the Review and Implementation

*Based on the impending proclamation of Bill 17 (legislative amendments to *The Regional Health Authorities Act* and *The Manitoba Evidence Act*, which will define specific Critical Incident reporting and investigation requirements) (Government of Manitoba 2005). "Critical incident" means an unintended event that occurs when health services are provided to an individual and results in a consequence to him or her that (a) is serious and undesired, such as death, disability, injury or harm, unplanned admission to hospital or unusual extension of a hospital stay and (b) does not result from the individual's underlying health condition or from a risk inherent in providing the health services.

Committee focussed on the patient experience, human resources, accountability, quality and risk management, and health authority policy and procedural issues.

The thrust of the recommendations sent the message that it is necessary to accept that the healthcare system will improve only if the system can respond to errors and concerns without fear of consequence from system errors. The recommendations were intended to promote a structure and environment within which highly skilled and talented people could establish healthcare teams that work together to provide a high standard of care.

A province-wide collaborative approach was undertaken to develop and implement eight provincial policies in response to the inquest in areas where risk to the safety of individuals were identified.

Collaborative working groups with representatives from a variety of health system stakeholders developed each policy, and corporate leadership from health authorities supported implementation, follow-up and monitoring of progress of policy implementation.

These policies were designed to improve quality of healthcare and to begin to change the culture of the system to one of openness in reporting critical incidents, of learning from our mistakes and of support for providers and patients in dealing with critical incidents. These policies and their purposes are described in the following table.

Policy Name	Purpose
Critical Occurrence and Critical Clinical Occurrence Reporting	To ensure that health authorities develop timely, comprehensive and factual reporting and investigating processes for critical incidents and other significant occurrences
Internal Disclosure of Staff Concerns	To ensure that health authorities have a process, whereby staff may disclose concerns, and that these disclosures are routed to appropriate people and addressed in a suitable and timely manner
Integrated Risk Management Strategy	To ensure that a comprehensive approach is taken to risk management within healthcare organizations, encompassing all elements that directly or indirectly affect the safety and well-being of clients, staff, medical staff and visitors
Quality Audits	To ensure that health authorities use the quality audit process to provide systematic, critical analysis of clinical care and services
Health Authority's Guide to Health Services	To ensure that health authorities provide the public with contact points for questions and complaints
Notification to Manitoba Health of Critical Occurrences and Critical Clinical Occurrences	To provide a consistent process for health authorities to notify Manitoba Health of critical occurrences and critical incidents
Board Governance and Board/Chief Executive Officer/Chief Operating Officer Accountability	To ensure that health authorities develop good governance practices and strategies for continuously improving programs and services
Reporting of Significant Changes to the Office of the Chief Medical Examiner	To ensure that all significant changes in healthcare programs and reviews that are conducted as a result of program-related deaths are reported to the Office of the Chief Medical Examiner by health authorities

Leaders from each health authority provided regular updates to Manitoba Health on the progress of addressing the Review and Implementation Committee recommendations.

The following nine key activities and initiatives are aimed at promoting a culture and environment of patient safety in Manitoba, which continue to be collaboratively undertaken by health authorities and other stakeholders:

1. On June 21, 2004 The Manitoba Institute for Patient Safety (MIPS) was established, with Dr. Paul Thomas, chair of the Board of Directors. MIPS objectives are:
   - to promote, coordinate, facilitate, participate in and/or stimulate research, activities and initiatives to enhance patient safety in the Manitoba healthcare system
   - to monitor emerging issues related to patient safety and quality care
   - to promote best practices related to patient safety and quality care
   - to raise awareness of patient safety and quality care issues
2. Manitoba Health has set proposed provincial objectives for improving patient safety based on feedback from with internal and external stakeholders in the spring of 2005.

The following "sources" have all identified three common areas for patient safety improvement: facility-based critical incidents, medication safety and infection control:

- Institute of Medicine (IOM) 10-Year Quality of Healthcare Project (Kohn et al. 1999)
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO) 2004-05 Goals (JCAHO 2004)

- 2004 Canadian Institute of Health Information (CIHI)/ Canadian Institute of Health Research (CIHR) *Incidence of Adverse Events Among Hospital Patients in Canada* (Baker/ Norton Study) (Baker et al. 2004)
- *CIHI & Health Canada Fifth Annual Report: Health Care in Canada* (CIHI and Health Canada 2004)
- The Canadian Council on Health Services Accreditation (CCHSA) Patient Safety Goals 06/07 (CCHSA 2005)

Based on this, Manitoba's proposed short-term provincial objectives are the promotion of regional, facility-based best practices in

- identification, reduction and/or prevention of critical incidents all areas
- medication administration
- infection control

A Provincial Patient Safety Action Plan will serve as a common reference point for those interested and involved in patient safety to work collaboratively for the common goal of enhancing the safety and quality of care provided to Manitobans.

3. On April 12, 2005, the *Safer Healthcare Now!* (2005) campaign was launched by a national steering committee comprised of patient safety leaders from across Canada, including the Canadian Patient Safety Institute (CPSI). The Manitoba Institute for Patient Safety is leading the *Safer Healthcare Now!* campaign in Manitoba.
4. Manitoba Health has commissioned the Manitoba Centre for Health Policy (MCHP) to undertake a research study entitled "Patient Safety Issues: A System-Wide Approach for Manitoba" (Manitoba Centre for Health Policy 2004). The study is due to be released in 2005.
5. Progress is underway to prepare for the Proclamation of Bill 17 – amendments to the Regional Health Authority (RHA) and Manitoba Evidence Acts that are aimed to have a positive impact in improving patient care through timely reporting and investigation of critical incidents.
6. In order to address Manitoba Health's commitment to provide healthcare professionals ongoing access to the latest developments and information available on patient safety, the following collaborative activities have been undertaken or are underway:

    - Advancing Quality in the Name of Patient Safety conferences are a series of provincial patient safety conferences held in collaboration with the College of Registered Nurses of Manitoba, the College of Physicians and Surgeons, the Manitoba Pharmaceutical Association, the Canadian College of Health Service Executives, the Winnipeg Regional Health Authority and, as of 2005, the Manitoba Institute for Patient Safety.
    - Manitoba was the first to partner with the Institute for Safe Medication Practices Canada (ISMP) in their Failure Mode and Effects Analysis workshop. A follow-up workshop was held where participants shared lessons learned in using these tools is their daily practices.
    - Manitoba was the first province to work with the CPSI to hold a Root Cause Analysis workshop for health authorities, sponsored in part by the MIPS.

7. The Institute for Safe Medication Practices Canada (ISMP) Medication Safety Self-Assessment is available and is being utilized by health authorities as part of their quality and risk-management strategy. The Department also sponsors and distributes the ISMP Medication Safety Bulletin and in Medication Alert Newsletter to all health authorities.
8. The Regional Health Authority Quality and Risk Management Network shares and promotes best practices in patient safety and quality of care.
9. Improved environments and structure to promote patient and family involvement in patient safety are being established. For example, the Winnipeg Regional Health Authority (WRHA) has recently announced their Patient Advisory Council.

These activities have given Manitoba thrust to achieve positive patient safety outcomes, and have placed Manitoba with other leaders of patient safety across the country.

Assessment of culture change from one of blame to one of learning may include increased reporting and investigation of critical incidents, evidence of development, implementation and sharing of best practices, increased use of tools (i.e., FMEA, RCA) implementation of culture surveys and evidence of teamwork.

Insights gained during the journey *From Inquest to Insight* are that there are many complex aspects to the culture of safety – not only systems changes, but the promotion of teamwork, culture assessment, openness and patient involvement, and accountability. Much has been accomplished; more is yet to be done.

References

Baker, G.R, P.G. Norton, V. Flintoft, R. Blais, A. Brown et al. 2004, May 25. "The Canadian Adverse Events Study: The Incidence of Adverse Events Among Hospital Patients in Canada." *CMAJ* 170(11).

The Canadian Council of Health Services Accreditation (CCHSA). 2005. Patient Safety Goals 2006/2007. Retrieved March 11, 2005. <http://www.cchsa.ca/pdf/PSGoalsandEvidenceJan05.pdf>.

CIHI and Health Canada. 2004. *Fifth Annual Report: Health Care in Canada.* Retrieved March 11, 2005. <http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=PG_376_E&cw_topic=376&cw_rel=AR_43_E>.

Government of Manitoba. 2005. *Bill 17: The Regional Health Authorities Amendment and Manitoba Evidence Amendment Act.* Retrieved June 20, 2005. <http://web2.gov.mb.ca/bills/sess/index.php>.

Joint Commission on Accreditation of Healthcare Organizations (JCAHO). 2004. *National Patient Safety Goals for 2005 and 2006.* Retrieved March 11, 2005. <http://www.jcaho.org/accredited+organizations/patient+safety/npsg.htm>.

Kohn, L.T., J.M. Corrigan, S.M. Donaldson, eds. 1999. *To Err Is Human.* Washington: National Academy Press.

Manitoba Centre for Health Policy. 2004. *Patient Safety Issues: A System-Wide Approach for Manitoba*. Retrieved June 20, 2005. <http://www.umanitoba.ca/centres/mchp/projects.htm>.

Manitoba Health. 2001. Report of the Review and Implementation Committee for the Report of the Manitoba Pediatric Cardiac Surgery Inquest. Winnipeg, MN: Author. Retrieved August 22, 2005. <http://www.gov.mb.ca/health/documents/cardiac/01pri.pdf>.

Safer Healthcare Now! A Canadian Campaign to Improve Patient Care. 2005. Retrieved June 20, 2005. <http://www.saferhealthcarenow.ca/en/Default.aspx>.

Sinclair, C. M. 2000. *The Report of the Manitoba Pediatric Cardiac Surgery Inquest: An inquiry into Twelve Deaths at the Winnipeg Health Sciences Centre in 1994.* Winnipeg, MN: Provincial Court of Manitoba. <http://www.pediatriccardiacinquest.mb.ca/>.

About the Authors

Valdine Berry, BN, MSA, is the Director of the Strategic Planning and Emerging Issues Unit, Policy and Planning Branch, Manitoba Health, whose portfolio is responsible for the Manitoba Provincial Patient Safety Strategy.

Linda Smyrski, RN, is a Policy and Planning Analyst with the Strategic Planning and Emerging Issues Unit, Policy and Planning Branch, Manitoba Health. Linda manages activities within a patient safety portfolio of the Department.

Laurie A. Thompson, BN, MN, is the Executive Director of the Manitoba Institute for Patient Safety, and was formerly Chair of a Joint Provincial Committee that developed the provincial policies in response to the Thomas Report recommendations.

Corresponding Author: Valdine Berry, Director, Strategic Planning and Emerging Issues, Manitoba Health, 2103, 300 Carlton St., Winnipeg, Manitoba, R3B 3M9. Phone: (204) 788-6749. E-mail: vberry@gov.mb.ca, Fax: (204) 948-2366

Patient Safety: Le Groupe Vigilance pour la Sécurité des Soins: A Québec Perspective

Micheline Ste-Marie

In 2000, following a series of tragic adverse events, the Quebec Health and Social Services Minister, Madame Pauline Marois, set up a committee to study adverse events in the province. Under the chairmanship of Mr. Jean Francœur, first Health and Social Services Ombudsman, the committee made a series of recommendations concerning all aspects of patient safety and including leadership, information to patients, research, management of healthcare facilities, risk management, accreditation and competency (Comité ministériel sur les accidents évitables dans la prestation des soins de santé 2001).

The first offshoot of the report was the creation in September 2001 of the Groupe national d'aide à la gestion des risques et à la qualité, forerunner of the current Groupe Vigilance pour la sécurité des soins. The second was the unanimous adoption of Bill 113 (L.Q. 2002, c. 71), as it is commonly known, by the Quebec National Assembly in December 2002 (Québec National Assembly 2002) (see text box). The provisions of the bill are fully integrated in the Quebec Health Act (Gouvernement du Québec 2005).

Bill 113

Bill 113 defines healthcare facilities' obligations on disclosure of accidents, declaration of accidents and incidents, allowance for support measures to patients, their families and healthcare workers involved in the accident, creation of a risk- and quality-management committee, accreditation on patient safety, quality and risk management and the development of a local registry. It also mandates the regional development of health services and social services agencies. As well, the Ministry is mandated to ensure the safe provision of health services and social services. The Bill also makes provision for a province-wide registry of incidents and accidents.

Le Groupe Vigilance pour la Sécurité des Soins

Composed of experts in all fields of healthcare and safety, the Groupe Vigilance is a permanent consultative body to the Quebec Minister of Health and social services. The Groupe's philosophy is based on positive reinforcement and transparency. It ensures that priority recommendations from the rapport Francœur are acted upon. Major terms of its mandate include

- promotion and application of a national policy on patient safety, declaration and disclosure of accidents
- promotion of a culture of transparency, open communication, interdisciplinary teamwork and systemic approach to patient safety
- education and incentives for patients and healthcare workers to contribute to the safety of their healthcare delivery and the decrease of adverse events
- advice and recommendations to the Minister of Health and social services, at his request or on their own initiative, on matters related to the safety of health services and social services

Outcomes (2001–2005)

The Groupe endorsed Bill 113 and promoted its early adoption. It made recommendations to support research on the incidence of adverse events in Quebec hospitals, develop a unique form for declaration of incidents and accidents and create a patient safety brochure. As an essential part of its mandate, the Groupe organized information and training sessions for healthcare workers on various aspects of patient safety and Bill 113.

Blais et al. (2004) reported a 5.6% overall incidence rate of adverse events in Quebec healthcare facilities. Thus, of the almost 435,000 annual hospital admissions in Quebec similar to the type studied, about 24,000 are associated with an adverse event; close to 6,500 of these are potentially preventable. These results compare very favourably with the Canadian study of Baker et al. (2004).

The revised unique form for declaration is about to be launched in an electronic version; this will help in the establishment of local registries and in developing the national one. A brochure for patients will be available in the fall.

An April 2004 survey showed that over 60% of healthcare facilities had established their quality- and risk-management committee, 64% had a local registry and more that two-thirds of them had solicited accreditation of their facility. Since September 2003, more than 45 information and training sessions were held throughout the healthcare network with more than 3,000 people attending. Over 12 briefs with advice and/or recommendations were submitted to the Minister of Health and social services; most of the recommendations were endorsed and put into place.

In late 2004, the Minister of Health and social services reviewed the Groupe Vigilance's mandate and confirmed its importance in the promotion of patient safety initiatives. A new Directorate, la Direction de la Qualité, was created; it will support the administrative services of the Groupe and promote its visibility within Quebec healthcare facilities and external organizations. In early 2005, through a multimedia information campaign, the Groupe continued to reinforce its education program for patients and families on patient safety. Finally, an intensive "train the trainers" program for healthcare workers is being developed and should be implemented in late 2005 or early 2006.

Bill 113 Explanatory notes

This bill makes amendments to the Act respecting health and social services as regards the safe provision of health services and social services.

It provides that a user has the right to be informed of any accident having occurred during the provision of services that has potential consequences for the user's state of health or welfare. Furthermore, any person working in an institution will be under obligation to report any incident or accident as soon as possible after becoming aware of it.

Every institution will be required to form a risk-management committee responsible for seeking, developing and promoting means to ensure the safety of users and to reduce the incidence of adverse effects and accidents related to the provision of health services and social services.

In addition, the board of directors of every institution will be required to make rules concerning disclosure of all necessary information to the user as well as measures to prevent the recurrence of such an accident.

Finally, the bill makes regional boards responsible, in their region, for ensuring users the safe provision of health services and social services.

The Future

The Groupe Vigilance will hold a province-wide consultation in late 2005 to seek feedback from healthcare workers and healthcare facilities. It now has its own visual identity and a Web site will be available shortly. Collaboration with Canadian patient safety groups such as the Canadian Patient Safety Institute (CPSI-ICSP) and the Canadian Council on Health Services Accreditation (CCHSA-CCASS) is established and links with a number of other organizations continue to be put in place. As well as continuing to work on the realization of its mandate, two major initiatives are in their initial stage of development and should be available in early 2006:

- a province-wide "train the trainers" program on the impact of human factors in the incidence of adverse events
- a pilot program to implement the MOREOB (Managing

Obstetrical Risk EfficientlyOB) program from the Society of Obstetricians and Gynaecologists of Canada in several hospitals with obstetrics and delivery units

We continue to promote a culture of transparency and interdisciplinary team approach to healthcare as the best way to ensure patient safety and eventually eliminate preventable adverse events. These should decrease not only in hospital and other facilities, but also in physicians' offices and clinics and other privately owned facilities such as drug stores and other partners in local healthcare networks. The support of the Ministry of Health and social services is essential; we are grateful that the current Minister of Health and social services has declared patient safety as one of his priorities in the delivery of stellar healthcare in Quebec.

References

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

Blais, R., R. Tamblyn, G. Bartlett, G. Tré and D. St-Germain. 2004. *Incidence d'événements indésirables dans les hôpitaux québécois*. Montréal, QC: Université de Montréal, Groupe de recherche interdisciplinaire en santé (GRIS).

Comité ministériel sur les accidents évitables dans la prestation des soins de santé. 2001. La gestion des risques, une priorité pour le réseau. Québec, QC: Ministère de la Santé et des Services Sociaux. Retrieved August 3, 2005. <http://publications.msss.gouv.qc.ca/acrobat/f/documentation/2000/00-915.pdf>.

Gouvernement du Québec. 2005. An Act Respecting Health Services and Social Services. R.S.Q., chapter S-4.2. Québec, QC: Québec Official Publisher. Retrieved August 3, 2005. <http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=2&file=/S_4_2/S4_2_A.html>.

Québec National Assembly. 2002. An Act to Amend the Act Respecting Health Services and Social Services as Regards the Safe Provision of Health Services and Social Services. Bill 113. Assented to 19 December 2002. Québec, QC: Québec Official Publisher. Retrieved August 3, 2005. <http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=5&file=2002C71A.PDF>.

About the Author

Micheline Ste-Marie, MD, FRCPC, is Chair Groupe Vigilance pour la sécurité des soins, and Associate Director, Professional Services, Montreal Children's Hospital of the McGill University Health Centre. The author is also a pediatric gastroenterologist at McGill University, with major interests in strategic planning, maintenance of professional standards, quality management and patient safety.

Contact: Montreal Children's Hospital Room F-393, 2300 Tupper, Montreal Qc, H3H 1P3, Phone: 514-412-4306, Fax: 514-412-4332

Developing a Comprehensive Patient Safety Strategy for an Integrated Canadian Healthcare Region

W. Ward Flemons, Chris J. Eagle and Jack C. Davis

The Calgary Health Region (the Region) is one of the largest completely integrated health regions in Canada, covering an area of 39,260 square kilometres. With four urban hospitals and eight rural hospitals (total of 2,104 acute care beds), the Region provides population health, preventive health, acute care, long-term care and home care services for 1.14 million residents, as well as tertiary care services for residents of southern Alberta, south-western British Columbia and south-eastern Saskatchewan.

In 2004, a batch of citrated renal dialysis solution was mistakenly prepared by the Region's central pharmacy with potassium chloride rather than sodium chloride. Two patients in our critical care units undergoing continuous renal replacement therapy who were dialyzed with this solution developed severe hyperkalemia and subsequently died. The Region immediately recalled the remaining dialysate solutions and also informed other acute care sites in Canada that produced this type of dialysate about the adverse event. A subsequent internal review led to changes in the storage and labelling of potassium chloride in the central pharmacy and also to the dialysate solution production process. The Region disclosed the details of the adverse events to the families of the involved patients and shortly thereafter, with their permission, the Region informed the public. The Region commissioned a comprehensive external review of its pharmacy services and its organizational approach to patient safety. From this, and through its own internal processes, the Region has developed a comprehensive organizational patient safety strategy.

In the last several years, many excellent reports have recommended approaches for improving healthcare safety (Institute of Medicine 2001; National Steering Committee on Patient Safety 2002; Institute of Medicine 2004). However, we were unable to find a report or guide written specifically for large integrated health regions that provided a comprehensive "how to" roadmap to address the complex area of patient safety. The internal and external reviews suggested opportunities that would assist the Region in creating a safer environment for patients. An important outcome of these efforts was the production of a framework that highlighted the key areas that needed to be addressed (**Figure 1**), and which has also served as the basis for the creation of the Region's patient safety strategy. We acknowledged that in its broadest context patient safety encompasses occupational safety, environmental safety, physical plant and equipment safety, and business risk management, as well as clinical safety (i.e., the day-to-day practices that directly impact patients). Our patient safety strategy, however, deals only with the narrower context of "clinical safety."

Figure 1. The Calgary Health Region's Safety Framework

Safety Management

The core piece of our Region's strategy is a cycle of safety management that starts with developing and formalizing hazard identification processes. These processes include the reporting of adverse events and close calls, investigations of critical adverse events and close calls, leadership walkrounds (Frankel et al. 2003), adverse event audits, mortality audits, focus groups, as well as safety alerts received from other organizations (e.g., the Institute for Safe Medication Practice). Once hazards are identified they require analysis and management including: (1) better understanding of the contributing factors, (2) prioritization, and (3) recommendations for system improvements that mitigate risks for patients. Analyses can be informal or structured, for example, when an adverse event or close call is reviewed using a root cause analysis framework (Bagian et al. 2002) or where a detailed process review is undertaken using a failure modes and effects analysis (DeRosier et al. 2002). The Calgary Health Region has chosen not to use a standard root cause analysis framework for reviews of adverse events or close calls. Instead, the Region is using a human factors approach adapted from aviation safety by one of our academic anaesthesia colleagues (Davies and Lange 2003). We refer to this approach as a health system safety analysis.

Mitigating risks to patients through system improvements encompasses both structural changes and process changes. Examples of structural changes include alterations in staffing, equipment and workspace. Process changes include all of the critical elements that are part of clinical process design or redesign that ensures reliable delivery of evidence-based care, for example, correct timing of antibiotic prophylaxis to prevent surgical site infections or rapid reperfusion of patients suffering an acute myocardial infarction.

The final part of our safety management cycle involves continuously checking the performance of the system through:

1. a set of safety performance outcome or process measures;
2. a formal evaluation of the system improvements that have been recommended (i.e., whether they have been implemented as planned, whether they have had the desired effect and whether they have resulted in creating unanticipated risk), and
3. researching new methods of delivering safer healthcare.

While we view safety management as the core piece of an overarching strategy in our Region, we believe there are four cornerstones that provide the foundation for long-term success: (1) committed and engaged leadership, (2) a supportive organizational structure, (3) a culture of safety, and (4) access to appropriate resources.

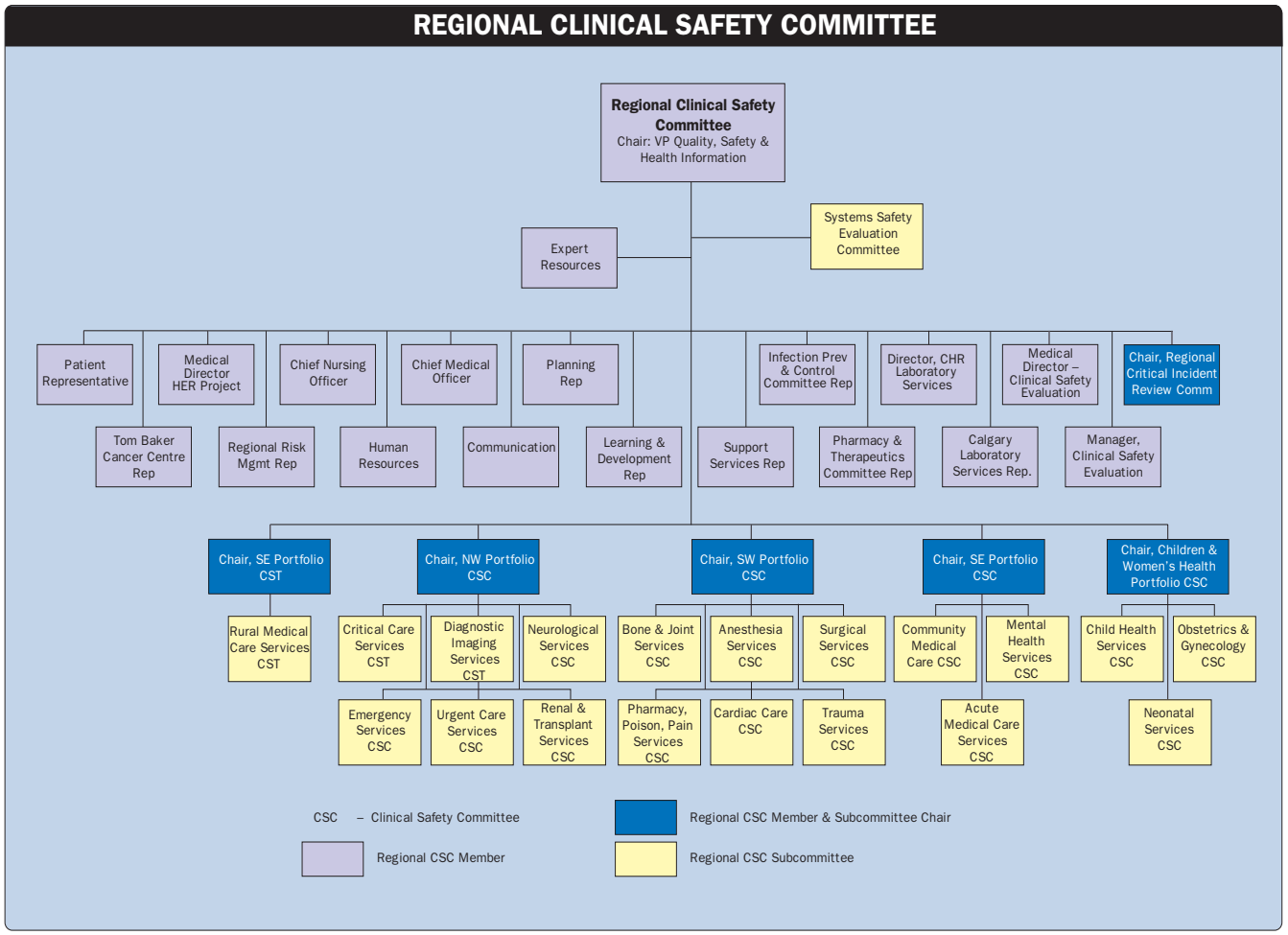
Leadership/Accountability

Regional/Hospital boards and their management teams have a key role in ensuring appropriate management for safety in their organizations. The Calgary Health Region's Board established a Safety Task Force to oversee the Region's safety strategy. The Region recently reconfigured its balanced scorecard to highlight quality and safety and is reviewing its mission and vision with the goal of better capturing patient safety. Leadership walkrounds (Frankel et al. 2003) have been initiated. Patient safety events are actively promoted and supported by the Executive Management Team, members of which routinely participate in forums and conferences. Assigning accountability for addressing safety issues and implementing recommendations has become more formalized; reports tracking progress on implementing safety recommendations are produced for management and are shared with the board.

Organizational Structure

The Region has created an integrated structure to exclusively address safety issues in response to a key observation of the external safety review. The Region's five clinical portfolios and all key organizational support areas are represented on a newly established Regional Clinical Safety Committee (**Figure 2**). In addition, each clinical portfolio is establishing a clinical safety committee that will address portfolio-specific issues and represent the clinical departments and service areas within that portfolio on the regional committee. Department-based quality assurance committees, with traditional physician-only membership, are being transformed into multidisciplinary service clinical safety committees that report to their respective portfolio. Pilot testing of unit-based safety action teams (Morath and Turnbull 2005) that are linked to appropriate service clinical safety committees has also started.

Figure 2. The Calgary Health Region's Structure and Membership of Its Regional Clinical Safety Committee



Safety Culture

To address deficiencies in our safety culture, we have adopted the approach of Reason (1997) and focused on reporting, learning, a just (and trusting) culture, and flexibility. Making improvements that address system weaknesses identified by our healthcare providers is a key goal. To create a culture where people feel safe to report hazards, we have established an organizational just and trusting culture policy and a reporting policy (see below). The reporting policy clearly outlines what the Region feels is appropriate for healthcare providers to report. The Region currently has an incident reporting process that is used mostly by employed staff and rarely by physicians. Reports predominately focus on individual behaviours (usually errors), are filed with a person's administrative supervisor and then recorded in a centralized database, which is not optimized to detect recurring system weaknesses. In our transformed reporting system, our healthcare providers will be encouraged (not required, which implies consequences for not reporting) to file "safety learning reports" (Morath and Turnbull 2005) with a focus on safety hazards, rather than incident reports. Safety learning reports will be filed, not with an immediate supervisor, but with a central reporting office that will maintain reporter confidentiality. De-identified safety reports will be available to appropriate managers so that local safety issues can be addressed in a timely manner. Feedback will be delivered to our healthcare providers about the reports they file and system improvements that result; this is a fundamental requirement to create a reporting and learning culture. The need for flexibility in our system has been addressed by providing contingency funds that can be easily accessed for making quick system improvements and by promoting a balance of local system fixes by safety action teams with region-wide system improvements for issues that affect multiple service areas.

Resources

The Region has invested several million dollars to build the infrastructure, training, communication and equipment required to support this strategy and to provide contingency funds for ongoing system improvements. These funds allow portfolios and service areas an opportunity to quickly invest in safer systems rather than wait for the annual budgeting approval process.

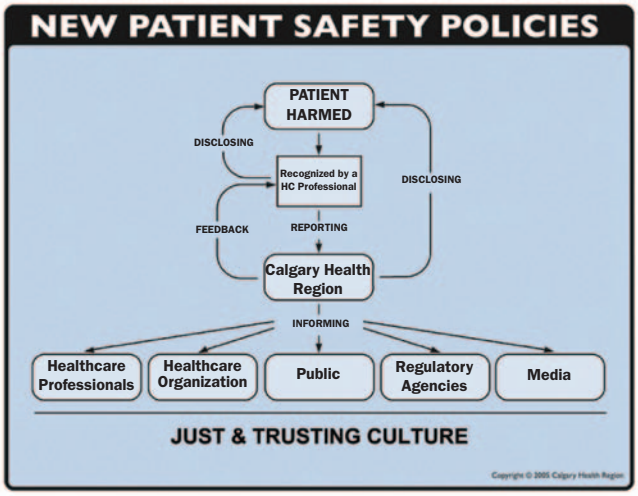
In addition to the four cornerstones of our patient safety strategy, we believe that there are two additional activities that are critical for creating a safer organization: (1) having appropriate safety policies and procedures, and (2) facilitating ongoing communication and education.

Policies and Procedures

Based on the recommendations of the external safety reviews, the Region formalized its approach to the management of potassium chloride in the form of a regional policy. In addition, to address the ethical issues of maintaining communication between the Region and its patients, its providers and its key partners and stakeholders, several policies have been developed to promote a safety culture and a culture of transparency. To avoid confusion over terminology, we defined three types of communication (**Figure 3**):

1. Reporting – communication between healthcare providers and the Region
2. Disclosure – communication between the Region (including its healthcare providers) and patients about circumstances when patients have been harmed by the care that they have received
3. Informing – communication between the Region and its key partners and stakeholders

Figure 3. The Relationship of Four Safety Policies on Disclosing, Reporting, Informing and Creating a Just & Trusting Culture



Finally, the Region developed a Just and Trusting Culture Policy to define the relationship with its healthcare providers in circumstances when care has not been appropriate and/or when patients are harmed.

Reporting Policy

The Region has defined two types of reporting that it will promote: (1) voluntary safety learning reports of hazards (including hazards that are recognized as having the potential to cause or contribute to harm but have not yet done so, situations in which patients are nearly harmed – close calls – and situations where patients are harmed but not severely), and (2) mandatory reporting when patients have suffered severe harm (defined as loss of limb or organ function or where a life sustaining intervention has been required) or fatal harm. We believe the voluntary system has the greatest potential as a source of information about where the system needs improvement to mitigate risk to patients as well as being an important vehicle to continue building the organization's safety culture.

Disclosure Policy

The Region's policy defines patient harm as an unexpected or normally avoidable outcome that negatively affects a patient's health and/or quality of life, and occurs or has occurred during the course of receiving healthcare or services from the Region (modified from the College of Physicians and Surgeons of Ontario 2003) The policy states that harm will be acknowledged, circumstances about the event will be communicated to the patient and an apology for the harm will be made. This has been a challenging policy to develop because of four important issues: (1) whether or not to mandate disclosure of close calls (the decision was made to leave this to the discretion of the primary healthcare provider(s)), (2) the concern over potential liability (for both the Region and physicians), (3) the conundrum that facts discovered during a quality assurance committee review are protected under provincial law (the *Alberta Evidence Act)* and cannot be revealed, and (4) the question of how to handle disclosure of harm to a patient when they suffered harm in another jurisdiction preceding the transfer of the patient to the Region. Guidelines are under development that will outline the Region's approach to these challenging issues.

The policy states that harm will be acknowledged, circumstances about the event will be communicated to the patient and an apology for the harm will be made.

Informing Policy

This policy describes the circumstances where the Region would communicate safety issues with: (1) its principal health partners, defined as the Region's patients (inclusive of all individuals who receive healthcare or services directly from the Region), its health care providers and other healthcare providers who are not Region employees or who do not have privileges with the Region but who provide health services to the Region's patients, and (2) stakeholders (individuals and organizations that have an interest or a stake in healthcare or services including the public, and local, provincial, national and/or international healthcare providers, and health-related agencies or organizations including regulatory, non-regulatory, government bodies). This policy addresses the Region's obligations to communicate safety information where a patient's health or welfare may be at risk and where this risk may impact the health or welfare of other patients, of healthcare providers or other stakeholders. The policy recognizes how a serious adverse event has the potential to weaken the trust of the Region's principal health partners, and the most responsible approach to deal with this is to maintain an atmosphere of transparency.

Just and Trusting Culture Policy

This policy describes the Region's response to its healthcare providers who are involved in an adverse event. Our policy acknowledges two distinct types of safety evaluations:

1. Safety analyses conducted using our health system safety analysis framework with its focus on understanding system-related contributing factors
2. Administrative reviews conducted in situations where an evaluation of an individual healthcare provider's performance is required

We have adapted the approach to evaluating unsafe acts outlined by Reason (1997) – errors, violations and sabotage. Based on feedback from consultations undertaken with our healthcare providers, we modified Reason's terminology and refer to "non-compliance" rather than violation and "intention to harm" rather than sabotage. The Region's response to the three types of active failures will be:

- *Errors* – in situations where patients have been harmed in the course of receiving health care or services from the Region, or in situations where patients have been nearly harmed and where healthcare providers did not deviate from established policies, procedures, standards or guidelines, healthcare providers will not be disciplined by the Region.
- *Non-compliance* – in situations where patients have been harmed in the course of receiving healthcare or services from the Region, or in situations where patients have been nearly harmed and where healthcare providers have deviated from established policies, procedures, standards, or guidelines, the Region will commit to evaluate as part of an administrative review: (1) the appropriateness of its policies, procedures, standards or guidelines, and (2) the circumstances that led to the non-compliant action(s), before determining an appropriate course of action.
- *Intention to harm* – in situations where patients have been intentionally harmed or where there is intent to cause harm to a patient by any of the Region's healthcare providers, the Region will seek disciplinary action and criminal investigations may result.

We have found moving forward with a comprehensive patient safety strategy very challenging because of the enormity and complexity of the task.

Communication and Education

Breakdowns in communication are a major contributing factor in the majority of sentinel events reported to the Joint Commission of Accreditation of Healthcare Organizations (2005). The Region has begun testing a structured communication tool – SBAR – situation/background/assessment/recommendation (Leonard et al. 2004) in some of our critical care units, as well as timeouts in some of our operating theatres. A region-wide rollout of these strategies is planned. Communication is also necessary to keep the Region's healthcare providers informed about the components of the Region's patient safety strategy. We recognize that education of our healthcare providers and administrative leaders is essential to advancing the safety agenda. For several years, the Region has involved hundreds of people in collaborative projects that teach rapid cycle testing of improvements. Formal courses on quality improvement and safety theory will be offered in late 2005 including instruction in health system safety analysis and human factors analysis. Education plans will also include training on specific issues (e.g., changes in the way high hazard medications are ordered).

We have found moving forward with a comprehensive patient safety strategy very challenging because of the enormity and complexity of the task. We have found a safety framework on which to base the strategy invaluable, but are still struggling with an optimal method of prioritizing the work that needs to be accomplished and maintaining a proper perspective on the timeframe that these changes will require. Having complete organizational commitment to such a strategy is of paramount importance.

References

Bagian, J.P., J. Gosbee, C.Z. Lee, L. Williams, S.D. McKnight and D.M. Mannos. 2002. "The Veterans Affairs Root Cause Analysis System in Action." *Jt Comm J Qual Improv* 28(10): 531–45.

Davies, J.M. and I.R. Lange. 2003. "Investigating Adverse Outcomes in Obstetrics." 2003. *Journal of Obstetrics and Gynaecology of Canada* 25: 505–15.

DeRosier, J., E. Stalhandske, J.P. Bagian and T. Nudell. 2002. "Using Health Care Failure Mode and Effect Analysis: The VA National Center for Patient Safety's Prospective Risk Analysis System." *Jt Comm J Qual Improv* 28(5): 248–67.

Frankel, A., E. Graydon-Baker, C. Neppl, T. Simmonds, M. Gustafson and T.K. Gandhi. 2003. "Patient Safety Leadership WalkRounds." *Jt Comm J Qual Improv* 29(1): 16–26.

Institute of Medicine. 2001. *Crossing the Quality Chasm: A New Health System for the 21st Century.* Washington D.C. National Academies Press.

Institute of Medicine. 2004. *Patient Safety: Achieving a New Standard of Care.* Washington D.C. National Academies Press.

Joint Commission of Accreditation of Healthcare Organizations. 2005. Root Causes of Sentinel Events. Oakbrook Terrace. Retrieved August 5, 2005. <http://www.jcaho.com/accredited+organizations/ambulatory+care/sentinel+events/root+causes+of+sentinel+event.htm>.

Langley, G.J., K.M. Nolan, T.W. Nolan, C.L. Norman and L.P. Provost. 1996. *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance.* San-Francisco, CA: Jossy-Bass Inc.

Leonard, M., A. Frankel, T. Simmonds and K. Vega. 2004. *Achieving Safe and Reliable Healthcare: Strategies and Solutions.* Chicago, Il: Health Administration Press.

Morath, J.M. and J.E.Turnbull. 2005. *To Do No Harm: Ensuring Patient Safety in Health Care Organizations.* San-Francisco, CA: Jossy-Bass Inc.

National Steering Committee on Patient Safety. 2002. Building a Safer System. Royal College of Physicians and Surgeons of Canada. Ottawa. Retrieved August 5, 2005. <http://rcpsc.medical.org/publications/building_a_safer_system_e.pdf>.

Reason, J. 1997. *Managing the Risks of Organizational Accidents.* Burlington, VT: Ashgate Publishing Company.

About the Authors

W. Ward Flemons, MD, is Vice-President, Quality, Safety & Health Information, Calgary Health Region, Calgary, Alberta, Canada.

Chris J. Eagle, MD, is Executive Vice-President and Chief Clinical Officer, Calgary Health Region, Calgary, Alberta, Canada.

Jack C. Davis is President and Chief Executive Officer, Calgary Health Region, Calgary, Alberta, Canada.

Corresponding Author: Dr. W. Ward Flemons, Calgary Health Region, 10101 Southport Road SW, Calgary, Alberta, Canada, T2W 3N2, Voice: (403) 943-0915, Fax: (403) 943-0916 (fax), Ward.Flemons@calgaryhealthregion.ca

Quality, Patient Safety and the Implementation of Best Evidence: Provinces in the Country of Knowledge Translation

Dave Davis

Long a world model, Canada's healthcare system faces many challenges to ensure its sustainability. Research evidence, generated at an exponential rate, is not readily available to clinicians. When available, it is often infrequently or incorrectly applied in clinical practice (Davenport and Glaser 2002; Covell et al. 1985; Ramos et al. 2003). This failure of rapid evidence adoption leads to sizable gaps between high-quality evidence and practice, significant practice variation, and in many cases lapses in patient safety (Chassin and Galvin 1998; Buchan 2004). This gap is deleterious to the health of Canadians, increasing morbidity and mortality and generating serious and detrimental cost implication (Olson et al. 2001; Villar et al. 2001; Boissel et al. 2004; Tsuyuki et al. 2005).

This finding, that providing evidence from research or from quality assessments is a necessary but not sufficient condition for the provision of care, has created the field of *knowledge translation,* the scientific study of the methods for closing the knowledge-to-practice gap and the analysis of barriers and facilitators inherent in the process. As defined by the Cambridge Conference, KT is "the iterative, timely and effective process of integrating best evidence into the routine practices of patients, practitioners, health care teams and systems, in order to effect optimal health care outcomes and to maximize the potential of the health care system" (11th Cambridge Conference 2003). For our purposes, KT is intended to subsume issues of patient safety, continuing education and guideline implementation, in order to achieve, in the words of CIHR, the "optimization of health care and health care systems" (CIHR 2005); they are, in this view, "provinces in the country of KT." Patient safety and quality improvement provide compelling examples of both process (how to improve care) and content innovation (what to do to improve it).

The significant gap in care and the quest for patient safety and in the Canadian context call for a programmatic *approach* to the testing and implementation of evidence-based health knowledge translation strategies.

A Framework for Action But What Approach?

Although the concept of the "gap" (between best and current practice) is easily grasped, frameworks for action to close it come to mind less readily. Any effective KT framework requires not only the "big picture" environmental or organizational view, but also the highly important microperspective of the individual. In this issue of the *Journal,* Flemons and his colleagues focus on an organizational view of patient safety; this essay, in contrast, focuses on the view from the perspective of the patient and the healthcare provider (Flemons et al. 2005).

KT can lay claim to many theoretical frameworks. Among these, one most tested is that of Lomas, whose research implementation model is widely known and utilized (Lomas et al.

1993). He describes a multidimensional world in which many external factors (for example, the administrative, community and economic environment), education, the practitioner and patient all play a role, clearly important elements in getting practitioners to use best evidence. In this model, however, the dissemination and adoption of new information (such as that related to patient safety methods) is assumed to be linear, resulting in optimal care. We know this is not the case.

Perhaps a more useful, flexible and interactive model is that proposed by Kitson and her nursing colleagues (1998). They describe *interactive variables* in the understanding of the adoption of evidence: the evidence or information; the manner of facilitation (that is, of communicating the information to the clinician), and the context in which these occur. My colleagues' work in the *Knowledge Translation Program* at the University of Toronto provides many examples of each of these (www.ktp.utoronto.ca): the evidence (about best practices) (Jackson 2005); contextual or environmental considerations (the long term or primary care settings) (JCEHP 2005); and facilitation or communication (dissemination methods such as print materials, web-based education, PDA-assisted information) (Flemons et al. 2005; Jackson 2005). Other examples from the perspective of patient safety also exist: the evidence or information (the format and content of patient safety or critical incident reports, for example), the method of dissemination (for example, computer-delivered or discussion in QI sessions) and the context in which they occur (for example, the regulations or culture of a healthcare setting). Where the factors in all or some of these three domains lend themselves to the acquisition of new evidence, Kitson states that adoption is more readily observed.

Clearly, thinking about variables is a step forward. Something is missing, however – an understanding of the clinician and his/her journey in practice, and for that matter, the patient, all citizens in the country of KT.

Focusing on the Health Practitioner (and Patient) in Patient Safety

So here we have a dilemma. On the one hand, adult educators consider the learning and change process on the part of healthcare practitioners and patients to be a subject of great importance (Knowles et al. 1998; Brookfield 1986; Houle 1984; Houle 1984; Knowles 1998; Tough 1979). On the other hand, QI specialists, guideline implementers, health system engineers and analysts and organizational learning scholars hold that macro, contextual or environmental views of KT as key to implementation success (Argyris and Schon 1978a; Dodgson 1993). Marck's article in this issue of the *Journal*, "Thinking Like a System," is a case in point.

To resolve the dilemma, let's look at the educational perspective. Here exist an array of useful ideas about adult learning and education, based mostly on the work of Knowles and others (Knowles et al. 1998; Brookfield 1986; Houle 1984; Houle 1984; Knowles 1998; Tough 1979). They promote a belief in the following success factors in effective education: that any educational content must be of relevance to the practitioner (not necessarily the teacher); that the learners must be able to interact with materials, teachers and others; and that teaching be supportive and respectful of, and sensitive to the needs of the learner (Knowles et al. 1998). Several other educationists describe the stages of change in an individual. Among the most useful is Prochaska's transtheoretical model, derived from the health promotion literature: here, practitioners move from precontemplation about an issue or need for change through contemplation and preparation for action to action itself, and finally to solidification of the action on a regular basis (Prochaska and Velicer 1997). This model is useful in understanding where clinicians (and for that matter, patients) are in this continuum, so that we can tailor-make educational strategies to suit each stage, and encourage change agents to determine the state of and readiness for change (Davis et al. 2003). There are similar stages of change proposed by others (Geertsma et al. 1982; Pathman et al. 1996; Grol and Jones 2000), but, no matter whose theory is described, it's relatively easy to see how practitioners can move along this continuum. Think about patient safety, for example.

The Change Study of Fox, Mazmanian and Putnam (1989) is another study that helps us think about QI or patient safety aspects of knowledge translation. Following in-depth qualitative interviews with over 300 North American physicians, Fox and his colleagues determined a several-step process of change: first, physicians (and one could easily suppose other health professionals), become aware of a need for change from intrapersonal forces (for example, the desire for increased competence or improved quality in a specific area), interpersonal issues (for example, input from team members or patients regarding a patient safety issue) or external forces (such as regulatory changes, utilization review and other information); second, they envisage what that change would look like (for example, improved physician-patient communication, better teamwork, fail-safe mechanisms); and third, they undertake (often) several steps to accomplish the change (consulting with colleagues, attending educational sessions, embarking on a QI process, et cetera). Derived from adult learning theory and studies of continuing medical education, the benefits of this model are obvious to the field of KT.

But how to put these models — and the idea of the learner-clinician — to work for us?

Next Steps in Solving the KT Puzzle

First, where we add the learner-clinicians' perspective into the mix of KT and patient safety issues, we need to create a curriculum. We are fortunate that the IOM's call to action, *Crossing*

the Quality Chasm (Institute of Medicine 2001) and its health professional education response possess several clear goals and recommendations in this area: increased training for health professionals to work as teams; teaching skills in informatics; recognizing and dealing with the overabundance of information and evidence; and increasing the attention to improvement in quality (Horak et al. 2004; Katon 2003; Berwick 2002; Bates 2002; Fernandopulle et al. 2003; Grol et al. 1999; Grimshaw et al. 2004).

Second, we must embed these curricular strategies in a cohesive and testable framework. What works? What doesn't work? Why? This process calls for action at the individual and the organizational level. Grol outlines educational tools (feedback and audit, opinion leaders, educational interventions, et cetera) to effect change and also calls for large-scale organizational changes by which this can happen (Grol et al. 1999). This seems a simple solution at the 20,000 feet level, but has some inherent problems — for example, the minute effect size of any intervention when considered by itself (Grimshaw et al. 2004); and the consideration that all evidence/information is the same, the lack of overall organizational change, to name a few. There are more robust frameworks to assist us in understanding clinical performance change and patient safety; we must find, create and test them.

Third and finally, it is apparent that this view, as comprehensive as it is, is still only a part of the story. Issues such as those in patient safety require an understanding of both perspectives, the micro and the macro, in order to be fully understood and ultimately optimized. However, they also require us to embrace an understanding of the patient in this area — also citizens of, and potent effector arms in, the "country" of KT.

References

Argyris, C., D.A. Schön. 1978a. *Organizational Learning: A Theory of Action Perspective*. Reading, MA: Addison-Wesley.

Bates, D.W. 2002. "The Quality Case for Information Technology in Healthcare." *BMC Med. Inform. Decis. Mak*. 23(2): 7.

Berwick, D.M. 2002. "A User's Manual for the IOM's 'Quality Chasm' Report." *Health Aff.* (Millwood) 21(3): 80–90.

Boissel, J.P., E. Amsallem, M. Cucherat, P. Nony and M.C. Haugh. 2004. "Bridging the Gap Between Therapeutic Research Results and Physician Prescribing Decisions: Knowledge Transfer, A Prerequisite to Knowledge Translation." *Eur. J. Clin. Pharmacol.* 60(9): 609–16.

Brookfield, S. *Understanding and Facilitating Adult Learning.* 1986. San Francisco, CA: Jossey-Bass.

Buchan, H. 2004. "Gaps Between Best Evidence and Practice: Causes for Concern." *Medical Journal of Australia* 180(6 Suppl): S48–49.

Canadian Institutes of Health Research. Knowledge Translation (KT). Available at: http://www.cihr-irsc.gc.ca/e/8505.html. Accessed August 15, 2005.

Chassin, M.R. and R. W. Galvin. 1998. "The Urgent Need to Improve Health Care Quality. Institute of Medicine National Roundtable on Health Care Quality. *JAMA* 280(11): 1000–5.

Covell, D.G., G.C. Uman and P.R. Manning. 1985. "Information Needs in Office Practice: Are They Being Met?" *Ann. Intern. Med.* 103(4): 596–99.

Davenport, T.H. and J. Glaser. 2002. "Just-in-time Delivery Comes to Knowledge Management." *Harv. Bus. Rev.* 80(7): 107–11, 126.

Davis, D., M. Evans, A. Jadad, L. Perrier, D. Rath, D. Ryan, G. Sibbald , S. Straus, S. Rappolt, M. Wowk, M. Zwarenstein. 2003. "The Case for Knowledge Translation: Shortening the Journey from Evidence to Effect." *BMJ* 5;327(7405): 33–5.

Dodgson, M. 1993. "Organizational Learning: A Review of Some Literatures." *Organization Studies* 14(3): 375–94.

Effectiveness and Efficiency of Guideline Dissemination and Implementation Strategies. 2004. *Health. Technol. Assess.* 8(6): iii–iv, 1–72.

11th Cambridge Conference. July 13–19, 2003. Niagara-on-the-Lake, ON, CDA.

Feldstein, A., P.J. Elmer, E. Orwoll, M. Herson and T. Hillier. 2003. "Bone Mineral Density Measurement and Treatment for Osteoporosis in Older Individuals with Fractures: A Gap in Evidence-based Practice Guideline Implementation." *Arch. Intern. Med.* 163(18): 2165–72.

Fernandopulle, R., R. Ferris, A. Epstein, B. McNeil, J. Newhouse, G. Pisano and D. Blumenthal. 2003. "A Research Agenda for Bridging the 'Quality Chasm.'" *Health Aff.* (Millwood) 22(2): 178–90.

Flemons, W.W., C.J. Eagle and J.C. Davis. 2005. "Developing a Comprehensive Patient Safety Strategy for an Integrated Canadian Healthcare Region. JCEHP current issue.

Fox, R.D., P.E. Mazmanian and R.W. Putnam. 989. *Changing and Learning in the Lives of Physicians.* New York, NY: Praeger Publications.

Geertsma, R., R.C. Parker, R.C. and S.K. Whitbourne. 1982. "How Physicians View the Process of Change in Their Practice Behavior." *Journal of Medical Education* 57: 752–61.

Grimshaw, J.M., R.E. Thomas, G. MacLennan, C. Fraser, C.R. Ramsay, L. Vale, P. Whitty, M.P. Eccles, L. Matowe, L. Shirran, M. Wensing, R. Dijkstra and C. Donaldson. 2004. "Effectiveness and Efficiency of Guideline Dissemination and Implementation Strategies." *Health Technol. Assess*. 8(6): iii–iv, 1–72.

Grol, R. and J. Grimshaw. 1999. "Evidence-based Implementation of Evidence-based Medicine." *Jt. Comm. J. Qual. Improv.* 25(10): 503–13.

Grol, R. and R. Jones R. 2000. "Twenty Years of Implementation Research." *Fam. Pract.* 17 Suppl 1: S32–5.

Houle, C. 1984. *Patterns of Learning: New Perspectives on Life-span Education*. San Francisco, CA: Jossey-Bass.

Knowles, M. 1998. *The Adult Learner: A Neglected Species, 5th edition*. Houston, TX: Gulf Publishing Company.

Horak, B.J., W. Welton and S. Shortell. 2004. "Crossing the Quality Chasm: Implications for Health Services Administration Education. *J. Health. Adm. Educ.* 21(1): 15–38.

Institute of Medicine (US). *Committee on Quality of Health Care in America.* 2001.

Crossing the Quality Chasm: A New Health System for the 21stCcentury/ Committee on Quality Health Care in America, Institute of Medicine. Washington, DC: National Academy Press.

Jackson. 2005. *JCEHP* current issue.

Katon, W.J. 2003. "The Institute of Medicine 'Chasm' Report:

Implications for Depression Collaborative Care Models." *Gen. Hosp. Psychiatry* 25(4): 222–29.

Kitson, A., G. Harvey and B. McCormack. 1998. "Enabling the Implementation of Evidence-Based Practice: A Conceptual Framework." *Quality in Health Care 7*: 149–58.

Knowles, M.S., E.F. Holton, R.A. Swanson, and E. Holton. 1998. *The Adult Learner: The Definitive Classic in Adult Education and Human Resource* Development. Houston, TX: Gulf Publishing Company.

Lomas. J., J.E. Sisk and B. Stocking, 1993. "From Evidence to Practice in the United States, the United Kingdom, and Canada." *Milbank Quarterly* 71(3): 405–10.

Mark. 2005. "Thinking Like a System." *JCEHP* current issue.

Olson, K.L., T.J. Bungard and R.T. Tsuyuki. 2001. "Cholesterol Risk Management: A Systematic Examination of the Gap from Evidence to Practice." *Pharmacotherapy* 11(7): 807–17.

Pathman, D.E., T.R. Konrad, G.I. Freed, V.A. Freeman and G.G. Koch. 1996. "The Awareness-to-adherence Model of the Steps to Clinical Guideline Compliance: The Case of Pediatric Vaccine Recommendations." *Medical Care* Sep. 34(9): 873–89.

Prochaka. J.O. and W.F. Velicer. 1997. "The Transtheoretical Model of Health Behavior Change." *Am. J. Health Promot.* 12(1): 38–48.

Ramos, K., R. Linscheid and S. Schafer. 2003. "Real-time Information-seeking Behavior of Residency Physicians." *Fam. Med.* 35(4): 257–60.

Tough, A. 1979. *The Adults Learning Project: A Fresh Approach to Theory and Practice in Adult Learning*. Toronto, ON: Ontario Institute for Studies in Education.

Tsuyuki, R.T., D.D. Sin, H.M. Sharpe, R.L. Cowie, C. Nilsson and S.F. Man. 2005. "Alberta Strategy to Help Manage Asthma (ASTHMA) Investigators. Management of Asthma Among Community-based Primary Care Physicians." *J. Asthma* 42(3): 163–67.

Villar, J., G. Carroli and A.M. Gulmezoglu. 2001. "The Gap Between Evidence and Practice in Maternal Healthcare." *International Journal of Gynaecology and Obstetrics*75 (Suppl 1): S47–S54.

About the Author

Dave Davis, MD, CCFP, FCFP, FRCPC(hon), Principal Investigator, Knowledge Translation Program, University of Toronto, Chair, Guidelines Advisory Committee, Ontario Medical Association/ Ministry of Health & Long-Term Care, Ontario. Contact: dave.davis@utoronto.ca

Building from the Blueprint for Patient Safety at the Hospital for Sick Children

Polly Stevens, Anne Matlow and Ronald Laxer

Introduction

The Hospital for Sick Children (Sick Kids) has an international reputation as a leader in children's healthcare. Our own experience, however, and evidence on the prevalence of error in healthcare has shown us that even the best, all too often, make mistakes. In 2002, responding to a compelling goal to make our hospital safer for the vulnerable children and families who turn to us for care, we launched the Blueprint for Patient Safety (Blueprint), a comprehensive and action-oriented plan. The plan has been updated annually and is currently on its fourth iteration. This article will touch on the 10 components of the plan, focusing on specific initiatives and lessons we have learned while using the Blueprint to build our patient safety program and develop a culture of safety within the organization.

External Review and Key Concepts

In 2002, when the Blueprint was being drafted, there were no regulatory nor accreditation requirements to guide us in its development. A review of the literature and best practices of local and international organizations yielded a number of concepts that informed our work. These are included in **Table 1**.

Table 1. List of key concepts and sources

Concept	Sample source
The "systems" approach	Reason 1997 and 2000
"Just" culture	Marx 2001
Complexity theory and complex adaptive systems	Zimmerman et al. 1998
High reliability organizations	Weick and Sutcliffe 2001
Hindsight bias	Bogner 1994
Human factors engineering	Vincent 2001
"Extreme" honesty and humanistic risk management	Kraman and Hamm 1999

Table 2. Factors affecting implementation of the plan

Facilitating factors	Challenging factors
A "burning platform" following two very tragic adverse events	Fear of reprisal
Strong leadership support	Strong program and professional autonomy
Good quality improvement culture and infrastructure	Inconsistent follow-up of ideas and initiatives
Well established morbidity and review processes	Fragmented risk-reporting mortality systems
Clinical information systems with computerized provider order entry and electronic order set capability	Fragmented clinical information systems
Committed teams	Relatively young workforce
Compelling mission to improve health of children	Inconsistent application of the policies, procedures and guidelines

Organizational Assessment

An internal review highlighted factors that we felt would facilitate implementation of the plan and ones that might make it more challenging. These are included in Table 2. Facilitating factors are included in **Table 2**, and challenging factors are included in **Table 3**.

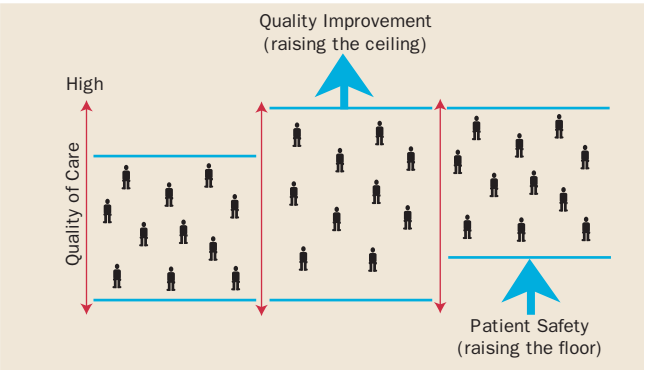
Table 3. Examples of improvements resulting from critical occurrence reviews

Implementation of a transfer checklist to improve communication at hand-overs
Comprehensive rare test proficiency testing
Standardization and controls in the use of heparin
Changes in the air traffic control of helicopters landing on the hospital's roof
Changes to consent processes
Changes to blood bank processes
Removal of concentrated potassium chloride from nursing units
Changes in equipment cleaning
Tighter clinic referral processes
Development of controls in the management of expressed breast milk
Standardization of correct site/procedure processes

Quality versus Patient Safety Concept

In order to build on a culture of quality improvement that was already well established in the organization, a graphic was developed to help teach staff the relationship between quality improvement and patient safety (**Figure 1**). The left side of the graphic depicts 10 children who have come to the hospital for treatment with each experiencing a specific level of care ranging from low to high quality. The middle section depicts the focus of quality improvement, which is to raise the ceiling so that higher levels of care can be achieved. The far right section depicts the focus of patient safety, which is to raise the floor so that fewer patients experience poor levels of care or are harmed. Ultimately, both quality improvement and patient safety work together to improve the overall quality of care provided.

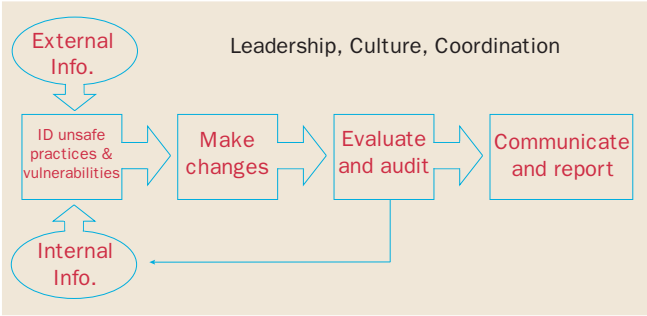
Figure 1. Relationship between quality improvement and patient safety



Program Model and Components

In order to quickly communicate the elements of the patient safety plan, a simple model was developed (**Figure 2**) to highlight the need for integrating external and internal patient safety information, for identifying vulnerabilities and unsafe practices, and for making and evaluating appropriate change. The model also emphasizes the overarching role of leadership, culture and communication.

Figure 2. Patient safety plan – conceptual framework



10 Components

The Blueprint is divided into 10 components:

1. Leadership and Culture
2. Management of Critical Occurrences
3. External Surveillance
4. Internal Surveillance
5. Policies, Procedures and Guidelines
6. Staff Education and Partnerships
7. Partnering with Patients and Families
8. Program Coordination
9. Proactive Risk Assessment and Audit
10. Evaluation and Research

Each of these components will be briefly discussed, focusing on actions, results and lessons learned.

1. Leadership and Culture

The first component represents the most critical element of the plan – leadership and culture. An organization's leaders are essential in advancing any new agenda. They set goals and establish priorities, develop plans and allocate resources. Just as important, they create a culture that promotes new initiatives by

articulating shared values, modeling appropriate behaviours and establishing expectations for staff. An organization committed to patient safety articulates this as an essential organizational goal and then translates this goal into specific actions (Kohn et al. 2000). Specific activities related to this component include ensuring that patient safety is included in the strategic plan, the annual goals and objectives, and in the operating plan and budget; as well, patient safety should be addressed at the time of hire and be part of regular performance reviews.

Patient safety has been firmly entrenched in organizational strategy and operations, and there are numerous examples of the organization putting the safety of children before other competing priorities, which include: the development of a pre-operative anesthesia clinic to better screen high-risk children before surgery; the purchase of state-of-the-art paediatric compatible, physiological monitoring equipment; and, despite an earlier focus on same-day admissions for surgery, recognizing that for some children, admission the night before provides an essential safety net to ensure they are properly prepared for surgery.

In November 2004, safety "walkarounds" were initiated, in which a member of the hospital executive and others meet with staff on a clinical unit and discuss patient safety and environmental safety concerns. Action items, responsibilities and feedback are essential components of the process. So far, common themes arising from the sessions include bed management, communication, equipment, staffing and patient transfers. A subsequent evaluation of the rounds has resulted in a guideline document to improve the operational and follow-up elements of the walkarounds; as well, a database has been developed to facilitate tracking of feedback and actions. Plans are in place to extend the walkarounds to non-clinical areas.

2. Management of Critical Occurrences

Unfortunately, despite our best intentions, errors happen that result in significant harm to patients. It is important that senior leadership, medical staff and employees handle these events with courage and honesty, and with a commitment to finding and improving system issues and to sharing these lessons with others. At Sick Kids, a policy and guideline for managing critical occurrences has been developed and includes immediate patient care and family considerations, support of staff involved in events and processes for investigating the event, developing recommendations and for ensuring appropriate follow-up of changes. A companion policy on disclosure highlights the patient's and family's right to be informed following an adverse event and provides direction for staff in managing these discussions.

Both policies are frequently requested by other organizations, and an article highlighting the unique aspects of disclosure in a paediatric institution was published in the *Journal of Pediatrics* (Matlow et al. 2004). The hospital has also been asked to provide expert testimony on our management of critical occurrences processes and provide advice to colleagues managing critical events in other organizations. Perhaps though, the most meaningful endorsement of our approach came following the inquest into the tragic post-operative death of a young patient at our hospital. One of the recommendations contained in the final report was the following:

> We, the Jury recommend that, for health care, the systems approach to patient safety be adopted...We endorse and encourage the use of the systems approach as adopted by The Hospital for Sick Children as a means of enhancing patient safety. (Chief Coroner of Ontario, 2002).

A primary focus of our critical occurrence reviews is the development of recommendations for improving the system and for preventing the recurrence of similar events. Some of the improvements that have been initiated following a critical occurrence review are listed in Table 3.

One of the challenges we have faced as a result of doing comprehensive reviews is ensuring that recommendations resulting from the reviews are implemented and have the intended effect. This was easier to do when the process began. However, with the hundreds of recommendations that have been generated to date, follow-up has become a significant challenge. We have recently developed an electronic database to facilitate tracking and trending of quality and risk management information, including recommendations from critical occurrence reviews.

3. External Surveillance

Thankfully, we do not have to experience harmful adverse events to learn from them. By making an effort to learn from the mistakes of others we have the opportunity to improve care without the human toll associated with an actual event. Recently, there has been an explosion of information on patient safety. Literature, conferences, agencies and networks abound that promote a greater understanding of medical error and communicate "best practices" in patient safety. With the amount of information that is available to us, we run the risk of either spending too much time in reviewing marginal material or failing to note information that could benefit the organization. As a result, we required a coordinated system for reviewing external information, evaluating its usefulness and ensuring the appropriate implementation of recognized safe practices.

At Sick Kids, we have created an inventory of external data sources, which we routinely survey for relevant safety information. In September 2004, a system was implemented to manage and track hazard alerts and recall information, primarily related to medical devices, supplies and medications. This entailed a database linked to our e-mail system, in which hazard or recall information is entered and appropriate individuals are identified

for follow-up. This information is conveyed through e-mail, and the subsequent responses are recorded for review by the Hazard Alerts Committee. To date, almost 600 entries have been made into the system (an average of 60/ month), and the response rate of notified individuals within an appropriate window of time has improved to almost 100% (up from 50% prior to the change).

4. Internal Surveillance

Improvements in patient safety require a comprehensive understanding of what is going on in the organization, including the incidence of error, harm and potential harm. Studies have shown that incidents are vastly under reported by staff; however, reporting rates can be improved when (1) staff feel safe in reporting events, (2) when reports are easy to complete and (3) when staff receive feedback about positive changes that were made as a result of this information (Zipperer and Cushman 2001). Emphasis on the reporting of potential incidents and close calls is also essential as it allows for learning without the challenges associated with actual events.

At Sick Kids, there were a number of different error-reporting systems (including patient and visitor, medication, staff and critical care), which resulted in some confusion at the front lines. Paper-based reporting led to delays in notification and follow-up, manual data entry was required to identify trends, and in some areas, incident reports were being used to evaluate staff performance.

In May 2004, a comprehensive, on-line safety reporting system for all events was launched with the goals of increasing the number of reports, increasing the proportion of potential or near-miss reports,, improving turn-around time for report follow-up and making improvements in patient safety. Anonymous reporting was provided as an option. In the 12 months since the system has been operational, we have seen a 60% increase in the number of reports and a similar increase in the proportion of potential reports (**Figures 3** and 4). About 16% of reports are entered anonymously, a number we would like to see decrease as staff learn to trust the system. However, our goal of increasing timeliness of report follow-up has not yet been achieved. We have found that with both the increase in the volume of reports and more onus on front-line managers to manage reports, timeliness of follow-up remains about the same as it was prior to the new system. Our plan to provide regular, area-specific indicators on outstanding reports is expected to help focus accountability on this important aspect of the system.

A number of hospital-wide projects have been initiated as a result of safety reporting, including improvements to bed safety, entanglement and patient identification.

Figure 3. Safety reporting system results – total reports

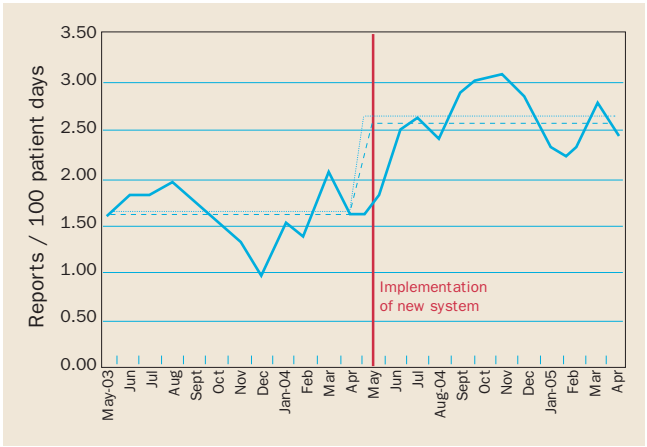


Figure 4. Safety reporting system results – % potential (near miss) reports

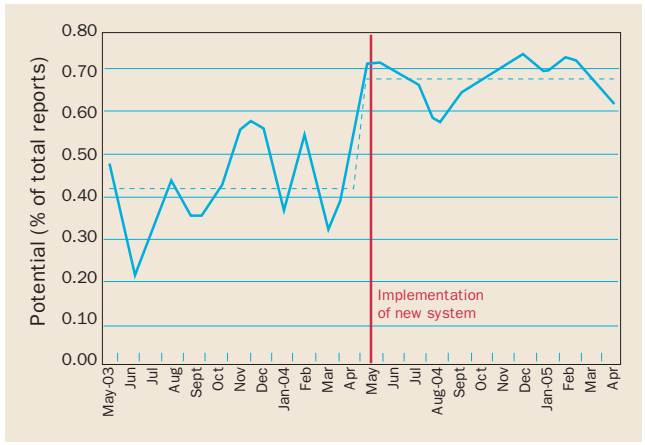


Figure 5. Logo for Sick Kids Partners in Patient Safety (PIPS) program

Partners in Patient Safety

In addition to the safety reporting system, there are numerous other internal sources of safety information, including morbidity and mortality rounds, satisfaction surveys and other reviews and audits. The new quality and risk management database will be used to track follow-up of actions from these sources as well.

5. Policies, Procedures and Guidelines

Research into complex adaptive systems (such as hospitals) has shown that having a common purpose and easily understood rules can lead to innovative system behaviour (Committee on Quality Health Care in America 2001). Good procedures and guidelines can provide clarity in situations where there is expert agreement about the appropriate course of action, and they can provide useful learning tools for less experienced staff. These tools, however, need to be kept up-to-date and accessible to staff.

At Sick Kids, a complete review of our policies and procedures was required as there were no standards for policy-creation, and approval processes were ambiguous at best. Policies, procedures and guidelines existed that were out of date and in conflict with one another, and distribution, communication, retrieval and archiving of policies were also concerns. Further, in two serious adverse events, it was determined that the lack of accessible guidelines for the management of a particular group of complex patients was a contributing factor. In both cases, it was noted that good evidence-based guidelines had been developed; however, they had not been formally approved and were not available to the staff who required them.

The hospital's e-mail database system was selected to provide on-line access to policies by all staff, and to support search capabilities and electronic approval and review processes. To facilitate timely implementation, all existing hospital-wide policies, procedures and guidelines (unless they were deemed clearly problematic) were migrated on to the new system, short review cycles were set and paper-based manuals and documents were removed from units and departments. Since implementation, more than 500 policies have been reviewed and updated, and approximately 300 have been permanently archived. Most recently, about 300 medical directives have also been added to the database and various departments are adding department-based documents to the system. Tighter controls have also been implemented to ensure that any new documents have supporting evidence, are developed with a hospital-wide perspective in mind and in consultation with appropriate stakeholders, and communication and evaluation plans have been developed. Each year, a selection of policies, procedures and guidelines undergo a formal audit. Some of the documents recently audited include introduction to innovative surgical procedures and devices, verbal orders and patient identification.

Currently, a large number of policies reside in draft mode and work continues to shorten the length of time between when a document is drafted to when it is approved and available to staff.

6. Staff Education and Partnerships

Healthcare workers need to know their role in providing safe care to patients and require education on general patient safety topics, area-specific safety initiatives and lessons learned elsewhere in the hospital and beyond.

In addition to informal mechanisms, such as one-on-one and team support, a number of formal opportunities for staff to learn about patient safety, to share "lessons learned" and to celebrate successes have been established and are listed in **Table 4**.

Staff also work with external partners to improve patient safety. The Blueprint has been shared in a number of external fora and was identified as a "good practice" in our recent

Table 4. Patient safety learning opportunities

Key lessons in patient safety at orientation
Regular news items in the hospital's weekly newsletter
"Branding" of the patient safety program – called Partners in Patient Safety (PIPS), including a logo (Figure 5) depicting the relationship between staff, families and patients in improving safety, and formal launch during patient safety week last fall
Publication of a quarterly PIPS newsletter
Monthly patient safety rounds
Ad hoc area specific rounds and meetings
Patient safety Web site and resources
Quarterly meetings of area quality representatives featuring new hospital-wide initiatives and team successes and lessons learned

Table 5. Feedback from Children's Council on patient safety

Make sure playrooms are safe
Make sure kids in infectious diseases clinic follow infection-control precautions
Make sure little kids cannot strangle on IV tubing
Provide lockers for families with a padlock like the kind at a fitness gym
Check often on kids who are alone in patient rooms to make sure they are safe
Improve the lighting in the parking garage
Cars double parked or stopped on the drive way make it unsafe
No smoking on property and especially around entrances to the hospital

accreditation with the Canadian Council on Health Services Accreditation. Sick Kids has been invited to participate in government and hospital association planning regarding patient safety in hospitals. Sick Kids staff have also participated in teaching patient safety at learning institutions, and are active participants in the Canadian Association of Paediatric Health Centres (CAPHC) patient safety collaborative. A symposium titled "Partners in Paediatric Patient Safety: Taking Care of the Kids" has recently been coordinated by hospital staff.

7. Partnering with Patients and Families

Patients and families play an important role in ensuring safe care. They represent an important line of defense and should be encouraged to question organizational routine, procedures and processes and whenever something does not look or seem "right" (Agency for Healthcare Research and Quality 2001).

At Sick Kids, a team of parents and staff has recently been established called the "Families as Partners in Patient Safety" working group with the goals of raising awareness among healthcare professionals on the role of parents in patient safety, empowering family members to speak up and providing education to families about patient safety. One of the group's first activities was to ask members of the Children's Council their thoughts on making the hospital safer. **Table 5** summarizes their feedback and underscores the value of listening to our young patients.

8. Program Coordination

The Department of Quality and Risk Management has primary responsibility for coordinating the patient safety plan, and, in February 2004, the role of Physician Liaison, Patient Safety was developed to enhance coordination and communication of patient safety throughout the organization. Direction has also been communicated to the program and department quality management leaders in regards to their role in patient safety, and plans are in place to enhance accountability for quality and safety through the development of regular reports and mandatory program elements. A major committee restructuring effort is currently underway to improve the value of committee work and to ensure alignment with hospital objectives including patient safety.

9. Proactive Risk Assessment and Audit

Risk assessment is the process of identifying processes and practices with either a high severity or high probability for patient harm. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in the United States has said that "proactive identification and management of potential risks to patient safety has the obvious advantage of preventing adverse occurrences, rather than simply reacting when they occur. This approach also avoids the barriers to understanding created by hindsight bias and the fear of disclosure, embarrassment, blame, and punishment that can arise in the wake of an actual event" (JCAHO 2000).

With input from stakeholders throughout Sick Kids, an annual system-wide safety assessment is completed, which identifies a number of potential areas of focus. This year, the process for selection has been more formally developed (**Figure 6**), and an extensive list of audits and projects has been developed. Projects that are currently underway are listed in **Table 6.**

Past audits have included equipment maintenance processes, fridges and freezers, patient falls, referral processes to ambulatory clinics, and sedation practices and documentation. Other audits are currently underway and include timeliness of the first dose of antibiotics and our "responsible physician" policy, an important component to ensuring coordinated care.

An improved method for tracking the progress of projects and recommendations arising from audits is in development.

Table 6. Current patient safety projects

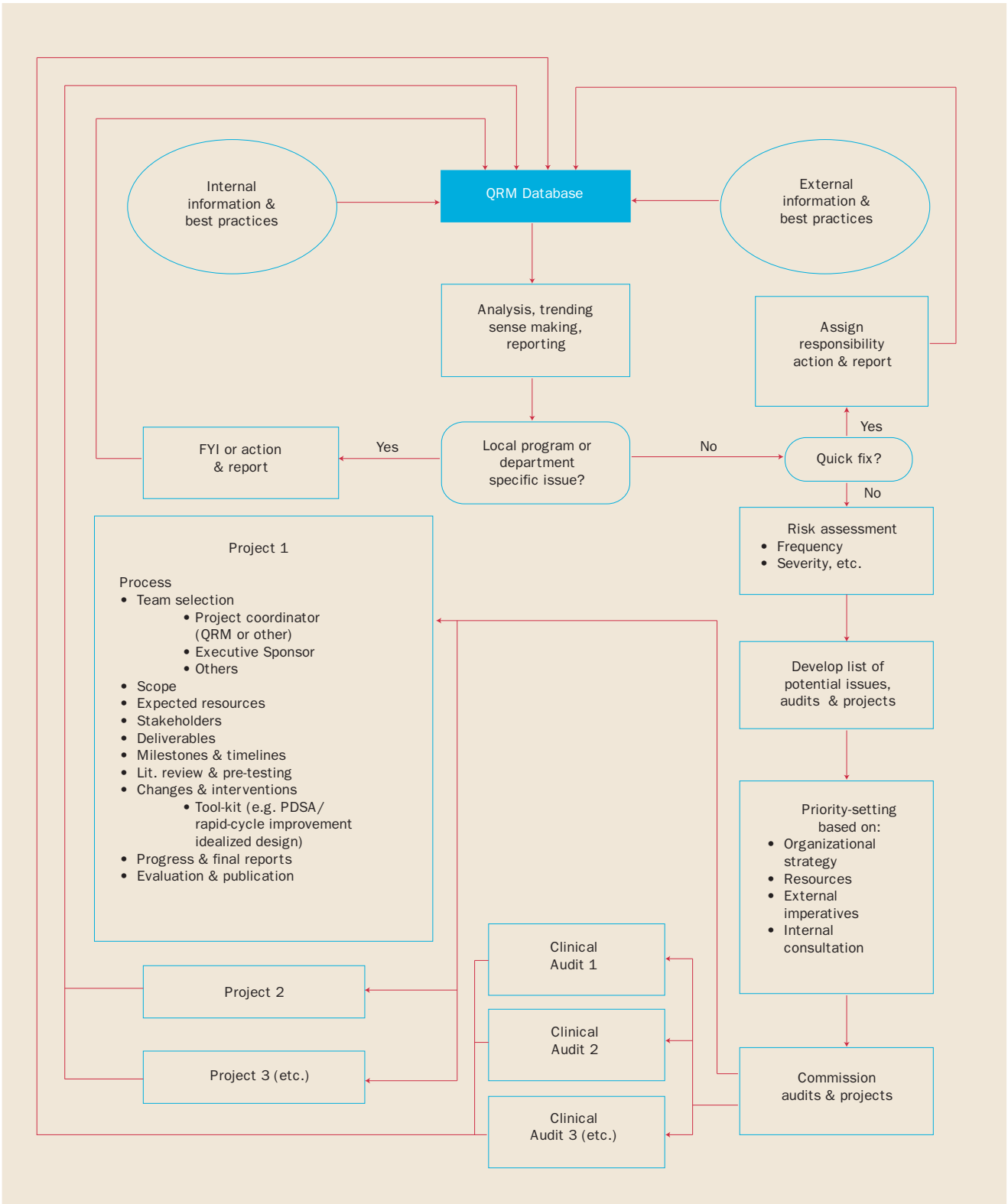
Correct site procedure
Critical laboratory tests
Entanglement / entrapment
Medication safety – heparin
Medication safety – high potency electrolytes
Medication safety – opioids
Medication safety – reconciliation
Patient identification
Prevention of central line infections
Prevention of surgical site infections
Transfer checklist roll-out

10. Evaluation and Research

All new safety projects are implemented with plans for their subsequent evaluation, including, if appropriate, plans for dissemination and publication of results. In the last few years, posters and presentations on various aspects of the plan have been presented at various conferences including CAPHC, the Ontario Hospital Association (OHA), the National Association of Children's Hospitals and Related Institutions (NACHRI), the National Initiative for Children's Healthcare Quality (NICHQ) and the Child Health Corporation of America (CHCA).

Patient safety, particularly in the paediatric environment, represents a relatively new area of study. At Sick Kids, a Patient Safety Research Interest Group has been formed to provide a venue for interchange of ideas and collaboration among Sick Kids staff. Research projects currently being developed include

Figure 6. Model for organizational patient safety, quality improvement and risk management priority-setting and planning



patient safety issues in ambulatory clinics and best practices in managing complex patients in the complex hospital environment. In conjunction with CAPHC, staff have also been instrumental in the development of a tool to examine the incidence of adverse events in hospitalized children in Canada.

Recently, Sick Kids championed a 10-centre CHCA study to enhance communication at patient hand-offs from the emergency department. The study found that by using a carefully designed checklist, significant improvements in medication management, duplication of laboratory tests and isolation precautions could be achieved. Plans are now in place to roll out the checklist to other areas of the organization, as well as to look for application of the concept to transfers between institutions.

Conclusion

The Blueprint for Patient Safety has provided us with a solid foundation for building our patient safety program. The 10 components of the program have served as a comprehensive framework for improving our safety culture, and for providing staff with insights into the many dimensions of patient safety. We consider the Blueprint to be a dynamic document, which will continue to grow and evolve over time as we move closer to our goal of providing safe care to every child who comes to us for care.

References

Agency for Healthcare Research and Quality. 2001. *Five Steps to Safer Health Care.* Rockville, MD: Author.

Bogner, M.S. 1994. *Human Error in Medicine*. Hillsdale, NJ: Lawrence Erlbaum Associates, Inc.

Chief Coroner of Ontario. 2002. *Report on the Inquest of Sanchia Bulgin.* Toronto, ON: Author.

Committee on Quality Health Care in America. 2001. Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century.* Washington, DC: National Academy Press.

Joint Commission on Accreditation of Healthcare Organizations (JCAHO). 2000. Patient Safety Standards. Oakbrook Terrace, IL: Author.

Kohn, L.T., J.M. Corrigan and M.S. Donaldson. 2000. *To Err Is Human: Building a Safer Health System.* Washington, DC: National Academy Press.

Kraman, S.S. and G. Hamm. 1999. "Risk Management: Extreme Honesty May Be the Best Policy." *Annals of Internal Medicine* 131(12): 963–67.

Marx, D. 2001. Patient Safety and the "Just Culture": *A Primer for Health Care Executives.* New York, NY: Columbia University.

Matlow, A., P. Stevens, C. Harrison and R. Laxer. 2004. "Achieving Closure Through Disclosure: Experience in a Pediatric Institution." *Journal of Pediatrics* 144(5): 559–60.

Reason, J.T. 1997. Managing the Risks of Organizational Accidents. Aldershof, UK: Ashgate.

Reason, J.T. 2000. "Human Error: Models and Management." *British Medical Journal* 320(7237): 768–70.

Vincent, C., ed. 2001. *Clinical Risk Management: Enhancing Patient Safety.* 2nd ed. London, UK: BMJ Books.

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

Zimmerman, B., C. Lindberg and P. Plesk. 1998. *Edgeware: Insights from Complexity Science for Health Care* Leaders. Irving, TX: VHA Inc.

Zipperer, L.A. and S. Cushman, eds. 2001. *Lessons in Patient Safety.* Chicago, Ill: National Patient Safety Foundation.

About the Authors

Polly Stevens, MHSc, is Director, Quality and Risk Management, The Hospital for Sick Children.

Anne Matlow, MD, FRCPC, is Physician Liaison, Patient Safety and Director, Infection Prevention and Control Program, The Hospital for Sick Children.

Ronald Laxer, MD, FRCPC, is Vice-president, Clinical and Academic Affairs, The Hospital for Sick Children.

Corresponding Author: Polly Stevens, Director, Quality and Risk Management, The Hospital for Sick Children, 555 University Avenue, Toronto, Ontario M5G 1X8, Tel: (416) 813-5357, polly.stevens@sickkids.ca

Legal Issues in Patient Safety: The Example of Nosocomial Infection

Tracey M. Bailey and Nola M. Ries

Introduction

"Preventable infections are out of control in Canadian hospitals," declared an April 2005 headline in the *British Medical Journal.* Hospitals face less stringent infection-control monitoring than do restaurants, warned a CBC news investigation. Recent events in Canada have indeed highlighted concern with infectious disease exposure through the healthcare system: the SARS outbreak led to criticism of lax hospital infection-control practices; various Canadian hospitals discovered that improper sterilization of equipment may have exposed patients to HIV, hepatitis and other diseases; virulent *C. difficile* infections claimed patient lives; and a Montréal children's hospital faced public concern in spring 2004 following disclosure that one of its former surgeons had died from AIDS. In an era of growing concern with patient safety in the healthcare system, these events raise important legal issues regarding liability, disclosure of information to patients and reporting to regulatory bodies, government agencies and others that have a paramount duty to protect the public from harm.

In this article, we review several key legal issues related to patient safety. Using the example of nosocomial infection, we begin by summarizing recent lawsuits that have stemmed from alleged lapses in infection-control practices. We then identify legal duties that healthcare providers and facilities owe to patients to ensure their safety. Next, we discuss disclosure quandaries that may arise in the patient safety context. If a patient has been harmed, or exposed to risk of harm, do providers have a duty to disclose that information to the patient? What about the situation of remote or theoretical risks? When errors have occurred, or where some risk of harm exists, what information must be disclosed to regulatory authorities such as professional colleges or government agencies? We describe several new legal requirements that mandate disclosure of errors and conclude by offering some thoughts on the role of law in promoting patient safety. Readers are advised that this article does not constitute legal advice and are urged to consult with legal counsel regarding specific questions or concerns.

"See You in Court"

Recent years have witnessed a growing number of lawsuits aimed at seeking redress for lapses in patient safety. In early 2004, an Ontario law firm filed a class action lawsuit on behalf of patients who contracted SARS in hospitals during the second wave of the outbreak in Toronto. This claim alleges that public health officials failed to maintain sufficiently rigorous infection-control precautions. Throughout 2003, a number of Canadian hospitals notified patients that improper sterilization of equipment may have exposed them to HIV, hepatitis and other diseases. In response, many patients filed legal actions alleging that those hospitals failed to meet an acceptable standard of care. As one example, in November 2003, Sunnybrook and Women's College Health Sciences Centre in Toronto disclosed that ultrasound equipment was not properly disinfected, placing over 900 patients at risk of infection. A $150 million class action lawsuit filed against the hospital alleges it was negligent in failing to meet adequate sterilization standards. Following these revelations, the Ontario government ordered a province-wide audit of hospital infection-control practices and the final report was released in January 2004.

In May 2005, Health Grades Inc., a U.S. company that evaluates safety and quality concerns in health facilities, reported that rates of hospital-acquired infections in the United States rose by 20% between 2000 and 2003, contributing to around 9,500 deaths. The report suggested that facilities with higher nosocomial infection rates tend to fare worse on other measures of patient safety, "suggesting that hospital-acquired infection rates could be used as a proxy of overall hospital patient safety." ("Medical errors..." 2005) Infection-control lapses are clearly a serious patient safety matter. Dr. Dick Zoutman, co-chair of the Ontario Provincial Infectious Diseases Advisory Committee, recently estimated that "a quarter of a million hospital-acquired infections occur every year in Canada.... And 8,000–12,000 people may die of infections year in and year out. It's a silent epidemic of a sort, which in sheer numbers puts it at the fourth leading cause of death" (College of Physicians & Surgeons of Ontario 2005).

… healthcare facilities have an obligation to provide a safe environment to protect patients from harm in the course of receiving care.

Legal Obligations

Healthcare providers and facilities owe a legal duty of care to their patients. Healthcare providers must "exercise that degree of care and skill which could reasonably be expected of a normal, prudent practitioner" in the same circumstances, as explained by the Supreme Court of Canada in the 1956 case, Crits v. Sylvester, which remains a leading authority ([1956] S.C.R. 991). They also owe their patients a fiduciary duty to act in that patient's best interests as set out in various court decisions, including the Supreme Court of Canada's judgment in *McInerney v. MacDonald* ([1992] 2 S.C.R. 138). Similarly, healthcare facilities have an obligation to provide a safe environment to protect patients from harm in the course of receiving care. They have "a duty not only to establish necessary systems and protocols to promote patient safety, [they] must also take reasonable steps to ensure that ... staff (including medical staff) comply with these protocols." (Picard and Roberts 1996).

In the context of healthcare-associated infections, what constitutes reasonable practices and protocols may be a moving target during a novel disease outbreak, particularly as infection-control measures are revised to reflect new evidence about the disease's virulence, transmission routes and key control methods. Indeed, significant criticism has been leveled at the "incoherent and at times completely untenable" infection-control measures disseminated during the SARS outbreak (Erlick 2003). The area of infection-control is one dominated by guidelines and directives, and failure to comply with recommended practices will be one factor that may indicate a failure to meet an appropriate standard of care.

In many areas of practice, courts often look to guidelines or standards of practice to help determine the legal standard of care. In the case of *Spillane* (*Litigation guardian of*) *v. Wasserman* ([1992] O.J. No. 2607), the judge found that the defendant physicians "neglected to follow the minimum standards set out in the notices provided by the College of Physicians and the guides for physicians prepared on behalf of the Canadian Medical Association." This fact supported the conclusion that the physicians were negligent.

The appropriateness of a healthcare practice must be evaluated against accepted standards at a particular point in time. The Supreme Court of Canada has cautioned that "courts must not, with the benefit of hindsight, judge too harshly doctors who act in accordance with prevailing standards of professional knowledge" (ter *Neuzen v. Korn*, [1995] 3 S.C.R 674, para. 34). In a 1930s case involving an allegation that a young girl acquired smallpox infection after exposure at a Vancouver hospital, a B.C. Court of Appeal judge addressed the challenge of protecting patients during a time of uncertainty: "In view of this uncertainty and limited knowledge, while it may be difficult to provide against unknown danger, the fact that it is known that this disease may be transmitted in ways not yet under-

stood suggests the need of rigorous precautions with the view, within reasonable limits, of closing every avenue from which danger might be apprehended" (*McDaniel v. Vancouver General Hospital,* [1934] 1 D.L.R. 557, p. 566). On further appeal, the hospital was absolved of liability, as the court found the hospital had acted in accordance with existing approved practices.

A patient who can establish she suffered harm as a result of a healthcare provider's failure to meet an appropriate standard of care may bring a negligence claim against the provider as well as the care facility. Recent examples of SARS-related litigation demonstrate that individuals may even sue provincial governments for allegedly failing to provide adequate funding to health facilities. In the context of nosocomial infection, patients may claim harm simply from exposure to a risk of infection and need not establish that they did, in fact, acquire an infection. For example, a gynecology clinic patient who is exposed to HIV or other viruses that are typically transmitted through sexual contact may suffer from the anxiety and uncertainty she experiences while awaiting test results and the restrictions on her personal life as she must protect others, including sexual partners, from possible exposure.

Disclosure Obligations

Different types of disclosure obligations may arise where a patient has been harmed, or faces a risk of harm, through his contact with the healthcare system. These include disclosure to a patient directly, and disclosure to regulatory bodies and government agencies.

Patient Disclosure

In regard to disclosure of medical error generally, Canadian law clearly establishes a positive duty on care providers to inform patients of errors that occur during their care, if a reasonable person in the patient's position would want to know about the mistake (Picard Robertson 1996: 170). For example, in one case, a surgeon was successfully sued for failing to tell a patient in a timely manner that a roll of surgical gauze had been left in her abdomen (*Shobridge v. Thomas*, 1999 BCJ No. 1747). In another case, a urologist implanting a device could not locate the tubing and balloon from a previous device that had been implanted. He decided to leave it rather than operating to attempt to locate it. While he informed his patient of this, he also inaccurately told the patient this posed no risk of harm. He was found negligent for failing to advise the plaintiff of the true risks, as well as a failure to follow up appropriately (*McCann v. Hyndman*, [2003] A.J. No. 1016).

In regard to nosocomial infection, when care providers realize that patients may have been exposed to infection from equipment, other patients or healthcare workers, a legal obligation may arise to contact patients to warn them of the risk and provide advice regarding appropriate follow-up testing and care.

Existing Canadian case law requires that healthcare facilities engage in timely review to identify patients who may be at risk and employ effective communication strategies to alert them. In *Pittman Estate v. Bain* ([1994], 112 D.L.R. [4th] 482 [Ont. Gen. Div.]), a case involving a failure to inform a patient that he may have contracted HIV through a blood transfusion, an Ontario General Division Court imposed "an obligation to notify the at risk recipients in a manner and in a time commensurate with the risk to their health" (para. 546). Depending on the circumstances, this duty may be discharged by notifying the patient's family physician about a risk. The physician then has a duty to inform the patient.

In the context of nosocomial infection, patients may claim harm simply from exposure to a risk of infection and need not establish that they did, in fact, acquire an infection

In addition to the existing court decisions on this issue, however, Canadians may see governments taking a more active role in mandating when and what a patient should be told after such an incident. The government of Quebec has recently amended legislation to specifically address this area. In *An Act Respecting Health Services and Social Services* (R.S.Q., c. S-4.2), a specific right to be informed of an accident (defined as "an action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user ...") has been set out for those receiving care in hospitals. Quebec has also approved codes of ethics of various health professions through legislation, thus giving them the explicit force of law. Some of these have recently been amended to include a duty to inform a patient of an error, for example: the *Code of Ethics of Physicians* (changed in 2002) (R.S.Q., c. C-26, s. 87, 2001, c. 78, s. 56), the *Code of Ethics of Pharmacists* (R.S.Q., c. P-10, c. C-26, s. 87, c. P-10, r.5) and the *Code of Ethics of Dispensing Opticians* (R.S.Q., c. O-6; c. C-26, s. 87; c. O-6, r.3.1).

While codes of ethics may not normally carry the force of law on their own (though often courts look to them to help determine legal standards), other recent steps have taken place to include an obligation to disclose errors to patients in this context. The Canadian Medical Association's Code of Ethics was recently amended to explicitly require the disclosure of harm. This Code has been officially adopted by certain Colleges of

Physicians and Surgeons across Canada, which would assist in making a case for successful disciplinary action against a physician who failed to make such disclosure. At least one College, New Brunswick's, has made this explicit (failure to disclose would equate to professional misconduct as the regulations set out that professional misconduct includes a breach of the code of ethics).

Some Colleges have taken the added step of drafting separate guidelines or policies addressing this issue (see those in Saskatchewan, Manitoba, Ontario and Newfoundland). For example, the Newfoundland Medical Board sets out more than the duty to disclose. It also provides some guidance as to whom to disclose, when disclosure should be made and other suggestions regarding how to appropriately convey the information in question.

At least some hospitals have also begun to implement relevant policies. Two of The McGill University Health Centre hospitals instituted policies as early as 1989 and 1990, and the Centre as a whole did so in 2001 (MUHC 2001). The University Health Network in Toronto did so in May of 2005. It seems likely that given the increase in attention to patient safety that many others will likely follow suit. One could argue that a failure to create and implement such policies could be a breach of the duty owed by healthcare facilities to create a safe environment (Robertson 2002).

Questions have arisen as to whether healthcare providers have a legal duty to notify patients of extremely low or theoretical risks of harm, such as possible exposure to Creutzfeld-Jakob disease (CJD). In 2002, health officials in Saskatchewan opted to notify 71 patients about a risk of possible exposure from medical equipment that had been used on a man who subsequently died from CJD. Nova Scotia health officials took the same notification measures in 2004 based on fear that equipment may have been exposed to CJD. Concern with theoretical risk is not limited to healthcare facilities but is a major ongoing concern for blood suppliers, such as the Canadian Blood Service, and safety regulators.

In a 1997 commentary in the *Canadian Medical Association Journal*, several legal, medical and ethics experts concluded "that there is a modest legal foundation for the premise that healthcare providers have an obligation to notify former patients about the theoretical risks associated with exposure to..." infectious agents (Caulfield et al. 1997: 1391). However, ethical principles, including the imperative to protect patients from undue harm, may militate against individual notification and favour a system of public notification.

While Canadian courts have not yet ruled on the issue of disclosing theoretical risks in the healthcare setting, administrators may choose to notify patients and the public generally to preserve trust. There is growing demand for openness and transparency in regard to medical errors and administrators would likely prefer to proactively manage the communication process rather than formulate a hasty response to provocative media stories that imply incompetence and cover-ups in the healthcare system.

In addition to disclosure to patients who may have been harmed (or exposed to harm) by past encounters with the healthcare system, providers may also have to confront the dilemma of whether to inform patients of potential risks they may face in receiving treatment. To obtain informed consent to treatment, healthcare providers have a legal duty to advise patients of material risks that a reasonable person in the patient's position would want to know (*Reibl v. Hughes*, [1980] 2 S.C.R 880). However, does this duty extend to mandate disclosure of information such as the fact that a care provider is HIV-positive? In 2004, Québec's Collège des Médecins investigated this issue following disclosure that a former surgeon at a Montréal hospital had treated patients while HIV-positive. The College concluded that a physician with a blood-borne infection is not required to inform the patient, but the infected physician must undergo periodic review and risk assessment by an expert panel of Québec's National Institute of Public Health (Bannady 2005). Where necessary to protect patients from possible harm, the physician will receive support to modify his or her professional activities.

This policy, which does not establish mandatory patient disclosure, is consistent with a 2001 Alberta decision in which the Court of Appeal found that a surgeon with controlled epilepsy did not have a legal obligation to disclose his condition to his patient. The Court stated that Canadian law does not impose "any liability in negligence on a doctor who fails to disclose his personal medical problems in a case where those medical problems cause no harm to the patient" (*Halkyard v. Mathew* 2001, ABCA 67, para. 11).

Reporting to Regulatory Bodies and Government Agencies

In addition to grappling with the issue of notifying patients of possible healthcare-associated harms, providers may face obligations to report risks and errors to regulatory officials, government agencies and others. Most healthcare facilities should have policies on the creation of incident reports. Many will have quality assurance committees to monitor and improve the quality of care provided in the facility, thus enhancing patient safety and learning from past mistakes. There will be obligations under certain policies to provide information or write reports regarding particular "incidents." All provinces to varying degrees have taken steps to protect certain information contained in these types of reviews, under certain conditions, with statutory privilege so that it cannot necessarily be used in any legal proceedings that may come about as a result of the same incident (for example, s.9 of the *Alberta Evidence Act*). However, the duty

to disclose this type of information for review purposes has not been previously legislated. This is beginning to change.

In 2002, for example, Saskatchewan became the first province in Canada to enact legislation requiring mandatory reporting of medical errors to the provincial Department of Health (*Act to Amend the Regional Health Services Act* (2004), *Saskatchewan Critical Incident Reporting Guideline and Saskatchewan Critical Incident Regulations*). Notification of "critical incidents" must be made by healthcare organizations to their regional health authorities, who in turn must notify the minister. Investigations and written reports are to follow. It will be interesting to see if other provinces decide to follow suit.

All provinces and territories have legislation mandating the reporting of deaths in certain circumstances (e.g., Manitoba's *Fatality Inquiries Act* and *Ontario's Coroners Act*). Though wording, and as a result the scope of what is included, in each of the Acts varies, deaths that may have been caused by negligence are reportable to medical examiners, coroners, investigators and/or the police. One of the purposes of a fatality investigation may be to prevent similar deaths in the future.

Alberta has legislation that mandates the reporting of "significant mishaps" at non-hospital surgical facilities to the health authority with which they have an agreement as well as the Minister (see *Health Care Protection Act* and the related regulation). The College of Physicians and Surgeons have amended their bylaws to allow disclosure of these mishaps by their Registrar to the relevant health authority.

Many provinces also have legislation that requires the reporting of various types of incidents that occur in care facilities (such as long-term care or child care facilities). While some of the facilities in question would not be considered healthcare facilities, reportable errors include things such as medication errors and harm suffered as a result of improper care or treatment. For example, under British Columbia's *Community Care and Assisted Living Act* and its *Adult Care Regulations* (B.C. Reg.536/80 including amendments up to B.C. Reg. 457/2004), licensees must report promptly to the medical health officer as well as the contact for the person in care and their primary care provider if a "reportable incident" occurs (s.10.6). Such an incident includes a medication error (Schedule 1). Saskatchewan's *Personal Care Homes Regulations* (R.R.S. 2000, c.P-6.01, Reg. 2 as amended by Saskatchewan Regulations 69/2002 and 89/2003), mandate reporting of "serious incidents." This includes "any occurrence, accident or injury that is potentially life threatening" as well as "any harm or suspected harm suffered by a resident as a result of unlawful conduct, improper treatment or care, harassment or neglect on the part of any person" (s. 13 (1)). Licensees must notify the "resident's supporter," their physician, the department responsible and the regional health authority. They are also obligated to provide a written report to the government department responsible outlining a number of things including "any actions taken ... to solve the problems ... and to prevent recurrences of the serious incident" (s. 13(2)(b)).

Individual healthcare facilities have also launched programs to encourage health professionals to identify and remedy sources of error, including regular patient safety meetings and internal tracking of adverse events.

Role of Law in Promoting Patient Safety

Law has an important role to play in promoting patient safety. Legal rules establish standards that healthcare providers and others must meet and also deter practices that fall below an accepted standard. Principles regarding information disclosure in the healthcare context ensure that patients receive information they may need to make informed choices and to pursue claims for damages where the error that led to an adverse event was negligent. Malpractice litigation provides a mechanism through which those who have been harmed may seek redress and, as the influential 1990 Pritchard report on liability in healthcare observed, "the threat of ... litigation against health care providers for negligence contributes in a positive way to improving the quality of health care provided and reducing the frequency of avoidable health care injuries" (A Report of the Conference ... 1990).

Recent legal developments help to encourage a culture of openness regarding patient safety concerns. One example is privilege over quality assurance activities that are aimed at minimizing future errors. Further, the law mandates reporting in appropriate circumstances, both to patients, regulatory bodies and others.

The concern that disclosure of errors will cause more lawsuits is not borne out in practice. Professor Gerald Robertson observes that "[r]ecent studies in the Unites States have demonstrated that hospitals which introduced an active disclosure policy experienced a reduction in the incidence of malpractice litigation...[t]he lesson that the medical profession must learn is that when an error occurs, silence does not prevent litigation, it promotes it" (Robertson 2002).

The law is an important tool which should continue to be used as issues around patient safety are examined and strategies are determined to create safer systems and decrease the incidence of preventable error. The Canadian Patient Safety Institute is optimally positioned to work with the provinces and territories in examining existing law and planning for future legislative reform. (Indeed, they cite the promotion of legislative reform as an important part of their action plan and have already initiated discussions with provincial and national governments). Studying the possible harmonization of existing Acts and regulations such as quality assurance and fatality legislation would likely be fruitful. Also worthwhile would be a consideration of legislation aimed at a national surveillance program to be used in gathering necessary information to analyze and plan

with the aim of reducing error. Governments would be remiss not to follow what is happening in Saskatchewan following the passage of their novel reporting legislation and to study whether it has helped to achieve the goals of its passage, and whether they should consider similar Acts within their own jurisdictions. Finally, it would be worth reflecting on the introduction of laws which would require regional health authorities and healthcare facilities to develop policies and procedures regarding the disclosure and reporting of error, and to mandate the subsequent training of staff.

References

A Report of the Conference of Deputy Ministers of Health of the Federal/Provincial/Territorial Review on Liability and Compensation Issues in Health Care. 1990. In *Liability and Compensation in Health Care.* Toronto, ON: University of Toronto Press.

Bannady, S. 2005. "Guidelines Set for Health-Care Workers with HIV." *Medical Pos*t 41: 7.

T. Caulfield, J. Dossetor, L. Boshkov, J. Hannon, D. Sawyer, and G. Robertson. 1997. "Notifying Patients Exposed to Blood Products Associated with Creutzfeldt-Jakob Disease: Integrating Science, Legal Duties and Ethical Mandates. *Canadian Medical Association Journal* 157: 1389-92.

College of Physicians & Surgeons of Ontario. 2005, March/April. "The Changing Face of Infection Control." Members' Dialogue.

Erlick, L. 2003. Ontario Medical Association. Quoted in Paul Webster, "Canadian Infection-Control Experts Push for Health Reform." *Lancet* 362: 1290.

"Medical Errors Edging up in US, Study Finds." 2005, May 2. Reuters.

MUHC. 2001, November 19. "The MUHC Becomes One of the First Canadian Health Centres to Adopt a Disclosure Policy." News Centre Archives of MUHC.

Picard and Roberts. 1996. *Legal Liability of Doctors and Hospitals in Canada*, 3rd ed. (p. 370). Thomson Canada Ltd.

Robertson, G.B. 2002. "When Things Go Wrong: The Duty to Disclose Medical Error." 28 *Queen's Law Journal* 353 at 360-61.

About the Authors

Tracey M. Bailey is Executive Director, Health Law Institute, Assistant Adjunct Professor, John Dossetor Health Ethics Centre, Assistant Adjunct Professor in the Postgraduate Medical Education Office, Faculty of Medicine and Dentistry, University of Alberta.

Nola M. Ries is Research Associate, Health Law Institute, University of Alberta, Lecturer in Health Law, University of Victoria. This paper builds on a presentation by the author at the 2004 Conjoint National Education Conference of the Canadian Infectious Disease Society, Community and Hospital Infection Control Association, and the Canadian Association of Medical Microbiologists.

Corresponding Author: Tracey Bailey, BA, LLB, Executive Director, Health Law Institute, Law Centre, University of Alberta, Edmonton AB T6G 2H5, tel: 780 492 6127, email: tbailey@law.ualberta.ca

Striking A Balance: Who Is Accountable for Patient Safety?

Edward Etchells, Robert Lester, Bronwen Morgan and Beth Johnson

Illustrative Case

An elderly patient develops acute pulmonary edema. The junior resident physician and nurse are providing urgent care. The physician asks for 2 mg of morphine to be given intravenously. The nurse selects a 10 mg ampoule, draws up the 10 mg dose, and gives it to the physician. The junior resident physician injects the entire dose. The patient quickly loses consciousness and develops a very slow respiratory rate. An antidote (naloxone) is given, and the patient recovers.

How should an organization manage this case from a safety perspective?

Introduction

The cornerstone of the patient safety movement is the systems approach, which is based on the theory that preventable adverse events are caused by the interaction between imperfectly designed systems and human error. Healthcare institutions that wish to enhance patient safety must strike an appropriate balance between focusing on the system of care and the individual members of the healthcare team. Our challenge was to understand the role and responsibilities of individual staff and our hospital as we tried to endorse and implement the systems approach.

Statement of the Problem

The role of individual staff in the systems approach must be carefully explored. One important element of the systems approach for individual staff is the concept of "non-punitive" or "blame-free" reporting of adverse events and incidents. These terms are intended to encourage voluntary staff reporting by removing the fear of punishment and blame.

We encountered two problems early in our attempts to share the systems approach within the hospital. First, some members of our senior leaders and board members expressed concern that a blame-free reporting policy suggested that the hospital was no longer being fully accountable for errors and patient safety in the care of the patients. If the individual healthcare provider was not accountable for safe care, who was? Second, we encountered some isolated events that suggested individual staff could misinterpret the intent of the systems approach. We heard of one student who stated that they had learned that "errors weren't their fault, it was the hospital's fault." We also attended a committee meeting where a staff member was discussing an adverse event, and a similar sentiment was expressed.

(Beginning) of a Resolution to the Problem

Other organizations had also begun to apply the systems approach, so we sought guidance and clarity from those

organizations. We learned three key concepts: balance, limited exclusion, and continuum. We learned the concept of balance at a local patient safety meeting in a presentation by a group from Toronto's Hospital for Sick Children. They talked of a "just" culture where the responsibilities of the individual are balanced with the responsibilities of the system. The systems approach shifts the balance of attention towards the system, but individuals must play an active role in system improvements, and there will be situations where individuals require remediation or discipline.

We learned the concept of limited exclusion from the Veteran's Administration National Centre for Patient Safety (NCPS) training program in June 2002. The NCPS staff generously shared their experience, knowledge and materials. Their algorithm for safety investigations states that certain events are outside of the scope of a safety review. These events could include episodes of deliberate harm, staff illness, patient abuse or practising outside one's scope of professional practice. A formal safety review could only occur once these issues had been screened out, and referred for institutional review, with possible remediation or discipline.[1]

Finally, we learned the concept of continuum at the Institute for Health Care Improvement (IHI) Patient Safety Officer Training Program in September 2004. There was a very helpful discussion on managing "unsafe acts," with heavy reliance on the United Kingdom's National Health Service (NHS) experience. The NHS has developed a Decision Tree for Unsafe Acts and an accompanying reference guide.[2] (**Figure 1**) This extremely useful material describes a continuum of unsafe acts, from honest mistakes through deliberate deviations from established protocols to deliberate attempts to harm. It outlines steps to be taken at the level of the individual and the system for each type of event along the continuum.

Together, these experiences helped us to formulate the concept of "shared accountability" for patient safety. The concept of balance told us that the individual and the system share accountability for patient safety. For each unsafe act, the individuals involved and the system (hospital) have clear accountabilities. The nature of these accountabilities will depend on where the event falls along the continuum. The conceptual shift is that the majority of unsafe acts will represent honest mistakes within a complex and imperfect system of care. In this case, the individual's accountability includes: (i) taking necessary steps to mitigate harm to the patient, (ii) reporting the incident, (iii) disclosing the event to patient and family when appropriate, (iv) participating in system review, (v) participating in development and implementation of improvement, (vi) making use of staff support services when needed.

The concept of balance told us that the individual and the system share accountability for patient safety. For each unsafe act, the individuals involved and the system (hospital) have clear accountabilities

The framework also addresses less common scenarios:

1. The event represents a significant deviation from accepted practice
2. The event involves a deliberate violation of an existing policy or protocol
3. The event involves a staff member suffering from illness that is affecting their ability to work safely
4. The event involves the intentional attempt to harm a patient

In these subsequent scenarios, the accountabilities of the system and individual are somewhat different. In each case, there is an assessment for mitigating factors, an evaluation of the availability and usability of existing protocols, an assessment of training and supervision. We expect that deficiencies in the design and implementation of protocols and procedures, training or supervision will often be uncovered. In some situations, however, there will be concerns for recklessness, incapacity or intentional harm, leading to additional responses focused on the individual.

Policy Development

Two of us (BJ and EE) drafted the initial policy, and had frequent consultation with the Executive Vice-President for Medical and Academic Affairs/Chief Medical Executive (BL), and the Director of Labour Relations (BM). We found it extremely helpful to gather input from a wide group. Most important, we sought input from occupational health, the Chief of Health Disciplines, the director of nursing and the vice-president for education and medical affairs. A draft policy was presented to several groups, including the senior leadership committee, the medical advisory committee, the nursing advisory committee and the professional advisory committee (representing the allied health professions). The policy was then presented to the quality subcommittee of the board for review. We did not encounter any significant concerns on this second "go-around." The concepts of balance, limited exclusion and continuum seemed to have addressed concerns that had previously been raised.

The policy was accepted in February 2005.

1. http://www.patientsafety.gov/SafetyTopics/CogAids/triage/index.html. Accessed July 5 2005.

2. http://www.npsa.nhs.uk/health/resources/incident_decision_tree. Accessed July 5 2005.

Figure 1: Individual and system accountabilities for different types of unsafe acts, based on the NHS framework. This is a sample framework and specific actions could vary from case to case.

	Individual	System
Honest mistake	• Report incident • Participate in systems review • Suggest remedial actions • Assist in development and testing of remedial actions	• Safety alert within and beyond organization when appropriate • Systems review • Develop improvements • Implement improvements
Honest mistake but fails substitution test	• As above plus • Additional training • Mentoring program when available	• As above • Search for mitigating factors such as training, supervision, workload
Deliberate violation of protocol	• As above plus • Consult with professional organization	• As above • Internal investigation • Search for mitigating factors such as training, supervision, workload • Modification of duties when appropriate
Possible ill health of staff, including substance abuse	• As above, plus • Assessment and treatment based on human resources and occupational health policies and procedures	• Internal investigation • Notify occupational health • Notify professional colleges when appropriate • Modification of duties when appropriate
Intentional harm or criminal act	• Seek counsel	• Internal investigation • Notify VP professional affairs and service chief • Notify police when appropriate • Notify professional colleges when appropriate • Suspension if patients or staff are perceived to be at immediate risk

Policy Implementation

We are now in the process of implementing the policy. (**Figure 2**).First, although we were pleased at the relatively smooth policy development, we were unsure about the existing staff beliefs regarding safety climate. We undertook a safety climate survey in May 2005. We achieved a 20% response rate, and we are currently analyzing the results. The results of the climate survey will help us develop proper resources for staff.

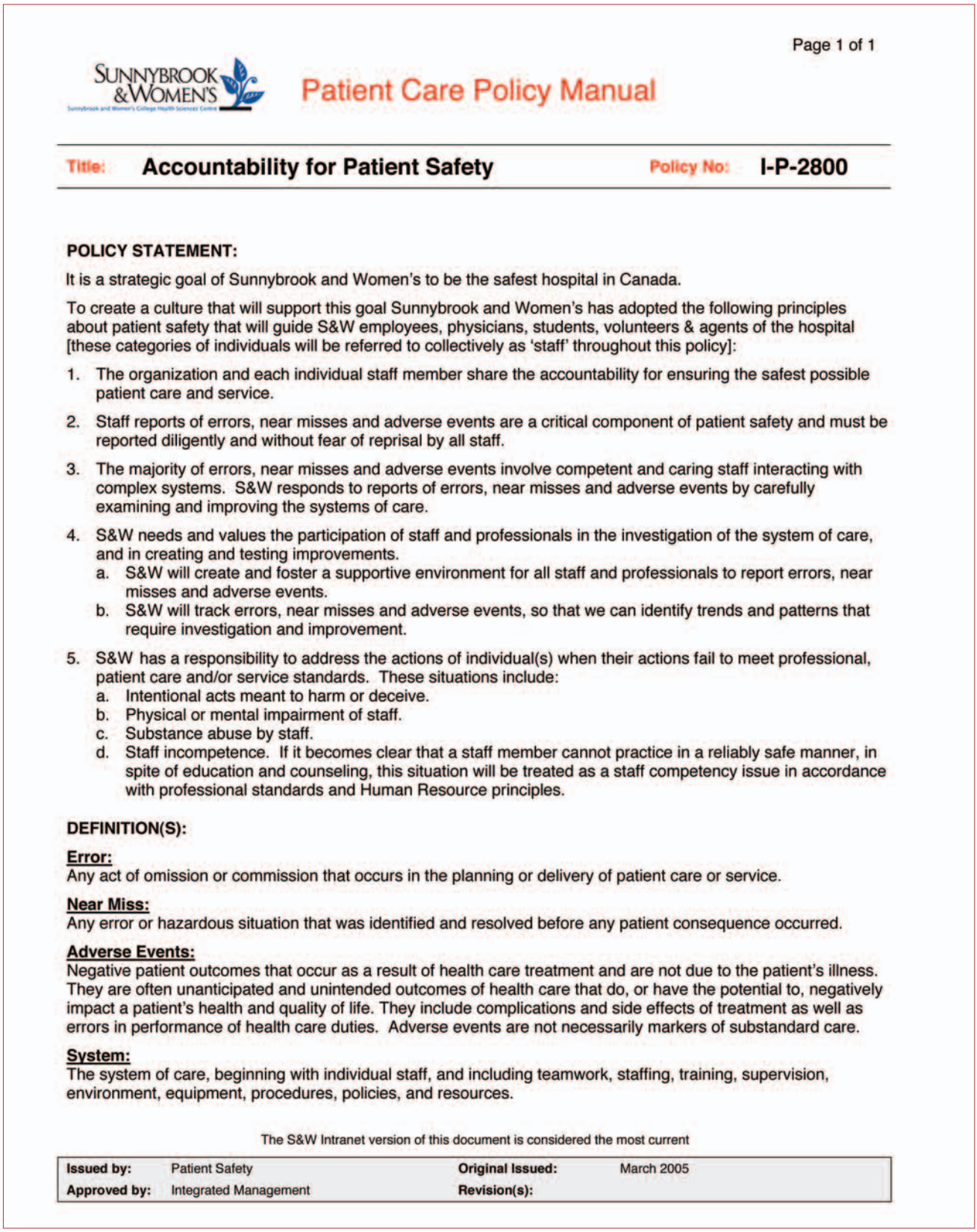
Second, we wanted to begin detailed discussions with staff who will be most affected by implementing the policy. We believe that front-line clinical staff will ultimately find the policy helpful and relatively undemanding. However, directors, managers, professional practice leaders and educators will experience new challenges. We will need the input and feedback from these groups as we implement the policy. As a starting point, we implemented "Safety Leadership Sessions" in April 2005. The purpose of these rounds is to communicate key safety developments within the organization to this target group, and to provide a forum for dialogue and discussion. Our CEO and Board Chair opened the first rounds in April 2005. All rounds were well-attended (average 40 attendees) and evaluations were uniformly positive.

Key Issues

1. Ensuring climate is right for more detailed implementation
2. Identify needs of program directors and managers
3. Providing appropriate training and resources
4. Ensuring that existing safety mechanisms are in harmony with policy (especially e-reporting)
5. Ensuring that staff and management have proper tools to ensure responsiveness to reported incidents

Concurrently, we implemented Patient Safety Walk Arounds. The purpose and conduct of these rounds is described in a separate article in this journal. We believed that these rounds were an essential complement to the accountability policy; our senior leaders were demonstrating their accountability to patients and staff by learning about and acting on issues raised by unit staff.

Figure 2



Page 1 of 1

SUNNYBROOK & WOMEN'S

Patient Care Policy Manual

Title: **Accountability for Patient Safety** Policy No: **I-P-2800**

POLICY STATEMENT:

It is a strategic goal of Sunnybrook and Women's to be the safest hospital in Canada.

To create a culture that will support this goal Sunnybrook and Women's has adopted the following principles about patient safety that will guide S&W employees, physicians, students, volunteers & agents of the hospital [these categories of individuals will be referred to collectively as 'staff' throughout this policy]:

1. The organization and each individual staff member share the accountability for ensuring the safest possible patient care and service.
2. Staff reports of errors, near misses and adverse events are a critical component of patient safety and must be reported diligently and without fear of reprisal by all staff.
3. The majority of errors, near misses and adverse events involve competent and caring staff interacting with complex systems. S&W responds to reports of errors, near misses and adverse events by carefully examining and improving the systems of care.
4. S&W needs and values the participation of staff and professionals in the investigation of the system of care, and in creating and testing improvements.
   a. S&W will create and foster a supportive environment for all staff and professionals to report errors, near misses and adverse events.
   b. S&W will track errors, near misses and adverse events, so that we can identify trends and patterns that require investigation and improvement.
5. S&W has a responsibility to address the actions of individual(s) when their actions fail to meet professional, patient care and/or service standards. These situations include:
   a. Intentional acts meant to harm or deceive.
   b. Physical or mental impairment of staff.
   c. Substance abuse by staff.
   d. Staff incompetence. If it becomes clear that a staff member cannot practice in a reliably safe manner, in spite of education and counseling, this situation will be treated as a staff competency issue in accordance with professional standards and Human Resource principles.

DEFINITION(S):

Error:
Any act of omission or commission that occurs in the planning or delivery of patient care or service.

Near Miss:
Any error or hazardous situation that was identified and resolved before any patient consequence occurred.

Adverse Events:
Negative patient outcomes that occur as a result of health care treatment and are not due to the patient's illness. They are often unanticipated and unintended outcomes of health care that do, or have the potential to, negatively impact a patient's health and quality of life. They include complications and side effects of treatment as well as errors in performance of health care duties. Adverse events are not necessarily markers of substandard care.

System:
The system of care, beginning with individual staff, and including teamwork, staffing, training, supervision, environment, equipment, procedures, policies, and resources.

The S&W Intranet version of this document is considered the most current

Issued by:	Patient Safety	**Original Issued:**	March 2005
Approved by:	Integrated Management	**Revision(s):**	

Finally, a climate of safety will only be maintained by developing skills in conducting system reviews and implementing wise safety improvements. We will use the Safety Leadership Sessions as a forum for demonstrating principles and methods for system review. Our initial sessions focused on key elements of high reliability organizations, and basic principles of Human Factors. We will be providing a series of more detailed human factors training sessions over the summer of 2005.

Ongoing Challenges

We were pleased at the uniform positive response for the policy. It seemed to set the proper balance between individual and system accountability. The challenge will be for supervisors, managers and directors to actually strike that balance when faced with incidents. We anticipate there will be difficult cases where the proper balance will be difficult to establish. The most difficult situations will involve extreme deviations from usual practice that test the meaning of "honest mistake," and judging whether there are sufficient mitigating factors when there is a deliberate violation of existing protocol. However, these difficult situations exist currently. We believe that the new policy represents an advance, because the majority of events will almost certainly fall into the category of honest mistake, where the desired response will be to support the individuals involved and conduct a systems review. Staff will know what to expect when such an incident is reported, the hospital will be able to conduct a wise and efficient systems review and, ultimately, will be able to implement and test wise safety improvements.

Back to the Case

An elderly patient develops acute pulmonary edema. The junior resident physician and nurse are providing urgent care. The physician asks for 2 mg of morphine to be given intravenously. The nurse selects a 10 mg ampoule, draws up the 10 mg dose and gives it to the physician. The junior resident physician injects the entire dose. The patient quickly loses consciousness and develops a very slow respiratory rate. An antidote (naloxone) is given, and the patient recovers.

How should an organization manage this case from a safety perspective?

Management

The nurse went back to check the narcotics drawer after the patient had improved. She recognized her error. She completed an incident report, notified her manager and the attending physician.

The manager quickly judged that this was an honest mistake. There was certainly no evidence of deliberate harm or staff illness. The nurse had followed all established protocols for ordering and dispensing of narcotics. Selecting the wrong drug during an emergency situation was an error that could occur to any competent practitioner; in fact, a similar incident had occurred the week before with different staff caring for a different patient. The manager thanked the nurse for reporting the incident, and a systems review was undertaken with the active involvement of the nurse and physician. Important findings included:

(i) the packaging for the 2 mg and 10 mg ampules had recently been changed
(ii) there was a remarkable similarity in appearance in the external packaging between the 2 mg and 10 mg ampules

The finding was reported to the Institute for Safe Medication Practices-Canada. ISMP Canada worked closely with the manufacturer, and a new distinct design for the 10 mg package was introduced within months of the report. The staff involved in the incident received feedback regarding the change in packaging.

About the Authors

Edward Etchells, MD, MSc, is Director, Patient Safety Service; Staff Physician, Division of General Internal Medicine, Sunnybrook and Women's College Health Sciences Centre. Associate Professor, Department of Medicine, University of Toronto.

Robert Lester is Executive Vice President, Medical and Academic Affairs/Chief Medical Executive, Sunnybrook and Women's College Health Sciences Centre, Professor Emeritus, Department of Medicine, University of Toronto

Bronwen Morgan, BA, LLB, LLM, is Director, Labour and Employee Relations Sunnybrook and Women's College Health Sciences Centre.

Beth Johnson is Director, Quality and Patient Safety, Sunnybrook and Women's College Health Sciences Centre.

Corresponding Author: Dr. Edward Etchells MD MSc FRCP, Sunnybrook and Women's College Health Sciences Centre, 2075 Bayview Avenue Room C410, Toronto, Ontario, M4N 3M5, voice: 416-480-5996 (private), fax: 416-480-5951 (private) e mail: edward.etchells@sw.ca

Trillium Health Centre's Journey to Disclosure

Lisa Droppo

Introduction

Disclosure has been defined in the Canadian Safety Patient Dictionary (Davies et al. 2003: 55) as "the imparting, by healthcare workers to patients or their significant others, of information pertaining to any health-care event affecting (or liable to affect) the patient's interests. The obligation to disclose is proportional to the degree of actual harm to the patient (or the realistic threat of such) arising from an untoward event." There has been increasing evidence to confirm that patients and their families (89–98%) and healthcare professionals (60–77%) believe that adverse events should be disclosed to patients (Blendon et al. 2002; Gallagher 2003; Hingorani et al. 1999; Witman et al. 1996). Organizations that have adopted disclosure policies have found that an honest apology, explanation of what happened and doing something to prevent future occurrences are important elements of an effective risk-management program (Hamm and Kraman 2001).

A study conducted in 2003 found that, in Canada, less than 50% of organizations have disclosure policies compared to 88% in the US and 74% in the UK (Blendon et al. 2004). It would appear that in those jurisdictions where disclosure policies are mandatory their existence is much greater. To date, the legal requirement for disclosure in Canada has been limited to a few provinces, including Quebec (National Assembly 2002). Some provincial Colleges of Physicians do have policy statements, including Saskatchewan, Manitoba and Ontario (College of Physicians and Surgeons of Ontario 2003; College of Physicians and Surgeons of Saskatchewan 2002; College of Physicians and Surgeons of Manitoba 2003). Beginning in 2006, organizations accredited by the Canadian Council on Health Services Accreditation will be required to have a disclosure policy (CCHSA 2004).

In 2003, as part of Trillium Health Centre's focus on developing an Enterprise-Wide Values-Based approach to risk management, including a strategic focus on patient safety, development and implementation of a disclosure protocol were identified as important. Further, it was noted that a comprehensive approach to incident reporting and management must include not only incident reporting and follow-up but also disclosure to patients and support for team members involved in incidents (second victims).

Background

Over the past 10 years, the issue of disclosure has become a significant topic of discussion in the literature. While this article will not provide a thorough review of the literature, it will draw linkages to relevant literature and resources, which were integral to the development and implementation of work at Trillium.

Prior to focussing on Trillium's journey, it is important, however, to focus on some of the well-documented advantages of an effective disclosure process and those beliefs and practices that may hinder an effective disclosure process, as these set the

context for some of the lessons learned identified later in this article.

Some of the advantages of an effective disclosure process include that disclosure allows the patient to obtain timely and appropriate treatment (Wu et al. 1997), may reduce litigation and liability costs (Boothman et al. 2001; Kraman and Hamm 1999; Vincent et al. 1994), maintains the physician's commitment to the fiduciary and trustful nature of the doctor-patient relationship (Hebert et al. 1997; Hebert et al. 2001; Wu et al. 1997), act as a driver for establishing investigation and follow-up processes (Australian Council for Safety and Quality in Health Care 2002) and may minimize the emotional distress of both patient, physician and the healthcare team (Wu et al. 1997).

Beliefs and practices that may hinder an effective disclosure process include fear of litigation, fear of reputation damage, a culture of infallibility among health professionals, confusion between providing an explanation of the facts and admitting liability (which may be the right and only thing to do in some situations), the limited support for health professions to discuss adverse events amongst colleagues and finally variation in communication skills amongst health professionals (Australian Council for Safety and Quality in Health Care 2002; Wu et al. 1997).

Increasingly, it is recognized that in the absence of disclosure, patients may turn to the legal process not only for financial compensation but to obtain an apology, explanation of what happened, and reassurance that others will not have the same experience (Australian Council for Safety and Quality in Health Care 2002; O'Connell and Keller 1999; Vincent et al. 1994)

Developing the Protocol: A Concurrent Process of Consultation, Awareness and Skill Building

The development of Trillium's disclosure protocol was a process deliberately undertaken over a lengthy period. This supported extensive consultation and ongoing dialogue with internal and external stakeholders regarding the protocol's content and the process for its implementation. At the outset, there was some interest in the direction coupled with hesitation primarily related to perceived barriers, which would prevent, in particular, physicians from participating in this process. Early recognition of these realities led to a thoughtful process of consultation and engagement, which continues today.

Early steps in developing the protocol included review of the literature related to disclosure and review of policies and position statements from other healthcare organizations and from professional colleges, insurers and malpractice carriers. It became clear that disclosure was a process that was well-supported.

The first draft of the protocol was generated in June 2003. As part of Trillium's National Healthcare Risk Management Week celebrations in June 2003, a series of focus groups with staff, physicians and volunteers who had been patients were conducted to elicit feedback about the protocol. Particular emphases of the focus groups were: What to call the process of open, frank conversation with patients? Which types of incidents should be disclosed to patients? Who should disclose to patients? A list of the focus group questions is provided in **Table 1**.

Table 1. Focus group questions related to disclosure process

Please provide some examples of incidents/adverse events.
Which incidents/adverse events should be disclosed to patients/families? • Incidents/adverse events that have resulted in injury or harm? • Incidents/adverse events that may result in injury or harm in the future, but extent may not be evident at the time of the event? • Incidents/adverse events that will not result in injury or harm?
When an incident/adverse event occurs, who should disclose this to the patient/family?
What supports do you need to effectively disclose?
How do we best learn from incidents/adverse events?
What terminology is most appropriate for use in our organization?

One of the most challenging elements of the protocol development was clearly defining what should be disclosed to patients. Dialogue with the Health Centre's ethicist resulted in some clarity regarding disclosure of near misses and assisted in generating some criteria to help determine when a near miss should be disclosed to the patient.

A year into the process, the Quality Healthcare Network launched two collaborative projects, one of which was called "Dialogue on Disclosure." The collaborative project was intended to bring member organizations together to learn from and share with each other along their disclosure journey. While the progress of the 22 healthcare organizations was varied, it proved to be a reflective opportunity for Trillium who had its policy well underway. The most substantial component of this project for Trillium Health Centre was the educational teleconferences, which brought opinion leaders and policy-makers together with industry leaders and experts on this topic to share their perspectives on disclosure. Members were encouraged to post their policies, as work in progress, in the spirit of learning together.

In March 2004, a draft policy was shared widely with key

internal stakeholders including the Medical Advisory Council, Leadership Executive Team, Patient Services Leadership Team and the Professional Advisory Council. While the Medical Advisory Council members were compelled by the ethical and fiduciary obligations for disclosure (Wu et al. 1997), despite transparent sharing of the College of Physicians and Surgeons of Ontario's Disclosure of Harm Policy (2003) and the Canadian Medical Protective Association's (CMPA) position statement on Disclosure of Adverse Events (Beilby 2001), many members continued to question the position of their malpractice carrier in particular. In recognition of this ongoing barrier, strategies to overcome this challenge were explored. With the assistance and support of the then Deputy Chief of Staff, a relationship was initiated with the CMPA. After some discussion, it was agreed that further educational sessions, as described in the next section, would be provided and that representatives of CMPA and their legal counsel would be invited to attend. In fact, in November 2004, the CMPA representatives were asked to play an active role by providing some introductory comments related to the CMPA's position prior to the trainer focussing on the workshop content. It was through this deliberate acknowledgement of the concerns and questions that the medical leadership began to embrace disclosure as not only the right thing to do, but also something that they were allowed and would be supported in doing.

Developing Knowledge and Skills

As part of the focus groups in 2003, it became clear that while healthcare providers wanted to engage in open and frank communication with patients and families regarding unanticipated clinical care or outcomes, many of them expressed a need for support in how to have these conversations. Others requested help with training materials and access to coaching support at the time of an incident.

As a result of these requests, it was decided that Trillium would benefit from the identification of a training program to support all those who may need to have disclosure conversations with patients and their families. A Patient Services Manager shared information about a training program, which she felt would be well-suited to Trillium. More details were obtained and references checked, resulting in a decision to develop internal expertise to deliver disclosure training through a train-the-trainer model (Bayer Institute for Health Care Communication 2004).

Recruitment of four trainers was undertaken with a particular emphasis on finding a physician trainer. Four trainers were identified, specifically an organizational development specialist, two social workers and the Director, Patient Safety. In partnership with another local healthcare organization, a two-day train-the-trainer workshop was launched in November 2003. In addition to training four workshop facilitators, 11 representatives were invited from the organization to experience the workshop. Careful consideration was given to identifying representatives from throughout the Health Centre in an effort to build interest and enthusiasm across clinical programs and disciplines. Two physicians attended this initial workshop and were enthusiastic about its content but expressed some hesitation about engaging physicians in a three-and-a-half-hour workshop on an ongoing basis.

Three of the trainers continued to develop their skill in delivering the workshop and hosted four three-and-a-half-hour workshops in April and May 2004 for the entire multidisciplinary team of the Birthing Suite. This team was already involved in the MOREOB™ Program (Managing Obstetrical Risk Efficiently), a risk-management program focussed on core clinical content, skill and emergency drills, and reporting and investigating adverse events. Coupling their commitment and enthusiasm for multidisciplinary learning with an opportunity to further broaden their risk-management skills created an ideal pilot environment.

Numerous workshops have been held since late 2003 with over 250 physicians and staff attending in total. The author has noted in her role as a workshop trainer that the most significant contribution and outcome for participants is the recognition of their previous tendency to control conversations with patients and families by telling them what they thought they needed and wanted to know. The workshop provides participants with an opportunity to understand and practice a non-defensive, empathetic listening approach that provides the patient or family the opportunity to guide the pace and content of the conversation.

In addition to the workshops, throughout the past few years, a collection of training videos and materials has been compiled and used for lunch'n learn sessions to continue building interest in disclosure and generate dialogue amongst professionals (American Society for Healthcare Risk Management 2001; Buckman 2004; National Patient Safety Foundation 2002; Partnership for Patient Safety 2004).

Trillium's Protocol

After reviewing the literature and engaging in dialogue through focus groups, it was decided that Trillium's disclosure protocol would be called "Communication of Unanticipated Clinical Care or Outcome" to draw on the therapeutic relationship between healthcare providers and their patients (ASHRM 2001; ASHRM May 2003). The use of the term communication recognizes the opportunity to move to more open and shared dialogue and decision-making between providers and patients. This increased involvement of the patient in all aspects of her care is an important element of a culture of safety. This process further recognizes that disclosure is a component of the informed consent process (ASHRM Nov 2003), which is

more than consent to a single procedure rather, involvement of the patient in daily decisions affect the overall treatment plan by creating an open forum for raising questions and concerns. Trillium's protocol states: "Communication begins when the relationship is first established and may involve discussion of proposed assessments, diagnosis, proposed treatment plans, their benefits and potential risks. The sharing of information about the care process and/or outcome is a natural extension of this relationship (Trillium Health Centre 2005)." It was felt that the term disclosure sounded like an event, whereas communication recognized that the conversation was ongoing.

Table 2. Criteria for considering whether to communicate a near miss

Board and leadership strategic focus and commitment to risk management and patient safety are of key importance.
Physician leadership and champions can have a profound effect on physician interest and adoption.
CPSO policy and CMPA position statement are useful drivers. Misconceptions regarding CMPA position, in particular that physicians would not be supported in disclosure, need to be formally addressed.
CCHSA patient safety goals and required organizational practices create further supportive rationale for creating and implementing a disclosure policy.
Patience allows for thorough consultation, response to concerns and fears and identification of mitigation strategies.
Guidance through consultation enhances the organization's support of the policy adoption.
Concurrent protocol development, training and implementation can be very effective.
Training programs and materials are imperative to support the learner.
Careful selection of early workshop attendees can be helpful in generating interest for future workshop attendance.
Ongoing challenge exists in recruiting a physician trainer(s) in a community hospital setting.
Shared learning through a collaborative project can validate and question your assumptions regarding implementation of an effective disclosure policy.
Disclosure requires a different communication style, in particular moving from professionals telling patients what happened to non-defensive empathetic listening.
Variations amongst professionals in identifying that an event is an incident leads to variation in initiating the disclosure process.
Further formalization of processes to access coaching and support would be beneficial.

Using the same information sources, it was determined that in most circumstances the most responsible physician would be expected to communicate with the patient/family regarding unanticipated care or outcomes (ASHRM November 2003, February 2004). Again, this was built on the philosophy of the provider-patient relationship. In the event of an incident, which does not involve medical care, the Manager or Director would take the lead in communicating with the patient/family ensuring that the patient's most responsible physician is aware of the incident and provided with an opportunity to participate in the discussion. In all circumstances where there has been a high-risk incident (sentinel event), at least two people will meet with the patient/family. In addition to defining who should be involved in the communication process with a patient/family, the protocol does clearly identify that the Director, Patient Safety is available for consultation and support to assist individuals and teams prepare for conversations with patients and families.

The protocol focuses on communicating those incidents where unanticipated clinical care or outcomes did result in harm, injury or upset to the patient/family. Criteria are provided to assist with the determination of whether or not to talk with the patient/family regarding a near-miss, "a type of incident, which does not result in harm, loss or damage, but has the potential to do so" (Trillium Health Centre 2003) as summarized in **Table 2**.

The protocol also provides direction on when the communication should occur, how to prepare for a meeting with the patient/family and what should be documented following the meeting.

Implementing the Protocol

Trillium's protocol for Communication of Unanticipated Clinical Care or Outcome was formally approved in March 2005. It is evident from the previous discussion that implementation of the protocol began in June 2003 and that there has been a concurrent process of development and implementation over the past two years. On reflection, there have been a number of lessons learned along this journey as captured in **Table 3**.

Table 3. Lessons learned

The patient is or may become aware of the near miss.
There is something documented in the health record.
A treatment or follow-up plan needs to be initiated as a result of the near miss.
There is potential future health risk associated with the near miss.
The potential benefit of open communication outweighs the potential harm for the patient/family/substitute decision-maker.

Early Evidence of Success

Some stories suggest that opportunities to communicate with patients about unanticipated clinical care and outcomes are increasingly being embraced at Trillium, including:

- telephone calls from healthcare professionals to the Director, Patient Safety the day after attending a workshop to discuss specific patients and incidents;
- an invitation to a family to return to the hospital so that the healthcare team could discuss an incident that may have hastened the death of their loved ones;
- timely meetings with patients and families to apologize in person, discuss what happened and share strategies to prevent the same incident from occurring in the future.

Efforts have been made by Trillium's team of trainers to design an evaluation process for this work. To date, a system for capturing evidence of effective disclosure has been challenging to develop. It is hoped that a more formal system of evaluation will evolve over the next year.

Next Steps

The journey to disclosure at Trillium has progressed and matured over the past two years. A substantial focus for 2005/06 will be the continued implementation of the protocol by providing interactive workshops and rounds to further develop healthcare providers' communication skills. Continued efforts to recruit at least one physician to join the team of trainers will be a priority recognizing the credibility and support that participants have experienced in the presence of a physician trainer. While the protocol clearly identifies that consultation and support are available from the Director, Patient Safety, to date, that assistance has been engaged to a limited extent. As open and frank communication with Trillium's patients and families becomes the norm, additional supportive processes for those participating in these conversations may need to be developed. Finally, but most importantly, there remains some hesitation and misconception regarding disclosure and admission of liability. It will be imperative that we begin to tell stories of the comprehensive approach to reporting and following-up incidents, including the communication with patients/families, support provided to members of the Trillium team and the learning and improvement arising from Trillium's reflective learning approach based on root cause analysis. This will enable Trillium to demonstrate the positive relationships arising from open communication and its impact on both patients and healthcare professionals.

References

American Society for Healthcare Risk Management. 2001, April. Perspective on Disclosure of Unanticipated Outcome Information. Chicago, IL: Author. Retrieved July 11, 2005. <http://www.hospitalconnect.com/ashrm/resources/files/Disclosure.2001.pdf>.

American Society for Healthcare Risk Management. 2001. Disclosure of Medical Errors: Demonstrated Strategy to Enhance Communication (video). Chicago, IL: Author. Available from <http://www.ahaonlinestore.com>.

American Society for Healthcare Risk Management. 2003, May. Disclosure of Unanticipated Events: The Next Step in Better Communication with Patients. Chicago, IL: Author. Retrieved July 11, 2005. <http://www.ashrm.org/ashrm/resources/files/Disclosure.Pt1.pdf>.

American Society for Healthcare Risk Management. 2003, November. Disclosure of Unanticipated Events: Creating an Effective Patient Communication policy. Chicago, IL: Author. Retrieved July 11, 2005. <http://www.hospitalconnect.com/ashrm/resources/files/DisclosurePart2.Policy.pdf>.

American Society for Healthcare Risk Management. 2004, February. Disclosure: What Works now & What Can Work Even Better. Chicago, IL: Author. Retrieved July 11, 2005. <http://www.hospitalconnect.com/ashrm/resources/files/Disclosure.Part3.0204.pdf>.

Australian Council for Safety and Quality in Health Care. 2002. When Things Go Wrong: An Open Approach to Adverse Events. Retrieved July 10, 2005. <http://www.nsh.nsw.gov.au/teachresearch/cpiu/CPIUwebdocs/Issues_paper.pdf>.

Bayer Institute for Health Care Communication. 2004. Disclosing Unanticipated Outcomes and Medical Error. West Haven, CT: Author. Workshop information and materials available from <http://www.bayerinstitute.org>.

Beilby, W. 2001, October. Disclosing Adverse Clinical Outcomes. Canadian Medical Protective Association.

Blendon, R.J., C. Schoen, C.M. DesRoches, R. Osborn, K. Zapert and E. Raleigh. 2004. "Confronting Competing Demands to Improve Quality: A Five-Country Hospital Survey." *Health Affairs* 23(3): 119–35.

Blendon, R.J., C.M. DesRoches, P.H.M. Brodie, J.M. Benson, A.B. Rosen, E. Schneider, D.E. Altman, K. Zapert, M.J. Herrmann and A.E. Steffenson. 2002. "Views of Practicing Physicians and the Public on Medical Errors." *N Engl J Med* 347(24): 1933–40.

Boothman, Hamm and Kraman 2001, Kraman and Hamm 1999, Vincent et al. 1994. Excited Actuaries at University of Michigan Hospital System. Retrieved July 18, 2005. <http://www.sorryworks.net/media22.phtml>.

Buckman, R. 2004. How to Deal with Anger and Other Emotions in Adverse Event and Error Disclosure. Available from <http://www.cinemedic.com/products/>.

Canadian Council on Health Services Accreditation (CCHSA). 2004, December. "CCHSA Patient Safety Goals and Required Organizational Practices." Communiqué #2. Retrieved July 10, 2005. <http://www.cchsa.ca/pdf/PSCommunique2.pdf>.

College of Physicians and Surgeons of Manitoba. 2003. Physician Disclosure of Harm that Occurs in the Course of Patient Care. Retrieved July 11, 2005. <http://www.cpsm.mb.ca/about/bylaws_guidelines/statements/Ethics/Statement169>.

College of Physicians and Surgeons of Ontario. Disclosure of Harm Policy. 2003. Retrieved July 10, 2005. <http://www.cpso.on.ca/Policies/disclosure.htm>.

College of Physicians and Surgeons of Saskatchewan. 2002. D*isclosure of Adverse Events and Treatments.*

Davies, J.M., P. Hebert and C. Hoffman. 2003. *The Canadian Patient* Safety Dictionary. Retrieved July 11, 2005.<http://www.crha-health.ab.ca/qihi/patient_safety_dictionary.pdf>.

Gallagher, T.H., A.D. Waterman, A.G. Ebers, V.J. Fraser and W. Levinson. 2003. "Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors." *JAMA* 289(8): 1001–07.

Hamm, G.M. and S.S. Kraman. 2001. "New Standards, New Dilemmas – Reflections on Managing Medical Mistakes." *Bioethics Forum* 17(2): 19–25.

Hebert, P.C., B. Hoffmaster, K.C. Glass and P.A. Singer. 1997. "Bioethics for Clinicians: 7. Truth Telling." *Canadian Medical Association Journal* 156(2): 225–28.

Hebert, P.C., V.L. Levin and G. Robertson. 2001. "Bioethics for Clinicians: 23. Disclosure of Medical Error." *Canadian Medical Association Journal* 164(4): 509–13.

Hingorani, H., T. Wong and G. Validis. 1999. "Patients' and Doctors' Attitudes to Amount of Information Given After Unintended Injury During Treatment: Cross Sectional, Questionnaire Survey." *BMJ* 318(7184): 640–41.

Kraman, S.S. and G. Hamm. 1999. "Risk Management: Extreme Honesty May Be the Best Policy." *Annals of Internal Medicine* 131(12): 963–67.

National Assembly. 2002. Bill 113: An Act to amend the Act respecting health services and social services as regards to the safe provision of health services and social services, *L.Q.* c.71

National Patient Safety Foundation. 2002. *Let's Talk: Disclosure After an Adverse Medical Event.* Available from www.npsf.org.

O'Connell, D. and V.F. Keller. 1999. "Communication: A Risk Management Tool." *JCOM* 6(1): 35–38.

Partnership for Patient Safety. 2004. First, Do No Harm Part 3: Healing Lives, Changing Cultures. Available from <http://www.p4ps.org>.

Trillium Health Centre. 2003, November. *Incident Reporting and Handling Protocol.*

Trillium Health Centre. 2005, March. *Communication of Unanticipated Clinical Care or Outcome Protocol.*

Vincent, C., M. Young and A. Phillips. 1994. "Why Do People Sue Doctors? A Study of Patients and Relatives Taking Legal Action." *Lancet* 343(8913): 1609–13.

Witman, A.B., D.M. Park and S.B. Hardin. 1996. "How Do Patients Want Physicians to Handle Mistakes? A Survey of Internal Medicine Patients in an Academic Setting." *Archives of Internal Medicine* 156(22): 2565–69.

Wu, A.W., T. Cavanaugh, S. McPhee, B. Lo and G. Micco. 1997. "To Tell the Truth: Ethical and Practical Issues in Disclosing Medical Mistakes to Patients." *Journal of General Internal Medicine* 12(12): 770–75.

About the Author

Lisa Droppo, MHSc, CHE, is Director, Patient Safety at Trillium Health Centre. In this role, Lisa is involved in creating a patient safety culture, implementing a system for reporting incidents and near misses, and developing and implementing protocols for open communication with patients following unanticipated care or outcomes and reflective learning to ensure that improvements arise from incidents and near misses. Lisa has worked in a number of healthcare organizations in Canada and the UK in the areas of quality management, risk management, patient relations, accreditation and operations. She is a certified trainer for the Bayer Institute of Health Care Communication's Disclosing Unanticipated Outcomes and Medical Errors Workshop.

Contact: Lisa Droppo, Director, Patient Safety, Trillium Health Centre, 100 Queensway West, Mississauga, ON, L5B 1B8, Phone: (905) 848-7580 ext. 2493, Fax: (905) 804-7979, Email: ldroppo@thc.on.ca

Acknowledgements

This journey to disclosure has drawn on the expertise and support of so many. I wish to acknowledge with thanks Jutta Schafler-Argao, Director, Quality Outcomes and Evaluation, Sally Lewis, Vice-President Performance Excellence, Dr. Norman Hill, Vice-President Medical Affairs (previously Deputy Chief of Staff), Pam Kister and Seth Moyse, Trillium's trainers, Ken White, President and CEO, the Leadership Executive Team and Trillium's Board of Directors, Dan O'Connell and Fred Platt, Regional Consultants for the Bayer Institute for Health Care Communication, Cynthia Majewski, Executive Director, Quality Healthcare Network and Dialogue on Disclosure Organizers and Participants, Marcia Sokolowski, Clinical Ethicist at Baycrest Centre for Geriatric Care and previously Ethicist for Trillium Health Centre's Transitional Ethics Service, Bill Beilby, Associate Executive Director & Managing Director Risk Management Services, Canadian Medical Protective Association and the Risk Management Team at the Healthcare Insurance Reciprocal of Canada.

Adopt him.

If you would like to learn how leading hospitals have successfully implemented **paperless incident reporting**, dramatically **improved the reporting of errors/near misses** and moved to a **culture of safety**, then contact us today.

888.737.7444
www.rl-solutions.com

Partnering to create the safest health care system

1-800-465-7357

www.hiroc.com