



The Patient Safety
Education Program™
CANADA

Plenary 1: Gaps in Patient Safety:
A Call to Action

Emanuel LL, Taylor L, Hain A, Combes JR, Hatlie MJ, Karsh B, Lau DT, Shalowitz J, Shaw T, Walton M, eds. *The Patient Safety Education Program – Canada (PSEP – Canada) Curriculum*. © PSEP – Canada, 2011.

This module was rewritten and significantly adapted for the Canadian context by Valerie Phillips from Saskatchewan Ministry of Health.

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Acknowledgements to Sandi Kossey, Canadian Patient Safety Institute, Erin Pollock, Canadian Patient Safety Institute, Ioana Popescu, Canadian Patient Safety Institute, and Morgan Truax, Canadian Patient Safety Institute for their work on the appendices, glossary, and Canadian reference list; to Hina Laeque, Canadian Patient Safety Institute, for her contribution to the Canadian editing process; to Denise Sorel and Anne MacLaurin for their review and insight of content pertaining to the *Safer Healthcare Now!* program; to Julie Langlois, Accreditation Canada, for her work mapping the Required Organizational Practices and Standards.

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PSEP – Canada is a partnership between the Canadian Patient Safety Institute (CPSI) and the Patient Safety Education Program, which is housed at the Buehler Center on Aging, Health & Society at Northwestern University, Chicago, USA. The PSEP – Canada Curriculum is an adaptation of the PSEP Core Curriculum. PSEP has received support from the Jewish Healthcare Foundation, the Pittsburgh Regional Health Initiative, the Zell Center for Risk Research, California Healthcare Foundation, The Commonwealth Fund, and the Health Research and Education Trust in the form of the 2008 Edwin L. Crosby Fellowship that was awarded to Dr. Emanuel. PSEP is a not-for-profit educational program. It began as a collaboration among Linda Emanuel, Martin Hatlie, John Combes, and Joel Shalowitz.

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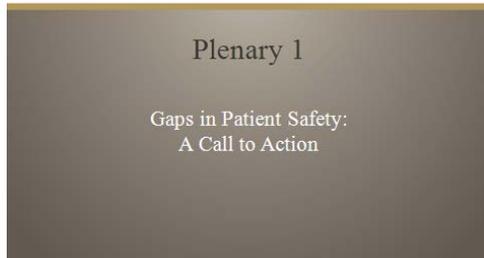
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[Revised 2017]

PSEP - Canada Objective	Related CPSI Safety Competencies
<p>The knowledge elements include an understanding of:</p> <ul style="list-style-type: none"> • The magnitude of the problem (large numbers of people are harmed) • The paradoxical role of progress in increasing complexity and risk • The challenges faced by provider communities in ensuring safety and transforming cultures <p>The performance elements include the ability to:</p> <ul style="list-style-type: none"> • Describe the case for patient safety • Identify the drivers of the patient safety movement • Describe the importance of aligning goals and strategies among all stakeholders 	<p>Domain: Contribute to a Culture of Patient Safety</p> <p><i>2. Health care professionals who are able to describe the fundamental elements of patient safety, understand:</i></p> <p>2.1. Core theories and terminology of patient safety and the epidemiology of unsafe practices</p> <p>2.10. The concept that health care is a complex adaptive system with many vulnerabilities, (e.g., space or workplace design, staffing, technology)</p>

Abstract

Slide 1



This plenary provides an overview of the patient safety movement and the shift to systems-based solutions for improving both safety and quality in healthcare. It starts with a story, summarizes progress to date, discusses challenges, and outlines a way forward. It welcomes all participants in healthcare to commit to being part of the solution. We can do it.

Keywords

Adverse event, autonomy, challenge, collaboration, complexity, culture, disclosure, education, environment, error, failure, harm, hazard, human factors, improvement, interprofessional, latent, leadership, learning, measurement, patient-centred, positive deviance, practices, profession, progress, provider, public, reporting, root cause analysis, research, risk, root cause analysis, safety, story, study, systems-based, teamwork, tools, training, trust

Teaching methods

Didactic

Learning objectives

Slide 2

Knowledge requirements

- Understand the magnitude of harm due to unsafe care
- Understand the relationship between complexity and increased risk
- Appreciate the challenges we face in ensuring safety and transforming care

Slide 3

Performance requirements

- Describe the case for making patient safety a priority
- Know the factors driving interest in patient safety
- Know the barriers to progress in reducing harm
- Understand the connections between safety, quality, access and efficiency.

The objectives of this module are to understand the systemic risks that face patients today and the need for a transformed approach to providing safe, reliable care.

Knowledge requirements

The knowledge elements include an understanding of:

- the magnitude of the problem (large numbers of people are harmed);
- the paradoxical role of progress in increasing complexity and risk; and
- the challenges faced by provider communities in ensuring safety and transforming cultures.

Performance requirements

The performance elements include the ability to:

- describe the case for patient safety;
- identify the drivers of the patient safety movement; and
- describe the importance of aligning goals and strategies among all stakeholders.

Introduction: It started with a story

Slide 4

Introduction: The Ben Kolb story

- Went in for routine ear surgery
 - went into cardiac arrest
 - topical Adrenalin vs. Lidocaine
 - hospital took a systems approach

Ben Kolb was a seven year old boy who went for routine ear surgery on December 15, 1995 at Martin Memorial Hospital in Stuart, Florida. Twenty minutes into the operation, the surgeon injected a local anesthetic into the four quadrants surrounding Ben's ear.

Almost immediately, the scrub tech began to feel the child's chest "pounding" through the surgical drapes and the certified registered nurse anesthetist (CRNA) saw precipitous changes in Ben's blood pressure and pulse. The supervising anesthesiologist was summoned to lead the management of hypertension and tachycardia. The child responded immediately to treatment and stabilized within minutes. The anesthesiologist, recognizing the timing of the event, instructed the scrub tech to save the syringes, intending to follow up on the cause of this unusual reaction to lidocaine 1% with epinephrine 1:100,000.

Nine minutes later Ben was in cardiac arrest. Two hours later he left the operating room in a profound coma and on a ventilator. Ben's mother Tammy Kolb had been wondering why the surgery was taking so long. Eventually, the surgeon and anesthesiologist brought her to a private room and gave her a thorough explanation of how Ben's heart had stopped and how difficult it had been to restart. The chaplain joined them to support Tammy. The syringes were sent to a laboratory at the University of Georgia.

Ben was transferred to a tertiary care center and died the following day. The risk manager called the hospital's defence counsel and insurer to alert them to the event, review the planned response, and obtain advice on the proposed investigation. The Board and senior management were called to a special meeting. The Coroner was contacted and told of the analysis underway in Georgia.

In the immediate aftermath of Ben's death, the risk manager contacted the Kolb family to express sympathy and renew her pledge to seek an answer. "Please, don't let this happen to another child. Please don't stop, don't ever, ever stop. Please find an answer," was Ben's mother's plea. The anesthesiologist attended the funeral home viewing. The surgeon attended the funeral.

Martin Memorial received the lab results three weeks after Ben died. The syringe that was supposed to contain lidocaine actually contained a highly concentrated form of

adrenaline intended for external use. Procedure at Martin Memorial “was for topical adrenaline to be poured into one cup, made of plastic, and lidocaine to be poured into a cup nearby, made of metal. The lidocaine syringe was then filled by placing it in the metal cup. It was a procedure used all over the country, a way of getting a drug from container to operating table. According to Richard Harman, the hospital’s CEO, ‘It has probably been done 100,000 times in our facility without error.’ But it was still a flawed procedure, the hospital learned. It allows for the possibility that the solution can be poured into or drawn out of the wrong cup. Instead, a cap, called a spike, could be put on the vial of lidocaine, allowing the drug to be drawn directly out of the labeled bottle and into a labeled syringe. The elimination of one step eliminates one opportunity for the human factor to get in the way” (Belkin, 1997).

The following day, the risk manager, accompanied by the anesthesiologist, went to the Kolbs’ attorney’s office. There, in the presence of the Kolb family, a number of lawyers and a court reporter, the risk manager explained what had happened. She told them on behalf of the hospital that Martin Memorial accepted full responsibility. The staff had somehow made a mistake in the transfer process. They were working diligently to make the process safer so that this event would never occur again. She told them sincerely that they were very, very sorry. That evening the Kolb family, their attorney, the risk manager, and the hospital attorney reached a confidential settlement and approved a mutually acceptable press release.

The story could have ended here. Martin Memorial, using their new procedure, would have eliminated one system problem that placed caring, competent professionals in an environment where error occurred. They could try to put this event, their darkest hour, behind them. Yet they knew that this story was not just about Martin Memorial; this was about healthcare as an international industry. The industry had accepted the use of intermediate containers. Any surgical staff member, given the right circumstances, could make the same mistake.

In the months following Ben’s death, the American Association for the Advancement of Science, the Annenberg Center for Health Sciences, The Joint Commission, the American Medical Association, and the U.S. Department of Veterans Affairs planned the first Annenberg Conference on Medical Error (held at the Annenberg Center in California). When they needed a case study, Martin Memorial and the Kolbs offered Ben’s story. In October of 1996, Ben’s story was told to a hushed audience of 300 researchers, clinicians and concerned citizens by a panel consisting of Ben’s family representative, the risk manager, the hospital CEO, hospital counsel, and the anesthesiologist who treated Ben the day he died. People in attendance talk to this day about how that event opened their eyes and created an unwavering commitment on their parts to prevent harm.

Ben’s story was covered in USA Today two days after it was presented at the conference. Several months later it anchored a New York Times Magazine cover story titled, “Getting past blame – how can we save the next victim?” Ben’s doctor, the risk manager, and the

hospital attorney were asked to address the Institute of Medicine in 1997, where they received a standing ovation.

As publicity grew, the calls to Martin Memorial began. Five calls were received where risk managers, insurers and attorneys who had heard about Ben inquired if their cases, all children having ear surgery, were similar to Ben’s experience. Four were. They were from all over the country, with children ranging from four to seven years of age. None had survived the surgery. The fifth call was about a young girl having ear surgery. Her pulse and blood pressure had risen. Her nurses called the risk manager, who called Martin Memorial’s risk manager for guidance. She was told what the investigation into Ben’s case had found. In real time, the team treating the girl realized that they had made the same mistake, and were able to respond differently. The child lived.

Ben’s family has supported continued reference to their tragedy. They are grateful that other families have been spared their loss. They still receive care from the same trusted healthcare providers.

Ben’s story helped shape the present patient safety movement, by demonstrating:

- that healthcare is complex, inherently risky, and prone to failure;
- the value of understanding the ways in which competent, well-intentioned healthcare professionals are set up to fail by practices and tools that do not sufficiently utilize understanding of human factors, training in teamwork, and other available tools; the importance of sharing lessons learned, broadly and transparently, so that discovered risks can be systemically addressed; and
- that ethical, compassionate care – which includes honesty and emotional support – provided after an adverse event occurs is a crucial part of our systems and culture change agenda.

To Err Is Human: Building a Safer Health System

Slide 5

To Err is Human: Building a Safer Health System

- 1999 To Err is Human
44,000-98,000 yearly iatrogenic deaths
this estimate now seen as low
- Resulting shift in view by all sectors of the health system
errors have systemic causes
traditional blame approach becoming untenable

When the Institute of Medicine (IOM) released *To Err Is Human*, American national news networks and other media sources reacted strongly to hearing that at least 44,000 and perhaps as many as 98,000 people die in U.S. hospitals each year as a result of

medical errors, and that more than one million patients are seriously harmed. To put these numbers into context, the report states that “Deaths due to preventable adverse events exceed the deaths attributable to motor vehicle accidents (43,458), breast cancer (42,297) or AIDS (16,516)” (Kohn et al, 2000). The report’s estimates were derived from two studies: the “Harvard Medical Practice Study” published in 1991 and based on an analysis of 1984 data from the state of New York, and the Colorado and Utah study, which used 1992 data.

“*To Err Is Human* converted an issue of growing professional awareness to one of substantial public concern in a manner and pace unprecedented in modern experience with matters of health care quality. The epidemiologic finding that more than 1 million injuries and nearly 100,000 deaths occur in the United States annually as a result of mistakes in medical care came from studies nearly a decade old, but it was new information for the public, and it resonated strongly” (Leape, Berwick, Bates, 2002).

The interest in *To Err Is Human* also lay in its explanation about the causes of error in healthcare and its comparison with other industries that seemed to be making faster progress in managing risk through a systems-based approach. The report included detailed analyses of system failures in healthcare and recommended steps hospitals could take to reduce their error rates. Taken as a whole, the report served as a call to action for healthcare providers to make safety a priority. It succeeded in creating a groundswell for change.

With respect to causation, the report’s “Aha!” message was that medical errors are seldom caused exclusively by the actions of a single provider. Rather, they are typically the result of a complex series of systems-related problems. The report called for the healthcare sector to systematically design safety into the processes of care.

Another legacy was the IOM’s frequent use of the word “error”. Terminology notwithstanding, the focus of the report was much more on the outcome of error for the patient: an adverse event, defined as “an injury caused by medical management rather than the underlying condition of the patient” (Kohn et al, 2000). Unfortunately, due to its popular appeal, the word “error” remains in common use where it continues to confuse discussion and engender defensiveness. Meanwhile, language related to patient harm and its causes continues to evolve.

To Err Is Human makes recommendations in four categories (Kohn et al, 2000):

1. to establish a national focus by creating leadership, research, tools, and protocols to enhance the knowledge base about safety;
2. to identify and learn from errors through immediate and strong mandatory reporting efforts, as well as to encourage voluntary reporting efforts, with the aim of making sure the system continues to be made safe for patients;
3. to raise standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers and professional groups; and

4. to create safety systems inside healthcare organizations through the implementation of safe practices at the delivery level. This level is the ultimate target of all the recommendations.

The report challenged all sectors of the healthcare system to make safety their priority and to engage in a concerted effort to reduce adverse events by more than half within five years. This would require changes in the way healthcare was being delivered, particularly in the relationships among professionals, and in the way healthcare workers interacted with each other and with the organizations where they practiced. It would also require a profound cultural shift within healthcare institutions to identify errors and discover their underlying systemic causes. Rather than seeing error identification as a prelude to punitive action, healthcare CEOs, governors, and medical, nursing and other staff must now recognize adverse events and near misses as opportunities to learn where to redesign systems for safety.

Crossing the Quality Chasm: A New Health System for the 21st Century

Slide 6

Crossing the quality chasm

- Broader look at how the healthcare delivery system could be designed to innovate and improve care
- Healthcare could be:

safe	effective
patient-centered	timely
efficient	equitable

In 2001, the IOM Committee on Quality Health Care in America published its second and final report, *Crossing the Quality Chasm: A New Health System for the 21st Century*. While *To Err Is Human* focused on patient safety, *Crossing the Quality Chasm* looked more broadly at how the healthcare delivery system could be designed to innovate and improve care (Committee on Quality Health Care in America, 2001). The report proposes six aims for improvement, stating that “Health care should be:

- **safe** – avoiding injuries to patients from the care that is intended to help them;
- **effective** – providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding overuse and underuse);
- **patient-centered** – providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions;

- **timely** – reducing waits and sometimes harmful delays for both those who receive and those who give care;
- **efficient** – avoiding waste, in particular waste of equipment, supplies, ideas, and energy; and
- **equitable** – providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status” (Committee on Quality Health Care in America, 2001).

Concurrent international developments

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Concurrent international development ...

- Special issue on medical error (British Medical Journal, 2000)
- “Let’s talk about error: leaders should take responsibility for mistakes” (Reinertsen, 2000)
- “An organization with a memory: report of an expert group on learning from adverse events in the NHS” (British National Health Service, 2000)

Meanwhile, the patient safety movement was also taking hold outside the United States (US). On March 18, 2000, the *British Medical Journal* (BMJ) published a special issue devoted to medical error. Don Berwick (founder and long-time President and CEO of the Institute for Healthcare Improvement (IHI), and then Administrator of the Centers for Medicare & Medicaid Services) and Lucian Leape (Adjunct Professor at the Harvard School of Public Health and one of the Harvard Medical Practice Study’s principal investigators) were the theme issue’s guest editors. Contributors included Dennis O’Leary (President of the Joint Commission), Michael R. Cohen (President of the [US] Institute for Safe Medication Practices), and James L. Reinertsen (CEO of CareGroup and Beth Israel Deaconess Medical Center, a teaching hospital of the Harvard Medical School). Reinertsen’s article titled “Let’s talk about error: Leaders should take responsibility for mistakes” begins: “In the time it will take you to read this editorial eight patients will be injured, and one will die, from preventable medical errors.” (Reinertsen, 2000) Echoing the case for focus and leadership outlined in *To Err Is Human*, Reinertsen goes on to say: “If ‘attention is the currency of leadership,’ all of us who have leadership roles have a responsibility to direct the attention of our fellow physicians, healthcare professionals, and communities to this problem and to keep attention on the problem until it is satisfactorily resolved.” (Reinertsen, 2000)

That same year, the British National Health Service (NHS) published *An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS*. This report outlines some of what was known about the magnitude of harm (including that, every year 400 people die or are seriously injured in adverse events involving

medical devices; nearly 10,000 people are reported to have experienced serious adverse reactions to drugs; adverse events occur in approximately 10% of hospital admissions, or about 850,000 a year) (Department of Health, 2000).

As the report's title suggests, its main focus was on learning from failures. "There is evidence that some specific types of relatively infrequent but serious adverse events happen time and again over a period of years. Inquiries and incident investigations determine that 'the lessons must be learned', but the evidence suggests that the NHS as a whole is not good at doing so" (Department of Health, 2000). The report acknowledges system causes of adverse events: latent conditions that underlie active failures. "Human error may sometimes be the factor that immediately precipitates a serious failure, but there are usually deeper, systemic factors at work which if addressed would have prevented the error or acted as a safety-net to mitigate its consequences" (Department of Health, 2000).

"Activity to learn from and prevent failures therefore needs to address their wider causes. It also needs to stretch beyond simply diagnosing and publicising the lessons from incidents, to ensure that these lessons are embedded in practice. The distinction between passive learning (where lessons are identified but not put into practice) and active learning (where those lessons are embedded into an organization's culture and practices) is crucial in understanding why truly effective learning so often fails to take place" (Department of Health, 2000). An organizational safety culture and systematic reporting of "near misses" as well as harm are both described as being essential for learning.

In charting the way forward, the report states that "the NHS needs to develop:

- unified mechanisms for reporting and analysis when things go wrong;
- a more open culture, in which errors or service failures can be reported and discussed;
- mechanisms for ensuring that, where lessons are identified, the necessary changes are put into practice; and
- a much wider appreciation of the value of the system approach in preventing, analysing and learning from errors" (Department of Health, 2000).

In 2001, the UK Department of Health created the National Patient Safety Agency (NPSA) as an NHS special health authority to improve patient safety and promote a more open and fair culture. "The NPSA aims to promote patient safety by:

- establishing and managing a national reporting and learning system for incidents that affect patient safety;
- assimilating safety-related information from other organizations;
- designing solutions that prevent harm;
- setting targets and monitoring progress;
- promoting research;
- advising ministers and others on patient safety issues;

- promoting an open and fair culture in the NHS;
- developing memoranda of understanding with other key healthcare organizations that have an interest or involvement in patient safety” (National Patient Safety Agency, 2003).

The year 2001 also saw the establishment of the Australian Council for Safety and Quality in Health Care, which was superseded by the Australian Commission on Safety and Quality in Health Care in 2006. “The Commission’s role is to:

- lead and coordinate improvements in safety and quality in health care in Australia by identifying issues and policy directions, and recommending priorities for action;
- disseminate knowledge and advocate for safety and quality;
- report publicly on the state of safety and quality including performance against national standards;
- recommend national data sets for safety and quality, working within current multilateral governmental arrangements for data development, standards, collection and reporting;
- provide strategic advice to Health Ministers on best practice thinking to drive quality improvement, including implementation strategies; and
- recommend nationally agreed standards for safety and quality improvement” (Australian Commission on Safety and Quality in Health Care, 2006).

Table 1 lists select modern Western milestones in patient safety, and includes developments in Canada.

Table 1: Select milestones in patient safety

1964	“The Hazards of Hospitalization” – Schimmel
1967	“Adverse reactions during hospitalization” – Ogilvie and Ruedy
1978	“Medical insurance feasibility study: A technical summary” – Mills
1991	Institute for Healthcare Improvement (IHI) founded
1991	“Harvard Medical Practice Study” – Brennan, Leape et al.
1995	“The Quality in Australian Health Care Study” – Wilson, Runciman et al.
1996	Annenberg conferences begin
1999	<i>To Err Is Human: Building a Safer Health System</i> [IOM Report] – Kohn, Corrigan and Donaldson
2000	<i>An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS</i> – U.K. Department of Health
2001	National Patient Safety Agency formed in the United Kingdom
2001	<i>Crossing the Quality Chasm: A New Health System for the 21st Century</i> – Committee on Quality Health Care in America, IOM
2001 – 2003	Halifax Symposia on Medical Error
2002	“Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care” [RCPCSC Report] – National Steering Committee on Patient Safety
2003	Canadian Patient Safety Institute (CPSI) established
2004	“The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada” – Baker, Norton et al.
2004 – 2010	Canadian Healthcare Safety Symposia (Halifax Series)
2004 – 2006	IHI 100,000 Lives Campaign
2005	<i>Safer Healthcare Now!</i> launched by CPSI
2006 – 2008	IHI 5 Million Lives Campaign

Building a safer healthcare system in Canada

Slide 8

Building a safer healthcare system in Canada ...

- Forum on patient safety (RCPSC, 2001)
- National Steering Committee and five working groups formed (2002)

In September 2001, The Royal College of Physicians and Surgeons of Canada (RCPSC) hosted a one-day forum on patient safety as part of its annual conference. “Over 50 leaders representing government, health-care associations, and other non-government organizations attended a roundtable discussion on developing a national strategy to improve safety. A National Steering Committee and five working groups were formed at the direction of the roundtable participants” (National Steering Committee on Patient Safety, 2002).

The working groups (System Issues, Regulatory/Legal Issues, Measurement/Evaluation, Education/Professional Development, and Information/Communication) met and conducted external consultations from January through April 2002. The following September, the National Steering Committee on Patient Safety, chaired by John Wade, published its report *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care*. It contained 19 recommendations in five categories.

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... Building a safer healthcare system in Canada

- Building a safer system: a national integrated strategy for improving patient safety in Canadian health care” (2002)
 - 19 recommendations in five categories
 - Establish a Canadian patient safety institute
 - Improve legal and regulatory processes
 - Improve measurement and evaluation processes
 - Establish educational and professional development programs
 - Improve information and communication processes

I. Establish a Canadian Patient Safety Institute to Facilitate a National Integrated Strategy for Improving Patient Safety

1. Establish and support a non-profit Canadian Patient Safety Institute

2. Base new practices, technologies and programs on evidence, and subject them to scientific evaluation (including an evaluation of potential benefits and costs)
 3. Implement system changes that have a demonstrated ability to improve patient safety
 4. Formalize responsibility and accountability for patient safety within the management structures and clinical processes of all healthcare organizations
 5. Develop and implement responsive patient-focused programs for the receipt, review and management of concerns within healthcare organizations
- II. Improve Legal and Regulatory Processes**
6. Adopt non-punitive reporting policies across the healthcare system
 7. Standardize the legislation on privacy and confidentiality of personal health information across Canada
 8. Develop a greater focus on improvement through education and remediation vs. blame and punishment, in legal, regulatory and human resource processes
 9. Review and, where applicable, revise *The Evidence Act* in all Canadian jurisdictions
 10. Hold further discussions regarding the tort and healthcare insurance systems and their effect on patient safety
- III. Improve Measurement and Evaluation Processes**
11. Undertake an analysis of the capabilities and cost of systems for monitoring adverse events, critical incidents and near misses
 12. Recommend the types of surveillance systems, including relevant patient-safety indicators, to be developed and supported in Canadian healthcare.
 13. Secure funding from federal/provincial/territorial jurisdictions for information technology to support identification, reporting and tracking patient safety data
 14. Adopt “patient safety” as a cross-cutting theme or designated area for research competitions
- IV. Establish Educational and Professional Development Programs**
15. Develop and implement healthcare education and professional development programs for improving patient safety
 16. Develop educational and continuing professional development programs in collaboration with accrediting bodies, academic institutions, provincial licensing authorities, and healthcare facilities/organizations/scholarly societies
- V. Improve Information and Communication Processes**
17. Publicly report measures of healthcare quality and safety
 18. Develop educational materials on personal measures for improving safety in healthcare for distribution to the public
 19. Create a website to facilitate the sharing of patient-safety resources and discussions.

In fulfillment of the first recommendation, the federal Minister of Health announced the creation of the Canadian Patient Safety Institute (CPSI) on December 10, 2003 (Bonney,

Baker, 2004). CPSI has since worked to fulfill many of the other recommendations made by the National Steering Committee.

The Canadian Adverse Events Study (Baker Norton study)

Slide 10

The Canadian adverse events study ...

- Used methods based on the protocol developed for the Harvard Medical Practice Study also used for studies elsewhere in the world
- Placed Canadian results within the international context
- Examination of 3,745 charts

Slide 11

... The Canadian adverse events study

- Results
 - ~7.5% of patients admitted to acute care hospitals in Canada in 2000 experienced 1 or more adverse events (AEs)
 - 36.9% of these AEs highly preventable

On May 25, 2004, the *Canadian Medical Association Journal* (CMAJ) published “The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada” (Baker, Norton, et al, 2004). This was an important and much anticipated study because little data had previously been collected on adverse events in Canada. The authors, G. Ross Baker, Peter Norton and others, defined an adverse event as “an unintended injury or complication that results in disability at the time of discharge, death or prolonged hospital stay that is caused by health care management rather than by the patient’s underlying disease process.... Health care management includes the actions of individual hospital staff as well as the broader systems and care processes and includes both acts of omission (failure to diagnose or treat) and acts of commission (incorrect diagnosis or treatment, or poor performance)” (Baker, Norton, et al, 2004). The methods used were based on the protocol developed for the Harvard Medical Practice Study. This protocol, with some modifications, had also been used for studies elsewhere in the US, Australia, New Zealand, the United Kingdom and Denmark (Baker, Norton, et al, 2004). The work of Baker, Norton, et al. would place Canadian results within this international context. Table 2 summarizes select information about the Canadian Adverse Events Study and similar international studies.

Four general hospitals (one teaching hospital, one large community hospital, and two small community hospitals) were randomly selected in each of five provinces (British Columbia, Alberta, Ontario, Quebec and Nova Scotia). Charts were then randomly selected in each facility, with the exclusion of pediatric cases and admissions with a most responsible diagnosis of obstetrics or psychiatry (Baker, Norton, et al, 2004). Ultimately, 3,745 charts were deemed eligible for full screening to determine whether an adverse event had occurred, whether it was likely caused by management of the case, and whether it was likely to have been preventable.

The authors concluded that “an estimated 7.5% of patients admitted to acute care hospitals in Canada in the fiscal year 2000 experienced 1 or more AEs [adverse events], [and that] 36.9% of these patients were judged to have highly preventable AEs. ... By extrapolation, our results suggest that, in 2000, between 141,250 and 232,250 [point estimate: 185,000] of 2.5 million similar admissions to acute care hospitals in Canada were associated with an AE [just under 70,000 of these preventable] and that 9,250 to 23,750 deaths from AEs could have been prevented” (Baker, Norton, et al, 2004).

Table 2: Comparison of results of adverse events studies

Country	# Charts Reviewed [# Hospitals]	Year of Charts Reviewed	Year of Study Publication	% of Patients with ≥1 Adverse Event	% of Adverse Events that were Preventable
U.S. (New York) ^{1,2}	30,195 [51]	1984	1991	3.7*	n/a
U.S. (Colorado & Utah) ³	14,700 [28]	1992	2000	2.9* ⁺	n/a
Australia ⁴	14,179 [28]	1992	1995	16.6 ⁺	51
New Zealand ^{5,6,7}	6,579 [13]	1998	2001	12.9	37
United Kingdom ⁸	1,014 [2]	1999-2000	2001	10.8 [^]	48
Denmark ⁹	1,097 [17]	2000	2001	9.0	40
Canada¹⁰	3,745 [20]	2000	2004	7.5	37
Brazil ¹¹	1,103 [3]	2003	2009	7.6	67
Sweden ¹²	1,967 [28]	2003-2004	2009	12.3	70
Netherlands ¹³	7,926 [21]	2004	2009	5.7	40
Spain ^{14,15}	5,624 [24]	2005	2006	8.4	43

The sources for this table are identified in the References at the end of this modules.

The emphasis in the U.S. studies was on finding negligence vs. emphasis in other studies on preventability and quality improvement, which may have contributed to the lower U.S. rates (Baker, Norton, et al, 1685). In addition, the American and Australian investigators subsequently harmonized the inclusion criteria and adverse event (AE) definitions between the two studies. This yielded adjusted AE rates of 3.2% (vs. 2.9%) in

the Colorado & Utah study and 10.6% (vs. 16.6%) in the Australian study (Baker, Norton, et al, 1684 and 1685). The U.K. study, based in 2 teaching hospitals, yielded an AE rate similar to the unadjusted rate identified in the 5 teaching hospitals in the Canadian study (10.9% vs. 10.8% in the U.K.) (Baker, Norton, et al, 1685).

Slide 12

Canadian Institute for Health Information (CIHI)

- 2004 report
 - shed light on specific issues
 - provided updated data
 - assessed healthcare risks
 - level of public concern does not always match the probability of risk
 - offered suggestions
- “Analysis in brief” (2007)
 - rates of several types of adverse events

A few weeks following publication of the Baker Norton study, the Canadian Institute for Health Information (CIHI) released its fifth annual Health Care in Canada report. The aim of this series, produced by CIHI with help from Statistics Canada, “has been to shed light on specific issues while providing updated data and analyses of topics of continuing importance” (CIHI, 2004). Health Care in Canada 2004 focused on patient safety. Examining Canadian and international research from a variety of sources, the report provides an assessment of healthcare risks and offers suggestions for mitigation and improvement.

In discussing the assessment of risk, CIHI notes that while high-profile events capture public attention, the level of public concern does not always match the probability of risk. “According to the experts, the risk of harm from the imperfectly sterilized hospital instruments and HIV-infected surgeons using standard practice guidelines is extremely low (with no reported illness to date). However, novel events such as these make the news and can raise public fears, and may lead to hastily developed plans to address relatively modest risks. Conversely, preventable adverse events are estimated to directly or indirectly cause morbidity and/or mortality for several thousand Canadians each year in hospitals and in the community. Yet, until recently, they have received relatively little public attention” (CIHI, 2004). In its August 2007 “Analysis in Brief”, CIHI gave an update on patient safety that included rates of several types of adverse events. Replicated in Table 3, this information shows the average number of people receiving a particular service (and therefore potentially exposed to a hazard) for each adverse event that occurred. For example, over 4,000 blood transfusions were given for every adverse blood transfusion event, whereas one in ten adults contracted an infection in a Canadian acute care hospital. Even if a patient receives several blood transfusions while in hospital, a nosocomial infection is still much more likely than an adverse event related to blood. This does not suggest that we begin to ignore rare, catastrophic events – rather, that we

strive to prevent all instances of harm, including those we may be tempted to dismiss as mundane.

Table 3: Likelihood of an adverse event (CIHI, 2007)

Type of Event	# Exposed / Event	Reported Year
Adults contracting a nosocomial infection while in an acute care hospital	1 in 10	2002*
Adults with health problems who report receiving the wrong medication or dose	1 in 10	2005**
Children contracting a nosocomial infection while in an acute care hospital	1 in 12	2002***
Medical/surgical patients in an acute care hospital experiencing an adverse event	1 in 13	2000†
Obstetrical traumas during childbirth (vaginal delivery)	1 in 21	Apr 2003–Mar 2006‡
Birth trauma—Injury to neonate	1 in 141	Apr 2003–Mar 2006‡
Death associated with preventable adverse events for medical/surgical patients in an acute care hospital	1 in 152	2000†
Post-admission pulmonary embolism or deep vein thrombosis	1 in 279	Apr 2003–Mar 2006‡
In-hospital hip fracture for adults 65 and older	1 in 1,263	Apr 2003–Mar 2006‡
Foreign object left in after procedure	1 in 2,998	Apr 2003–Mar 2006‡
Adverse blood transfusion events	1 in 4,091	2003§
Fatal events definitely, probably and possibly related to transfusion of blood components	1 in 87,863	2002§

Sources:

- * Gravel D, Matlow A, Ofner-Agostini M, et al, 2007.
- ** Commonwealth Fund International Health Policy Survey of Adults With Health Problems, 2005.
- *** Gravel D, Matlow A, Ofner-Agostini M, et al, 2007.
- † Baker GR, Norton PG, Flintoft V, et al, 2004.
- ‡ Discharge Abstract Database/Hospital Morbidity Database, April 1, 2003, to March 31, 2006.
- § Transfusion Transmitted Injuries Surveillance System Program Report, Public Health Agency of Canada, 2005.

The table above presents **the number of people** who receive care or are exposed to a risk per patient safety event for selected indicators, with the exception of blood transfusion–related indicators. The blood transfusion–related indicators present the number of **blood transfusions** per patient safety event. A higher number suggests less risk.

Five years after *To Err Is Human*

In 1999, *To Err Is Human* had challenged the healthcare system to reduce adverse events by more than half within five years. In an article published in the May 18, 2005 issue of *The Journal of the American Medical Association* (JAMA), Lucian Leape and Don Berwick assessed the progress made, and reflected on why this goal had not been met. They noted that “small but consequential changes have gradually spread [and] ... all hospitals have implemented some new practices to improve safety” (Leape, Berwick, 2005). Examples included fewer patients dying from accidental injections of potassium chloride now that it had been removed from nursing unit shelves, and fewer patients having complications from warfarin now that many people taking anticoagulants were being treated in dedicated clinics. The authors observed: “Although these efforts are affecting safety at the margin, their overall impact is hard to see in national statistics” (Leape, Berwick, 2005).

Disappointing as this was, *To Err Is Human* had accomplished two things: one, it had drawn attention to the large number of patients who suffered adverse events in the course of their care; and two, it proposed the idea that systems, not individuals, were ultimately responsible for most cases of harm. The IOM report had, in Leape and Berwick’s words, “truly changed the conversation.... The concept that bad systems, not bad people, lead to the majority of errors and injuries, which is a crucial scientific foundation for improvement of safety in all successful high-hazard industries, has become a mantra in health care” (Leape, Berwick, 2005). In order to provide context for subsequent patient safety initiatives, some additional background on systems thinking and the study of human factors is given below.

Systems thinking

Slide 13

Systems thinking

- Both theory and practical methods
- System can be analysed both prospectively (FMEA) or retrospectively (RCA)
- Moving away from a “silo” mentality
- Quality and safety cannot be improved solely by addressing individual behaviour
- More focus on hazards than error

Systems thinking is both a theory and a set of practical tools. “Systems” are the conditions under which people live and work. They include environments and processes, which of course also involve other people. Systems can be analysed:

- prospectively, by anticipating what might go wrong, using tools such as Failure Mode and Effect Analysis (FMEA) (McDermott et al, 1996), and

- retrospectively, by studying what *has* gone wrong, using tools such as Root Cause Analysis (RCA) to determine the underlying causes (Hoffman et al, 2006).

Using this latter approach, systems thinking seeks to be comprehensive, both in determining the causes of adverse events and in learning from them.

Systems thinking requires looking at systems and processes in their entirety. This involves moving away from what is often termed a “silo” mentality, in which a worker does not take into account how his or her work affects the work of others. Instead, the goal is to study and improve all aspects of the process of care. Related to this is an important idea behind the systems approach in healthcare: that quality and safety cannot be improved solely by addressing individual behaviour. “If all humans err, and the conditions that create error are beyond the control of individuals, then systems that rely on error-free performance by individuals are doomed to fail.... Punishing the individuals who were closest to the patient when the error occurred may not result in safer healthcare if the latent conditions that contributed to the error are not changed” (Baker, Norton, 2004). Systems thinking, in this sense, focuses more on hazards than error.

Human factors

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Human factors

- Systematical design of safety into the processes of care
- Can also be applied to process design or analysis
- Strive to establish a “just culture”
not “blame-free” but with appropriate accountability

Don Berwick from IHI once said that “Every system is perfectly designed to achieve exactly the results it gets.” In order to reduce the harm patients experience in our current healthcare system, *To Err Is Human* urged us to systematically design safety into the processes of care. “Human factors science provides an understanding of the ways in which the design of machinery, tools and patient-care settings can be altered to reduce the likelihood of errors. ... Error cannot be eliminated, but we can design systems to reduce the possibility of errors, to make errors more visible when they do occur so that they can be recognized and intercepted, and to mitigate the adverse effects of errors that are not detected and intercepted. Anaesthesiology has benefited from the redesign of operating rooms, monitoring devices and anaesthesia equipment to reduce errors. Accidents caused by mix-ups between oxygen and anaesthesia gas lines no longer occur in hospital operating rooms because the fittings for coupling these lines are different. This ‘forcing function’ prevents the hook-up of the oxygen line to the nitrous oxide outlet” (Baker, Norton, 2001). Knowledge of human factors can also be applied to process design or

analysis. This includes, for example, considering how people behave when they are tired or hungry.

Ben Kolb’s story showed us that well-intentioned healthcare professionals can be set up to fail by practices that overlook human factors. The use of unlabelled intermediate containers for different drugs meant that, in time, a mix-up was inevitable. When (as is most often the case) systems and processes are found to be at the root cause of harm to a patient, an individual provider should not be blamed. It is important to note that organizations valuing safety will strive to establish a “just culture”, which is not synonymous with a “blame-free” culture. Rather, a just culture is one having appropriate accountability, in which people are held responsible for their actions, but are not treated as scapegoats.

When an organization learns from things that go wrong, makes needed changes, and treats its staff fairly, this helps it to be forthright with patients, families and others. When Martin Memorial determined what had caused Ben’s death, the hospital’s full, immediate and compassionate disclosure to the Kolb family earned back their trust. Sharing what they learned with other hospitals helped save the life of at least one child.

Origins of systems thinking

Slide 15

Origins of systems thinking

- Improving safety in environments in nuclear energy, aviation and automobile manufacturing
- Pioneer of ergonomics (Ramazzini, 1700)
- Operating room processes (Gilbreth, 1910)
- Plan-Do-Study-Act (PDSA) cycle (Shewhart & Deming)
- Contributions from the fields of organizational psychology, sociology and informatics

Since taking a systems approach to patient safety, many health researchers have looked to other traditionally high-risk industries that have succeeded in making their work environments nearly hazard-free. Nuclear energy, aviation and automobile manufacturing are the three industries most commonly studied by interested parties in healthcare. Many successful examples use some form of Quality Improvement (QI) science stemming from industrial engineering. The work of Walter A. Shewhart and W. Edwards Deming and their development of the PDSA (Plan-Do-Study-Act) cycle has been particularly influential, but healthcare-related safety research can be traced back much earlier.

Bernardino Ramazzini (1633-1714) is known today for his detailed clinical descriptions of occupational debility related to a wide variety of work. These were recorded in his *De Morbis Artificum Diatriba* [Diseases of Workers] printed in 1700 and 1713 (Franco 2001) A pioneer of ergonomics, “Ramazzini visited workers and workplaces and

observed firsthand how various types of work were performed and the stresses they placed on the body” (Gochfeld, 2005).

One hundred years ago, Frank and Lillian Gilbreth conducted some of the earliest research in the fields of time and motion study. “Since 1910, the Gilbreths used movies to conduct motion studies in surgery. They analysed each movement by the surgeons to see if their work could be more efficient and therefore less fatiguing.... One of their conclusions was that operating room nurses could improve efficiency. The Gilbreths observed that surgeons spent more time searching for their instruments when operating than actually performing the operation. The new method significantly reduced operation times, thereby improving the quality of care. In addition, the Gilbreths recommended that surgical instruments should be organised and laid out in regular and consistent patterns. The alignment of work of physicians and nurses played (and still plays) an important role in the efficiency of operating room processes” (Baumgart, Neuhauser, 2009) .

Fun Fact: Frank and Lillian Gilbreth’s family life has been described in a 1948 book by Frank Gilbreth, Jr. and Ernestine Gilbreth Carey titled *Cheaper by the Dozen*. The book showed that Frank and Lillian’s scientific management thinking and use of time and motion studies carried over into the private lives of the Gilbreths and their 12 children.

In addition to the theories, tools, methods and measures from industrial engineering and human factors science, the fields of organizational psychology, sociology, and informatics have also made contributions to patient safety. Troyen Brennan (one of the principal investigators for the Harvard Medical Practice Study) has argued that these fields should “be considered the basic sciences of quality, just as we consider molecular biology, pharmacology, and genetics the basic sciences of medicine.” Other improvement tools come from the world of management and business, and include the (all similar) approaches known as Total Quality Management, Lean Production, Six Sigma, and Continuous Quality Improvement.

The 100,000 Lives Campaign

Slide 16

The 100,000 Lives Campaign

- Launched in 2004 by the Institute of Healthcare Improvement (IHI) to hasten the adoption of proven practices
- Every U.S. hospital invite to participate
- Goal of saving 100,000 lives in 18 months
- Presented 6 highly feasible interventions backed up with literature

“Healthcare is a highly complex system with many broken parts. The good news is that for every broken part in our system, there are remarkable examples of excellence –

organizations that have overcome enormous obstacles to redesign the way patient care is delivered. Unfortunately these examples are too few. ... Health care does not yet reliably transfer best-known science into action, and processes frequently fail, despite the best intentions of a dedicated and highly skilled workforce” (IHI, “Overview of the 100,000 Lives Campaign” webpage).

In 2003, McGlynn et al. published the results of their study “The quality of health care delivered to adults in the United States.” The researchers telephoned a random sample of adults living in 12 metropolitan areas in the United States and asked them about some of their healthcare experiences. They also asked for written consent to copy participants’ medical records for the most recent two-year period and used this information to evaluate performance on 439 indicators of quality of care for 30 acute and chronic conditions such as asthma, breast cancer, diabetes and hypertension. Analysis showed that the 6,712 participants (those who gave consent and had at least one medical record) had received only 54.9 percent of the care recommended for their condition(s) (McGlynn et al, 2003).

To hasten the adoption of proven practices, the Institute for Healthcare Improvement created the 100,000 Lives Campaign. Berwick et al. explain their approach: “Healthcare can benefit now from a new sense of urgency, with levels of discipline and pace akin to those of a political campaign. Political campaigns cannot afford patience. Political campaign professionals often cite the rule: ‘Some is not a number; soon is not a time.’ A campaign works with a firm target: 50% plus one: the number of votes needed to win – one less is not enough – and a firm deadline: election day” (Berwick et al, 2006). IHI launched its 100,000 Lives Campaign on December 14, 2004, using the keynote address of its 16th Annual National Forum. Every US hospital was invited to participate, with the goal of collectively saving 100,000 lives in 18 months – by June 14, 2006. The campaign proposed that hospitals “implement as many as possible of 6 highly feasible interventions for which efficacy is documented in the peer-reviewed literature and is reflected in standards set by relevant specialty societies and government agencies” (Berwick et al, 2006). The interventions (each of which entails use of a set of steps or a “bundle” of practices) are:

- deploy rapid response teams (a rapid response team is one that is summoned *before* a code occurs);
- deliver reliable evidence-based care for acute myocardial infarction;
- prevent adverse drug events through medication reconciliation;
- prevent central-line infections;
- prevent surgical site infections; and
- prevent ventilator-associated pneumonia.

The above interventions had been chosen based on four factors:

1. each was strongly supported by evidence in the medical literature (some available for more than a decade) that it prevents avoidable deaths and injuries;

2. each had been implemented in a variety of settings, not just in isolated research environments, with impressive results;
3. all related to common problems that were associated with thousands of deaths; and
4. none required major investments in capital or information technology (Gosfield and Reinertsen 2006).

When the campaign ended, an estimated 122,300 lives had been saved by 3,100 participating hospitals representing 78% of all acute care beds in the US (IHI, “An Introduction to the 5 Million Lives Campaign” presentation). With its 100,000 Lives Campaign, IHI had begun to address the problem of needless deaths. However, for every patient who died, many more were being harmed and suffering needless pain.

The 5 Million Lives Campaign

Slide 17

The 5 Million Lives Campaign

- IHI’s follow-up to the 100,000 Lives Campaign (2006-2008)
- Preventing 1/6 of the 30 million injuries over a 2 year period would protect 5 million lives
- Six new interventions added
- Success
 - enrollment of 4,050 hospitals
 - signs of progress in improving patient outcomes

In follow-up to the 100,000 Lives Campaign, IHI launched the 5 Million Lives Campaign, which asked participating hospitals to prevent five million incidents of medical harm over the next two years (December 2006 to December 2008). This goal was based on a calculation of 15 million injuries per year (37 million admissions multiplied by 40 injuries per 100 admissions, a rate determined using IHI’s Global Trigger Tool). Preventing just one sixth of the 30 million injuries that occur in a two-year period would protect 5 million lives from harm. Six new interventions were added, these targeted at harm:

1. prevent pressure ulcers;
2. reduce Methicillin-resistant *Staphylococcus aureus* (MRSA);
3. prevent harm from high-alert medications (anticoagulants, sedatives, narcotics, insulin);
4. reduce surgical complications;
5. deliver reliable, evidence-based care for congestive heart failure; and
6. Get Boards on Board (a patient safety education program for hospital Boards of Directors) (IHI, “An Introduction to the 5 Million Lives Campaign” presentation).

In addition to avoiding five million incidents of harm, the campaign had three further aims: “to enroll more than 4,000 hospitals ... to strengthen the national learning network of field offices and mentor facilities, and to continue to raise the profile of hospitals’ important efforts to improve care with a broader public audience” (McCannon, Hackbarth, Griffin, 2007).

“At its formal close in December 2008, the Campaign celebrated the enrollment of 4,050 hospitals, with more than 2,000 facilities pursuing each of the Campaign’s 12 interventions to reduce infection, surgical complication, medication errors, and other forms of unreliable care in facilities. ... Above all, we also witnessed striking signs of progress in improving patient outcomes. For example, 65 hospitals reported going a year or more without a ventilator-associated pneumonia, and 35 reported going a year or more without a central line-associated bloodstream infection in at least one of its ICUs.” (IHI, “Frequently Asked Questions about the 5 Million Lives Campaign” webpage)

Safer Healthcare Now!

Slide 18

Safer Healthcare Now!

- Launched in 2005 in Canada
 - initially focused on the same six interventions
- Phase II in 2008
 - added four interventions
- Currently supports 10 interventions
- Flagship program of CPSI
 - invests in frontline providers and the delivery system

Launched in April 2005, *Safer Healthcare Now!* (SHN) was patterned after IHI’s 100,000 Lives Campaign. “In perhaps characteristic Canadian fashion, *Safer Healthcare Now!* adopted a much softer approach. No specific targets were set in terms of lives saved, and the campaign goal was more generally focused on enhancing patient safety” (Davies, 2006). Both campaigns initially focused on the same six interventions.

In 2008, SHN began Phase II, adding four interventions:

1. Antibiotic Resistant Organisms / Methicillin-resistant *Staphylococcus aureus* (ARO/MRSA);
2. Medication Reconciliation for Long-Term Care (MedRec LTC);
3. National collaborative on falls in long-term care (Falls); and
4. Venous Thromboembolism (VTE).

Currently, SHN supports 10 interventions:

1. Acute Myocardial Infarction (AMI) (7 components);

2. Central Line-Associated Bloodstream Infection (CLABSI), consisting of a Central line insertion bundle (3 components), and a Central line maintenance bundle (5 components);
3. Falls – Reducing Falls and Injury from Falls (4 approaches);
4. Medication Reconciliation (MedRec) in acute care, long-term care and home care;
5. New Approach to Controlling Superbugs (NACS) reducing transmission of MRSA, Vancomycin Resistant *Enterococcus* (VRE) and *Clostridium difficile* (7 steps);
6. Rapid Response Teams (RRT) (7 steps);
7. Safe Surgery Saves Lives (SSSL) implementing the Surgical Safety Checklist;
8. Surgical Site Infection (SSI) (4 components);
9. Ventilator-Associated Pneumonia (VAP), consisting of adult and pediatric bundles (each with 4 components); and
10. Venous Thromboembolism (VTE) (8 steps).

Safer Healthcare Now! has become the flagship program of the Canadian Patient Safety Institute. SHN invests in frontline providers and the delivery system to improve the safety of patient care throughout Canada by implementing interventions known to reduce avoidable harm. *Safer Healthcare Now!* has resources and expertise for frontline healthcare providers and others who want to improve patient safety. The tools and resources (including ‘Getting Started Kits’ and other support materials; collaboratives and WebEx ‘Action Series’ on particular initiatives; mentorship for new teams or those that need help; etc.) are customizable, improving care, and include defined measures. SHN also allows enrolled teams to submit their data.

Recognizing that improvement requires more than tools, SHN also provides substantial infrastructure to support teams in their effort to adopt its evidence-based tools and bundles. Support is organized regionally, with dedicated coordination for local needs in the following areas: the Atlantic Region (New Brunswick, Nova Scotia, Prince Edward Island, and Newfoundland and Labrador); Ontario (Ontario and Nunavut); the Quebec Campaign: Together, let’s improve healthcare safety!; and the Western Region (British Columbia, Alberta, Saskatchewan, Manitoba, Northwest Territories, and Yukon). Each region manages its own network of enrolled teams, facilities and partners. However, all regions come together with the national infrastructure to support the SHN program as an integrated whole.

Complexity and culture in healthcare

Slide 19

Complexity and culture in healthcare

- Scientific, technological and structural change has made healthcare more complex
difference in background or training
- Importance of getting beyond social and psychological barriers to systems thinking
- Complexity science
study of complex adaptive systems (CAS)
study of self-organizing structures

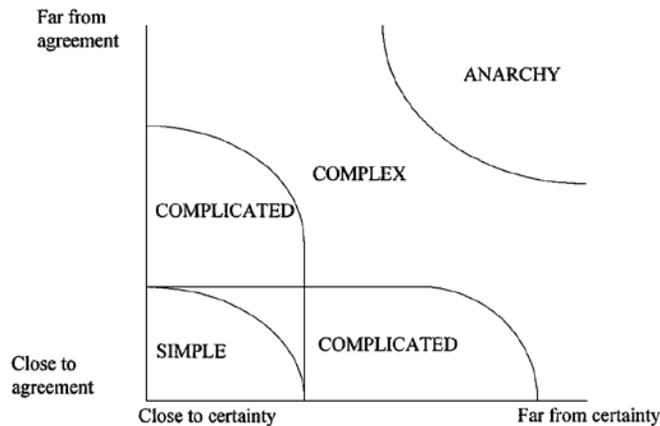
Medicine's increasing ability to treat more illnesses and symptoms comes at the price of greater complexity and accelerating change, technologically and otherwise. For example, one hundred years ago, there were only a few medicines and procedures available to physicians. Fifty years ago, doctors had 500 or so medicines to choose from, and could often keep track of these in their heads. Today, there are over 6,000 drug products approved by Health Canada for use in humans. The proliferation of medical specialties is also a fairly recent but important development. There are "more than 50 different types of medical specialties and subspecialties interacting with each other and with an equally large array of allied health professions" (Leape, Berwick, 2005). In 1996 at the first Annenberg conference, attention was drawn to the complexity of modern healthcare and the importance of getting beyond social and psychological barriers to systems thinking. Complexity science can help us to understand why many change efforts fail, and suggests how we might do things differently.

Complexity science is the study of complex adaptive systems (CAS). "Complex adaptive systems are ubiquitous. Stock markets, human bodies and hospitals are all examples. What is a complex adaptive system? Each word is significant. 'Complex' implies diversity – a great number of connections among a wide variety of elements. 'Adaptive' suggests the capacity to alter or change – the ability to learn from experience. A 'system' is a set of connected or interdependent things. The 'things' in a complex adaptive system are independent agents. An agent may be a person, a molecule, a species or an organization" (Zimmerman, 1999). In other words, complexity science studies self-organizing structures.

Figure 1 is based on a matrix developed by Ralph Stacey. "Stacey created this matrix to indicate that management decisions differ in two dimensions: the degree of certainty about the issue and the level of agreement about the solution to the issue" (Zimmerman, Hayday, 1999). He argued that most of the management literature deals with decisions in which there is both a high degree of certainty and strong agreement (simple problems), or one or the other of these (complicated problems). Anarchy or chaos reign where there is

extreme uncertainty and disagreement. The middle zone – the zone of complexity – is where real innovation happens, and where traditional approaches seldom work.

Figure 1: Simple, Complicated and Complex Problems (Zimmerman, Hayday, 1999)



Paul Plsek uses an example drawn from Glouberman and Zimmerman to illustrate how simple, complicated and complex problems differ.

- Baking a cake is a simple problem. Simple problems lend themselves to a recipe approach. The process and results are generalizable, and while special skill at cooking is a plus, it is not essential for success.
- Sending a rocket to the moon is an example of a complicated problem. Complicated problems are best dealt with using formulaic and expert-knowledge approaches. The overall problem can be mechanically broken down into component parts (booster rocket, cabin environment, navigational equipment, etc.) and assigned to teams of experts who apply the proven methodologies of their disciplines. Rockets are similar in important ways, meaning that success with one rocket provides reasonable assurance of success with future rockets. When surprising events do occur, we can study these, build improvements into the system, and thus raise the probability of future success.
- In contrast to simple and complicated issues, an example of a complex issue is that of raising a child. Success in raising one child is no guarantee of success in raising another. Experience, coupled with advice from experts, can serve as a starting point, but we know that simply applying the formula that worked before may not lead to success, and may even lead directly to failure because of the second child's resentment at being treated this way (Plsek, 2003).

Rapid scientific, technological and structural change has made healthcare more complex by increasing uncertainty and offering a greater number of choices. However, another factor adding to the complexity of healthcare is that differences in the professional training and background of participants makes it difficult for them to agree on either the problem or its solution.

Pippa Hall has studied the traditional differences in training between nurses and physicians. “A long history of class differences and gender issues underlies current challenges to collaborative teamwork in health care” (Hall, 2005). The industrial revolution saw the rise of the concept of the “profession”, which led to the disciplinary boundaries we see today. These boundaries are evident in professional training: “physicians traditionally learn independently in a highly competitive academic milieu, [whereas] nurses learn early in their careers to work as a team, collectively working out problems and efficiently exchanging information across shifts to insure appropriate continuity of care” (Hall, 2005). Ultimately, such differences manifest themselves in different “cognitive maps” so that physicians and nurses (and members of any other profession) can look at the same problem and see it differently.

Developing a culture of safety

Slide 20

Developing a culture of safety ...

- Requires major changes in behaviour
- Learning a nonblaming systems-oriented approach
- Lessons must be embedded into an organization’s culture and practices
- Communication across professions
different vocabulary, approaches, understanding of issues and values (Hall, 2005)

Slide 21

... Developing a culture of safety

- The Safety Competencies” (CPSI, 2008)
describes safety competencies in six domains
lists associated knowledge, skills and attitudes for each domain
contribute to a culture of patient safety
work in teams for patient safety
communicate effectively for patient safety
manage safety risks
optimize human and environmental factors
recognize, respond to and disclose adverse events

In 2005, when Leape and Berwick reflected on the lack of progress in patient safety, they asked themselves why it had proven so difficult to implement the practices and policies needed to deliver safe patient care. The answers, they suggested, “are to be found in the culture of medicine, a culture that is deeply rooted, both by custom and training, in high standards of individual performance” (Leape, Berwick, 2005). They go on to describe “medicine’s tenacious commitment to individual, professional autonomy” as a challenge that must be overcome. “Creating cultures of safety requires major changes in behavior, changes that professionals easily perceive as threats to their authority and autonomy.

Overlay this demand to change individual behavior with the challenges of learning a nonblaming systems-oriented approach to errors and establishing new lines of accountability, and it is not surprising that progress in achieving safety in health care is slow” (Leape, Berwick, 2005).

An Organisation with a Memory observed that we seem not to learn from adverse events. To change this, the report suggested, lessons must be embedded into an organization’s culture and practices (Department of Health, 2000). This is not easy. In launching the 100,000 Lives Campaign, Berwick cautioned that “although the 6 interventions are conceptually simple and feasible, implementing them can be complex, requiring cultural changes, such as empowering nurses to engage a rapid response team without reprisal and persuading physician staffs to endorse the standardization upon which reliable implementation of these interventions will depend” (Berwick et al, 2006).

“Communication skills that are taught to students [in professional schools] usually focus on interactions with patients and families from the perspective of his/her profession, not on communication across professions. ... [Health professionals] begin their careers with interprofessional barriers of unfamiliar vocabulary, different approaches to problem-solving, and a lack of common understanding of issues and values” (Hall, 2005). “To develop collaborative skills that can bring down the walls of the professional silos, health professional students need opportunities to spend time together, to learn and to work together in meaningful ways. Experiential learning is particularly important in *interprofessional* education” (Hall, 2005). This is still in its early days in Canada.

Aviation was not unlike healthcare in having clear status hierarchies. “Pilots were the unquestioned leaders. Repeated air crashes that occurred when the plane was mechanically sound but the crew got into trouble convinced airlines that they needed to invest in team training. Air crews in both commercial and military aviation are now required to take courses in ‘crew resource management’ where they are taught to communicate ‘against the authority gradient’” (Baker, Norton, 2001).

In 2008, the Canadian Patient Safety Institute published *The Safety Competencies: Enhancing Patient Safety Across the Health Professions*. This document describes safety competencies in six domains, and lists associated knowledge, skills and attitudes for each. The domains and their definitions are (Frank, Brien, 2008):

1. Contribute to a Culture of Patient Safety (commitment to applying core patient safety knowledge, skills and attitudes to everyday work);
2. Work in Teams for Patient Safety (working within interprofessional teams to optimize both patient safety and quality of care);
3. Communicate Effectively for Patient Safety (promoting patient safety through effective health care communication);
4. Manage Safety Risks (anticipating, recognizing and managing situations that place patients at risk);

5. Optimize Human and Environmental Factors (managing the relationship between individual and environmental characteristics in order to optimize patient safety); and
6. Recognize, Respond to and Disclose Adverse Events (recognizing the occurrence of an adverse event or close call and responding effectively to mitigate harm to the patient, ensure disclosure, and prevent recurrence).

Applying complexity science to teamwork

Slide 22

Applying complexity science to teamwork

- o Positive deviance approach
 - develop a team of people
 - define the problem
 - identify positive deviants
 - discover their uncommon practices
 - design solutions based on these practices and other ideas
 - document activities and results
 - disseminate findings

“Complexity science suggests that when you cannot predict outcomes, experimenting or growing solutions chunk by chunk can be a highly effective learning approach. Rather than centralizing control in times of uncertainty, distributing control increases the potential for self-organization and emergent solutions” (Zimmerman, 1999).

An example of this approach is the *Safer Healthcare Now!* initiative “A New Approach to Controlling Superbugs”, which relies on “positive deviance” – a concept based on complexity science. The positive deviance approach has seven steps:

1. develop a team of people interested in solving the problem (they will self-select);
2. define the problem together;
3. identify positive deviants (people already achieving the desired outcome in the face of similar challenges);
4. discover their uncommon practices;
5. design solutions based on these practices and other ideas;
6. document activities and results; and
7. disseminate findings (*Safer Healthcare Now! Getting Started Kit* 2010).

Similarly, aviation safety did not have large-scale practices:

“[It] was not built on evidence that certain practices reduced the frequency of crashes. Instead, it relied on the widespread implementation of hundreds of small changes in procedures, equipment, training, and organization that aggregated to establish an incredibly strong safety culture and amazingly effective practices.... In health care, the progress in anesthesia safety is a comparable example.... Anesthesia is the only system in health care that begins to approach the vaunted

‘six sigma’ level of perfection that other industries strive for. Mortality from elective anesthesia has declined 10-fold in the past several decades as the result of a concerted effort to improve safety. This outstanding achievement is attributable not to any single practice or development of new anesthetic agents or even any type of improvement (such as technological advances) but to the application of a broad array of changes in process, equipment, organization, supervision, training, and teamwork. However, no single one of these changes has ever been proven to have a clear-cut impact on mortality. Rather, anesthesia safety was achieved by applying a whole host of changes that made sense, were based on an understanding of human factors principles, and had been demonstrated to be effective in other settings. Safety, they showed, is doing a lot of little things that, in aggregate, make a big difference” (Leape, Berwick, 2002).

Success stories

In 2003, a group of attendees at the Rocky Mountain Critical Care Conference “strategized how to overcome barriers to patient safety that are common within the existing processes and systems of every critical care unit in Canada” (Northway, Mawdsley, Couves, 2006). They decided to form the Canadian Intensive Care Unit (ICU) Collaborative. “The collaborative approach brings together teams that share a commitment to making significant and rapid improvement. The method relies on spread and adaptation of existing knowledge. Integral to the success of a collaborative is the rapid implementation of changes in ‘small steps’” (Mawdsley, Northway, 2006). When their results were published in late 2006, the Canadian ICU Collaborative had already worked with more than 90 adult and pediatric ICU teams from 50 centres. They had six goals:

1. improve appropriateness of red blood cell transfusions by 80% in participating ICUs within 12 months;
2. reduce incidence of ventilator-associated pneumonia (VAP) by 50% within 12 months;
3. reduce harm from the administration of selected high-risk medications by 90%;
4. reduce mortality from sepsis by 10% by using approaches to prevent or provide early management of sepsis;
5. reduce in-hospital cardiac arrests by 50% using medical emergency teams (MET) (analogous to rapid response teams); and
6. reduce the overall incidence of central venous catheter-related blood stream infections (CLABSI) by 50% within 12 months (Northway, Mawdsley, Couves, 2006).

Achievements by participating teams include:

- 309 days with no VAP diagnosed in the ICU at St. Paul’s Hospital, Saskatoon, SK;
- no VAP for six months in one ICU, and nine months in another in Calgary, AB;

- 90% appropriate blood transfusion in Calgary, AB;
- 26% reduction in cardiac arrests on medical units with implementation of MET at Trillium Health Centre, Mississauga, ON;
- 61% reduction in CLABSI at BC Children’s Hospital; and
- 50% improvement with targeted fluid resuscitation in the ICU during the first eight hours of severe sepsis and septic shock at University Hospital, London Health Sciences Centre, ON (Mawdsley, Northway, 2006).

In 2010, the Medication Reconciliation and Spread Team at Royal Jubilee and Victoria General Hospitals in Victoria, BC received the *Safer Healthcare Now!* Improving the Safety of Patient Care in Canada Team Award. Their goal was to prevent adverse drug events, specifically to reduce the number of unintentional discrepancies by 75 percent within the first year by reconciling patients’ home medications upon admission. The multidisciplinary medication reconciliation team achieved a 98 percent decrease in unintentional discrepancies (from 1 to 0.02 per patient) within their first month of implementation and had, at the time of the award, sustained this improvement for three and a half years (*Safer Healthcare Now!* SHN! Newsletter 2010).

Taking action

On its title page, *Crossing the Quality Chasm* displays a quote from Goethe: “Knowing is not enough; we must apply. Willing is not enough; we must do.”

To all who, in whatever capacity, are striving to make patients safer:

“The names of the patients whose lives we save can never be known. Our contribution will be what did not happen to them. And, though they are unknown, we will know that mothers and fathers are at graduations and weddings they would have missed, and that grandchildren will know grandparents they might never have known, and holidays will be taken, and work completed, and books read, and symphonies heard, and gardens tended that, without our work, would never have been” (IHI, “Overview of the 100,000 Lives Campaign” webpage).

Summary

Slide 23

Summary

- In 2000, between 9,000 and 24,000 patient died from adverse events (Canadian Adverse Events Study)
- Many proven interventions have yet to be fully implemented
- Systems thinking, human factors and complex adaptive systems can help us overcome barriers

“The Canadian Adverse Events Study” told us that approximately 185,000 people suffered an adverse event in a Canadian hospital in 2000. Between 9,000 and 24,000 patients died from adverse events that could have been prevented. We do not know if, and by how much, these numbers have improved, but without doubt, there is still work to do.

Adoption of *Safer Healthcare Now!* interventions and other well-researched safety practices has begun, but many proven interventions have yet to be fully implemented. There is also a limitless number of new ideas waiting to be conceived and tested by inventive champions of patient safety. Systems thinking and an understanding of human factors and complex adaptive systems can help us overcome the inertia of professional and organizational culture to see our efforts succeed.

We are on the forefront of measurable advances in patient safety. Together, we can make a difference.

Potential pitfalls

Slide 24

Potential pitfalls

- Overemphasis on professional autonomy may inhibit cooperation
- Even the most clearly-indicated changes may be hard to implement

1. Overemphasis on professional autonomy may inhibit cooperation.
2. Even the most clearly-indicated changes may be hard to implement.

Pearls

Slide 25

Pearls

- Ethical, compassionate care following adverse events (inc. honesty and emotional support) is a crucial part of our systems and culture change agenda
- The more complex a system is, the more chances it has to fail. Complexity therefore demands cooperation and alignment, even as it increases the array of specialties and subspecialties
- To make progress we must substitute new systems of care for current broken ones

1. Ethical, compassionate care following adverse events, which includes honesty and emotional support, is a crucial part of our systems and culture change agenda.
2. The more complex a system is, the more chances it has to fail. Complexity therefore demands more cooperation and alignment, even as it increases the array of specialties, and subspecialties.
3. To make progress we must substitute new systems of care for current broken ones.

Resources

- ***Safer Healthcare Now! website homepage: Safer Healthcare Now!*** <http://www.saferhealthcarenow.ca/EN/Pages/default.aspx>  
- **Global Patient Safety Alerts: Canadian Patient Safety Institute.** <http://www.globalpatientsafetyalerts.com/English/Pages/default.aspx>  
- ***The Safety Competencies: Enhancing Patient Safety Across the Health Professions***, First Edition (Revised August 2009): Frank JR and Brien S (editors), on behalf of The Safety Competencies Steering Committee (Ottawa, ON: Canadian Patient Safety Institute, 2008). <http://www.patientsafetyinstitute.ca/English/toolsResources/safetyCompetencies/Documents/Safety%20Competencies.pdf>  
- ***The Basics of FEMA***: McDermott RE, Mikulak RJ, Beauregard MR (Portland, OR: Productivity, Inc., 1996).
- ***Canadian Root Cause Analysis Framework: A tool for identifying and addressing the root causes of critical incidents in healthcare***: Hoffman C, Beard P, Greenall J, U D, White J (Edmonton, AB: Canadian Patient Safety Institute, March 2006). <http://www.patientsafetyinstitute.ca/English/toolsResources/rca/Documents/March%202006%20RCA%20Workbook.pdf>  

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Plenary 1 Trainer's Notes

Principal message

The single most important message your audience should come away with is that *there are persistent barriers within the healthcare system that affect quality and therefore safety*. As part of this insight, participants should realize that *there are methods and tools available to improve safety, but they have not been widely implemented*.

Plenary overview

The issue of patient safety, or reducing harm to patients, gained national importance in the mid-1990's. Lucian Leape's article, *Error in Medicine*, which estimated that approximately 100,000 people died in hospitals each year while undergoing medical treatment, along with prominent cases of medical error, forced a shift in thinking within the healthcare community. Instead of viewing medical errors as merely isolated incidents, healthcare professionals and others began to see errors as a result of system breakdowns in healthcare delivery.

This plenary summarizes the current gaps and barriers in implementing safer care for patients. Current barriers to safety include the increasing complexity of both healthcare technologies and institutions, the medical culture of physician autonomy, the failure to prioritize safety by healthcare executives, a reimbursement structure that subsidizes unsafe care, and the fear of litigation. The plenary also outlines current research in patient safety and gaps that still need to be addressed, such as inadequate safety training. Finally, the plenary addresses the issues of access to care and provider trust in the healthcare system.

Preparing for a presentation

1. Assess the needs of your audience

Choose from the material provided in the syllabus according to the needs of your expected participants. It is better for participants to come away with a few new pieces of information, well learned, than to come away with a deluge of information from which they can remember little or nothing.

2. Presentation timing

Allow sufficient time to collect participants' demographic data and complete the pre-test.

The suggested timing for each part of this module is:

Introduction 2-3 minutes

DVD trigger tape & discussion 10-12 minutes

Presentation	30 minutes
Summary	2-3 minutes
<u>Post-test & Evaluation</u>	<u>5 minutes</u>
Total	49-53 minutes

3. Number of slides: 26

4. Preparing your presentation

The text in the syllabus was not designed to be used as a prepared speech. Instead, the text provides material you may want to use. The slides have been designed to trigger your presentation. Although the slides closely follow the text of the syllabus, they do not contain all of the content. Their use presumes that you have mastered the content.

You may want to make notes on the slide summary pages to help you prepare your talk in more detail and provide you with notes to follow during your presentation.

Remember that you can adjust the slides to suit your presentation content, your style, and to make it feel fully familiar and your own.

Practice your presentation using the slides you have chosen, and speaking to yourself in the kind of language you expect to use, until it is smooth and interesting and takes the right amount of time. The most accomplished presenters and teachers still practice prior to a presentation; don't miss this step.

5. Preparing a handout for participants

The syllabus text and slides in the **Participant's Handbook** were designed to be reproduced and provided to participants as a handout. Take the portion you need; they can be used in their entirety, module by module, or for just one specific topic. Please include the following in each set of handouts:

- **PSEP – Canada Front Cover Page;**
- **PSEP – Canada Acknowledgment Pages** (to acknowledge the source of the material);
- syllabus and slides for **your topic**; and
- appendix material as relevant.

6. Equipment needs

- Projector and screen
- Computer and monitor
- Flipchart and markers for recording discussion points

Test your equipment beforehand to ensure that it works.

Review your video segments to assess which trigger tapes or portions you would like to use.

Have a back-up plan so that if there is any equipment failure you can move without panic to your back-up plan. For instance, have in mind that:

- if the video fails, you can read the vignette of the trigger tape story;
- if the slides cannot be shown, you can refer to the hand out slides; and
- if flipcharts and markers are not available, you can have participants list items on their hand outs that you would have written up for all to see.

Making the presentation

1. Introduce yourself

If you have not already done so, introduce yourself. Include your name, title, and the organization(s) you work for. Briefly describe your professional experience related to the information you will be presenting.

2. Introduce the topic

Show the title slide for the module. To establish the context for the session, make a few broad statements about the importance of topic as a patient safety matter. Tell participants the format and time you will take to present the session. Identify the teaching styles that you intend to use.

3. Review the session objectives

Show the slide with the session objectives listed. Read each objective and indicate those that you are planning to emphasize.

4. Show the trigger tape

After reviewing the objectives for the session, show the trigger tape. It has been designed to engage the audience and provide an appropriate clinical context for the session.

Trigger tape content

This plenary's trigger tape features clinicians discussing barriers to safety in healthcare, including medicine's traditional tolerance of error as inevitable and the conflict between individuals and the system.

5. Present the material

Recommended style: didactic lecture

This was designed to be presented as a lecture without much audience interaction. Use the slides to trigger the subject. Prepare ahead and practice so that it is smooth and interesting. The use of your voice, body, language, and gestures can all add to your presentation and the clarity of the message you are delivering.

6. Key take-home points

1. Quality and safety have been successfully proven to work in diverse and high-risk industries and must now be emphasized and put to use in healthcare
2. Centralized accountability allows for greater standardization and enforcement of safety standards.
3. Physicians, nurses and others need to be able to trust that they are working within a system in which they can perform without the fear of being scapegoated by the media and the malpractice system.
4. Lack of integration within hospitals creates distinct professional views that may inhibit cooperation.

7. Summarize the discussion

Briefly, review each part of the presentation. Recap two or three of the most important points that were discussed.

8. Post-test/evaluation

Ask the participants to complete the post-test questions for this plenary and to evaluate the session in the provided brief questionnaire.