



The Patient Safety  
Education Program™  
CANADA

Plenary 3: What is Patient Safety?:  
A Conceptual Framework

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.

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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 Laeeque, 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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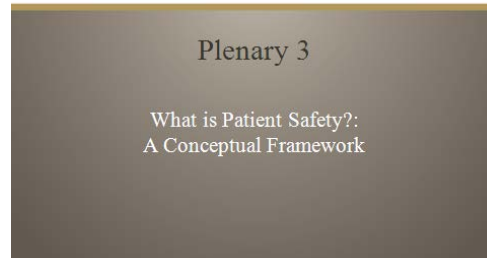
[Revised 2017]

<b>PSEP – Canada Objectives</b>	<b>Related CPSI Safety Competencies</b>
<p>The knowledge elements include an understanding of:</p> <ul style="list-style-type: none"> <li>• The origins of patient safety and its conceptual framework</li> </ul> <p>The performance elements include engaging in exercises to:</p> <ul style="list-style-type: none"> <li>• Demonstrate the nature of patient safety as a discipline through its definition, nature, locus, methods, components, clinicians, and stakeholders</li> </ul>	<p><b>Domain: Contribute to a Culture of Patient Safety</b></p> <p>2. <i>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>



## Abstract

Slide 1



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This plenary explores the intellectual history, definition, description and model of patient safety. It is defined as a discipline in the healthcare professions that applies safety science methods toward the goal of achieving a reliable and trustworthy system of healthcare delivery; and also an attribute of healthcare systems that minimizes the incidence and impact of, and maximizes recovery from adverse events. Our description includes answers to: why it exists (the high prevalence of avoidable adverse events); what are the nature and the properties of each components and what is its essential focus of action (the microsystem); how its essential mechanisms work (high reliability design, use of safety sciences, methods for causing change including cultural change); and who are its clinicians (all healthcare workers, patients, administrators, board members, and advocates). Our model is simple and overarching; it identifies four domains of patient safety (recipients of care, providers, therapeutics, and methods) and elements (we describe eleven) that fall within the domains.

## Keywords

Adverse event, error, latent error, system failure, human factors engineering, core domains, content areas, high-reliability design, open learning, beyond blame, safety science, systems thinking, continuous improvement, partnership between patients and providers, quality, risk, co-negotiation, team work, organizational structure, culture, accountability

## Teaching method

Didactic

# Objectives

Slide 2

## Knowledge requirements

- Know the origins of patient safety and its conceptual framework

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Slide 3

## Performance requirements

- Demonstrate the nature of patient safety as a discipline
  - definition
  - nature
  - methods
  - components
  - practitioners
  - stakeholders

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## Knowledge elements

The knowledge elements include an understanding of:  
the origins of patient safety and its conceptual framework.

## Performance elements

The performance elements include engaging in exercises to:  
demonstrate the nature of patient safety as a discipline through its definition, nature, locus, methods, components, clinicians, and stakeholders.

# Introduction

Slide 4

## Introduction

- Hospitals are not always safe
- Patient safety discipline
  - what are the challenges?
  - what is its content and philosophy?

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A defining realization of the 1990s was that, despite all the known power of modern medicine to cure and ameliorate illness, hospitals were not safe places of healing. Instead, they were places fraught with risk of patient harm. It was also during this decade that key healthcare leaders published these findings. *To Err is Human*, the preliminary report from the Institute of Medicine was released in late 1999 followed by the full text in 2000. These texts issued a call to action. One important response has been the growth of interest in patient safety. It is increasingly clear that patient safety has become a discipline, complete with an integrated body of knowledge and expertise, and that it has the potential to revolutionize healthcare -- perhaps as radically as molecular biology once dramatically increased therapeutic power in medicine. Patient safety is now recognized in many countries, with global awareness fostered by the World Health Organization's World Alliance for Patient Safety. And yet, challenges to implementing patient safety policies and practices are significant. One fundamental requirement for adopting any new approach is a clear articulation of its fundamental principles and assumptions. Components of patient safety have been expressed by thought leaders and models have been presented. However, a single rendition that can help a thorough adoption of patient safety throughout healthcare has not been available. This plenary aims to offer that. After introducing salient points in its intellectual history, it explores a definition, a description and, finally, conceptual framework for patient safety.

# Intellectual history of patient safety

Slide 5

## Shift in paradigm

- Patient safety changed thinking about:
  - causes for errors that lead to adverse events
  - health care delivery

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Critical assumptions in healthcare were rewritten by patient safety thinking. Understanding why people make the errors that are involved in adverse events shifted from an individual-cause, legalistic framework to a systems/engineering-design framework, and in so doing it changed forever the way many people thought about healthcare delivery.

## Limiting blame

Slide 6

## Limiting blame

- Trained perfectibility
  - errors = incompetence
  - punishment used as motivation
  - practitioners more likely to hide mistakes
- Factors that affected blame culture
  - high rate of healthcare injuries
  - “blunt end” vs. “sharp end” errors

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The first quantum leap defined patient safety’s entry into healthcare thought. The realization was that adverse events often occur because of system breakdowns, not simply from individual ineptitude. The traditional approach assumed that well-trained, conscientious clinicians do not make errors. Traditional thinking equated error with incompetence, and regarded punishment as both appropriate and effective in motivating individuals to be more careful.

The use of this kind of blame had a toxic effect. Clinicians rarely revealed mistakes, and patients and supervisors were frequently kept in the dark. Low reporting made learning from errors nearly impossible, and legal counsel often supported and encouraged this approach so as to minimize the risk of malpractice litigation. This mindset made a wary, antagonistic backdrop to the therapeutic interaction. It also created a paralysis of fear for all concerned when failure did occur.



Thinking began to change in the 1990s in response to several kinds of new information. First, medical injury was acknowledged as occurring far more often than heretofore realized, with many of these injuries deemed preventable. Secondly, was the idea that “active” errors at the “sharp end”—where clinicians interact with patients or equipment—result from “latent” errors, as demonstrated by James Reason and others.

Latent errors are upstream defects in the design of systems, organization, management, training, and equipment (“blunt end”) that increased the likelihood of individuals making mistakes at the sharp end. Thus, to punish individuals for such mistakes made little sense, since errors are bound to continue until underlying causes are remedied.

## Systems thinking

Slide 7

**Systems thinking**

- Reduced error by redesigning systems
- Applies industrial engineering concepts to health care processes  
technology, management and organization
- Evolution of systems thinking
- Understanding blunt-end factors

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Thought leaders in healthcare were persuasive in sharing their belief that harm can be reduced by redesigning systems and processes using human factors principles, which reduce mistakes through design features such as standardization, simplification, and the use of constraints such as forcing functions (design characteristics that make error impossible, e.g., incompatible connectors that prevent connecting an anesthetic gas to the oxygen port of an anesthesia machine).

The second, corollary quantum leap in viewing healthcare as a system took place as people applied these engineering design concepts to healthcare. Some of these systems changes were related to tools and technology, such as using better intravenous pumps or computerizing physician medication prescribing. Others were related to organization and people, such as training physicians and nurses to work more effectively in teams or including a pharmacist in the team during rounds. Many of the strategies were adapted from other industries such as aviation (John Nance’s *Why Hospitals Should Fly*) and nuclear. Some were more successful than others. But the important change was that people were thinking of healthcare delivery in terms of systems. There was an uncomfortable awareness that the rate of preventable injury and death in healthcare was too high and it began to propel many clinicians, administrators and policy makers into action. For example, the Regina Health District (Saskatchewan) developed a root cause analysis methodology for determining the applicable system issues (1998).

Interestingly, in earlier phases of medical history different forms of systems thinking were dominant. However, these focused on the biological systems within the individual patient, rather than on care and interactions between individuals in the environment of care. The notion of humors, and then the understanding of the circulatory system are two examples from the period prior to the modern scientific era. As the scientific era dawned and the field of medicine began applying the scientific method with success, systems thinking within physiology continued. Perhaps this was helpful as clinicians took on a systems understanding of the delivery of healthcare as well.

Initially, perhaps, blunt-end factors were typically thought of as organizational policies and processes that shape the behaviour of individuals at the sharp end-point of service (where care is delivered). But awareness also emerged that there are extra-organizational blunt-end factors, including provincial/territorial governments, economic policy makers, professional licensing authorities, insurance and liability protection organizations, and technology and equipment suppliers. These parties influence and shape demands and incentives within the healthcare organizations. So healthcare had to be seen as an open not a closed system, and policy also began to be thought of as a feature of the system.

## Transparency and learning

Slide 8

**Transparency and learning**

- Adverse events yield information
- Sharing of error related information essential
- Culture and professionalism
  - manage risk and reduce injury through culture change
  - change rooted in the value of non-maleficence

The idea that adverse events can yield information was not new. But as it was newly applied in healthcare it acquired a new potency. The notion was that for effective patient safety outcomes, information sharing about harm in healthcare was essential and had a greater sense of urgency. Commentators asserted that the more adverse event-related information was shared, the better solution could be implemented industry-wide. The possibility that knowledge of systems might require an understanding how things go wrong was demanding attention.

## Culture and professionalism

Clinicians, governing boards, executive leaders, and middle managers of healthcare delivery organizations were all increasingly being encouraged to think in terms of building high-reliability organizations. This required a culture change to one that refrained from assigning “sharp end” blame for mistakes; incentivized learning by fully

disclosing information about mistakes, failure and close calls; trained and provided support to clinicians involved in inherently risky work; and disclosed all relevant facts to injured parties.

These transformations in thinking resulted in approaches that were remarkably well rooted in the essential ethical underpinnings of profession. The call for safety went directly to the central medical professional imperative to ‘above all, do no harm.’ The value at issue was non-maleficence. The call for system-wide transparency cohered with fundamental professional standards requiring honesty and disclosure of material facts to the patient, as a matter of justice, human rights or the fiduciary obligations intrinsic to the unequal power structure of the provider/patient relationship.

## Accountability for delivering effective, safe care

Slide 9

**History of accountability**

- Early medical malpractice  
individuals accountable for adverse events
- Medicine becomes accountable to society  
scientific method, 3-phase clinical trials  
standards for education and certification



Early Western medical traditions were organized through guilds which kept the special knowledge and skills involved in medical practices a secret. At a time when many medical methods were of dubious foundation, rarely beneficial, and frequently harmful, the challenge of securing the trust of society was significant. The primary method was to root out the charlatans. As modern concepts of negligence developed, emphasizing litigation to deter substandard behaviour and individual accountability for procedures and actions causally linked to adverse outcomes became embedded in both medicine and law.

In an important parallel development, as treatments were discovered and became increasingly effective, the medical field began to establish methods for accountability, and its credibility in society rose. The scientific method was essential in that development and, with good reason, medicine has adhered to it. The three-phase approach to establishing the efficacy and safety of new medical therapies: (phase 1 clinical trials to assess safety; phase 2 clinical trials to ascertain efficacy; and phase 3 trials to compare it with another standard intervention) was essential, too. The dependence on the randomized clinical trial as the touchstone of the scientific method was critical to that process. The goal was to be sure that medicine was, and was seen as, a clinical-research-driven, reliable practice. The effort was successful; society recognized that medicine merited its standing as a profession with specialized expertise to use powerful methods

applied appropriately. Consequently, these scientific and clinical research methods and their associated ways of thinking became well entrenched.

The growth of medical sciences also changed standards in medical education, licensure and peer review. The early apprenticeship model was supplemented by requirements for a phase in which didactically acquired knowledge was transmitted prior to the apprenticeship. As specialties developed, they sought to codify and legitimize their expertise through testing and certification. With the development of safer and more effective surgery, medical care delivery systems began focusing on hospitals; standards for these delivery systems were understood to be necessary. Certification of hospitals and other healthcare delivery systems followed, often with professional groups such as the Royal College of Physicians and Surgeons of Canada or Accreditation Canada (formerly known as Canadian Council on Health Services Accreditation) serving quasi-government oversight and public protection roles. The nascent realization that healthcare, including its clinicians and other components, also needed to be accountable for learning from adverse event was harder to grapple with.

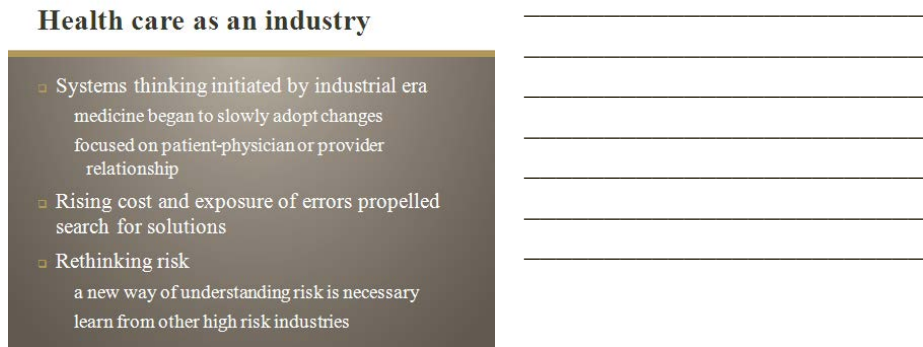
A model for accountability of clinicians that included accountability for continuous learning set the stage for but stopped short of a full rendition of what accountability for understanding and optimally designing safe healthcare systems requires.

## Healthcare as an industry?

Slide 10

**Health care as an industry**

- ❑ Systems thinking initiated by industrial era  
medicine began to slowly adopt changes  
focused on patient-physician or provider  
relationship
- ❑ Rising cost and exposure of errors propelled  
search for solutions
- ❑ Rethinking risk  
a new way of understanding risk is necessary  
learn from other high risk industries



Since the first half of the twentieth century, the industrial era of society phased into the service industry era. Systems-thinking was an established part of industrial engineering and was applied in production lines and service industries. And yet medicine maintained a separation from these changes. This may have occurred because of medicine's standing as a profession with a privileged relationship to society, and because of the protected the one-on-one model of the physician-patient relationship.

Thus, the healthcare paradigm remained focused on the patient-physician/patient-provider relationship and on a therapy's point-of-application, rather than on the systems of application. The clinician was trained and certified to apply therapy at the point of the illness-causing disorder.

Even in the more expansive bio-psychosocial model, safety-oriented systems thinking was missing, although the role of the patient’s immediate relationship circle and of the community and society was acknowledged. Public health efforts also co-existed, but tended to not focus on the systems of health care delivery.

Rising, apparently-uncontrollable costs of healthcare coupled with increasing evidence of poor quality ushered in a continuous cycle of government budget cuts then increases and various kinds of provincial/territorial accountability agreements with the applicable healthcare delivery structures along with demands from the public for accountability. Additionally, increased media exposure of preventable patient safety events raised troubling questions that propelled a search for new solutions. Leape’s earlier publication of the theoretical possibility of applying industrial human factors engineering concepts to healthcare and subsequent demonstration with Bates and colleagues of their work on medication error and systems analysis later that year provided that new type of thinking. The first conference on patient safety and systems error at the Annenberg Center for Health Sciences in 1996 was a natural next step toward a new type of thinking.

## Rethinking risk

Thought leaders from medicine and policy makers began to crave a new way of understanding risk, new ways to reaffirm relationships with patients, and a new way of addressing the shocking realities that epidemiology studies such as Leape’s 1994 landmark study, *Error in Medicine*, had presented. A decade earlier, anesthesiology had made substantial improvements by applying systems thinking translated from methods used in aviation and mechanical engineering, but the rest of medicine had failed to generalize it. Quality improvement and risk management both had developed as disciplines within healthcare, with an emphasis on health service delivery research and measurement. These and other developments produced a readiness for looking at what might be learned and adapted from other high-risk industries and complex organizations.

## Emphasizing team work as well as dyadic relationships

Slide 11

### Emphasizing teamwork

- ❑ Dysfunctional relationships block change
- ❑ Teamwork important in communication across all levels of authority
- ❑ Teamwork training
- ❑ Expanded concept of healthcare delivery

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Early attempts at systems change revealed one Achilles heel of implementation: dysfunctional relationships between clinicians and other workers. Mirroring some of the

developments in aviation, in which a focus on teamwork complemented attention to refinement of mechanical systems, healthcare began to recognize the importance of team functioning – particularly for communicating across authority gradients both in everyday practice and crisis situations. Training in teamwork became a foundational building block for the new field of patient safety.

The discipline of patient safety rejected the concept of healthcare delivery as an exclusive dominion of the medical profession over the patient-physician relationship. The vision was more inclusive and demanding. It included patient-centered care and the biomedical model, and focused on interdisciplinary teams and families. It also included the technical and administrative aspects of healthcare delivery in a complex system.

## Defining patient safety

Slide 12

### Defining patient safety

- A discipline in the health care sector that applies safety science methods toward the goal of achieving a trustworthy system of health care delivery
- Attributes of health care systems
  - minimize the incidence and impact of adverse events
  - maximize recovery from adverse events

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As the intellectual history of patient safety developed, it became increasingly important to define patient safety. Thought leaders began to examine their different assumptions. Is patient safety a way of doing things – that is, a philosophy (with its own explanatory framework, ethical principles and methods) and a discipline (with a body of expertise)? Or is it an attribute – that is, a goal and a condition (being safe), a property that emerges from the system? Existing definitions seem to vary on the question.

Although the Institute of Medicine (IOM) defined safety as “freedom from accidental injury,” patient safety as a discipline or field of inquiry and action has not been fully defined in the major consensus statements to date of the organizations that have propelled its existence. Part of the challenge lies in distinguishing safety from quality, a line which remains important to some while being dismissed by others as an exercise in semantics. In 1998, the IOM convened the National Roundtable on Health care Quality which adopted the following definition of quality that was widely accepted: “Quality of care is the degree to which healthcare services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”

Healthcare quality problems were classified into three categories: underuse, overuse and misuse, all of which the evidence shows are common. Misuse was further defined as the

preventable complications of treatment. Although the roundtable was careful to distinguish misuse from error – the latter may or may not cause complications – the misuse category became a common reference point for conceptualizing patient safety as a component of quality.

In 2003, the Canadian Patient Safety Dictionary recommended that patient safety be defined as the reduction and mitigation of unsafe acts within the health-care system, as well as through the use of best practices shown to lead to optimal patient outcomes.

The National Patient Safety Foundation identified the key property of safety as emerging from the proper interaction of components of the healthcare system, thereby leading the way to a defined focus for patient safety, namely systems. Vincent has defined its goal as: “[t]he avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of care.”

In 2006, Leape and Berwick observed that as attention to patient safety has deepened, the lines between the overuse, underuse and misuse categories have blurred. They noted that patients are subject to harm from both unnecessary care and failure to receive necessary care.

The following definition is used in the *Core Curriculum*:

Patient safety is a discipline in the healthcare sector that applies safety science methods toward the goal of achieving a trustworthy system of healthcare delivery. Patient safety is also an attribute of healthcare systems; it minimizes the incidence and impact of, and maximizes recovery from adverse events.

This definition acknowledges that patient safety is both a way of doing things and an emergent property. It seeks to identify essential features of patient safety.

## The why, what, where, how and who of patient safety

Going further with the definition, each of its components is expanded in what follows to offer a deeper description of patient safety.

### Why does the field of patient safety exist?

Slide 13

#### Why patient safety?

- Adverse medical events are widespread and preventable
- Goal to minimize adverse events and harm

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Patient safety began in response to evidence that adverse medical events are widespread and preventable, as was noted above. In the words of James Conway: ‘There is too much harm.’ Its goal is minimizing adverse events and eliminating preventable harm in healthcare.

In Canada, the rate of adverse events in healthcare was established in the Canadian Adverse Events Study. The revealed the following:

- incidence rate of 7.5% in hospitals;
- estimated 70,000 preventable adverse events (est.); and
- 9,000 - 24,000 preventable adverse event deaths in Canada.

The results were widely discussed in the media and no jurisdiction, including governments, hospitals, regions, or regulatory bodies, debated the findings.

## What is the nature of patient safety?

Slide 14

### Nature of patient safety

- Discipline in health care professions
- Emerges from systems design
- Designed for the nature of illness
- Depend on open learning
- Trustworthiness essential

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## A discipline in the healthcare professions

Patient safety is a relatively new discipline within the healthcare professions. Graduate degree programs are newly being introduced as part of patient safety’s recognition as a discipline. It is a subject within that of health care quality. However, its methods come largely from disciplines outside of medicine, particularly cognitive psychology, human factors engineering, and organizational management science. That, however, is also true of the biomedical sciences which propelled medicine forward to its current extraordinary capacity to cure illnesses. Their methods came from biology, chemistry, physics, and mathematics, among others. Applying safety sciences to healthcare requires inclusion of experts with new source disciplines such as engineering but it requires no divergence from the goals or inherent nature of the medical profession.

## A property that emerges from systems design

Patient safety must be an attribute of the healthcare system. Patient safety seeks high reliability under conditions of risk. Illness presents the first condition of risk in healthcare. Patient safety applies to the second condition: the therapeutic intervention.



Sometimes the therapeutic risk is audacious, such as when a patient's heart is lifted, chilled, and cut and sewn in cardiac transplantation surgery. Risk and safety are flip sides of the therapeutic coin.

Patient safety is a property of systems design. It demands design of systems to make risky interventions reliable. Two tenets of complexity theory apply: first, the greater the complexity of the system, the greater the propensity is for chaos. Second, in open interacting systems, unpredictable events will happen. The better the therapeutic design, the more resilient it is in the face of both predictable and unpredictable possible or impending failures so that they can be prevented or rescue achieved. Safety systems include design of materials, procedures, environment, training, and the nature of the culture among people operating in the system.

Berwick and others have collaborated with Rene Amalberti to apply Deming's notion of statistical quality or error levels to healthcare. Systems are categorized by their level of adverse events. Barriers to progression from one level to another are identified. Interestingly, leaders of high reliability organizations in other industries, view the level of adverse events in healthcare as so high that many of them would consider the health industry as existing in a state of chaos. The patient safety discipline seeks systems that can move healthcare to higher and higher levels.

## **A property designed for the nature of illness**

High-reliability design is a concept that was not originally developed for healthcare. However, healthcare has some essential features in common with how high-reliability design has evolved. While often complex and unpredictable it can have the ultimate high stakes outcome: preservation of life.

A unique feature of patient care is its highly personal nature. Provision of care almost always requires healthcare workers to cross significant personal boundaries, both psychological and physical. To protect patient integrity the health professions have developed codes of professional ethics that guide how best to provide healthcare without doing dishonor to the ill person. Patient safety designs must allow for these important restrictions, which include confidentiality, physical privacy and others.

Healthcare providers and healthcare organizations are responsible for protecting a patient's health information appropriately. The law requires breaching confidentiality in only certain situations, such as reporting specific communicable diseases, suspicions of child abuse, and a few others.

For understanding, the healthcare team members directly involved in the care of a patient can be referred to as being within the "circle of care". Canadian laws allow the sharing of personal health information within the "circle of care", unless the patient has withdrawn his or her consent. Quality of care and safety depends on good communication and sharing of information among the providers themselves and the patient.

Consent to share information within the circle of care is generally implied – a patient would expect that his or her information will be shared. For example, the patient with a surgical condition will expect the family physician to share appropriate information with the surgeon. In turn, the patient expects that appropriate information would then be shared with the operating room team so that the surgery can be safe and successful.

Another unique feature is the natural progression of illness. By definition, when illness care begins, something, namely whatever caused the illness, has already gone wrong. Thus, in many medical situations, failure to provide the correct and timely intervention causes a person harm. A delayed diagnosis of appendicitis or of a dissecting aneurysm, for example, may leave the patient with the condition's progression to death. The patient safety discipline acknowledges the need to include harm due to omission of action as well as the more obvious harm that may occur from actions taken.

The vast diversity of possible etiologies and manifestations of illness makes systems design in healthcare a unique challenge. Nonetheless, the reality is that a majority of conditions are common and of common etiology; this allows for optimal design if not infallible outcomes. In the words of James Conway: 'If 80% of, say, breast cancer is best treated according to protocol and 20% needs off-protocol, tailored treatment, we can design systems for that.'

## **A property dependent on open learning**

Patient safety has another inherent feature that derives directly from its dependence on adverse events as a main source of understanding. That is, it depends on a culture of openness to all relevant perspectives in which those involved in adverse events are treated as partners in learning. In this sense, patient safety espouses continuous cycles of learning, reporting of adverse events or near misses, dissemination of lessons learned and the establishment of cultures that are trusted to not unfairly blame. The patient safety field marries principles of adult education and effective behavioural learning with the traditional approaches of the medical profession. Known from its early days as the field that seeks to move 'beyond blame' to a culture trusted by all to be just patient safety has pushed for a much deeper understanding of the mechanisms of errors that often lie beyond the actions or control of the individual.

Patient safety advocates turn away from the traditions of the healthcare professions in which social standing and privileged knowledge once shielded clinicians from accountability, while at the same time rejecting the defensive posture of old risk management approaches in which clinicians and leaders of health care organizations were advised as part of a legal paradigm of zealous advocacy to admit no responsibility and defend all malpractice claims, whether or not they were justified.

The Canadian Medical Protective Association (CMPA) aims to be consistent with patient safety philosophy. It is a not-for-profit mutual defense association. The CMPA provides

an ethical defense that “defends the defensible,” seeks settlement if warranted, and uses alternative dispute resolution approaches when reasonable.

Patient safety embraces organizational and personal accountability, but recognizes the dimensions, while maintaining accountability and integrity in interactions with patients and families who have suffered avoidable adverse events.

## Trustworthiness is essential to the concept of patient safety

The healthcare system designed for patient safety is trustworthy. This is not because adverse events will never happen but because the healthcare system holds itself accountable to applying safety sciences optimally. Patient safety (as an attribute) prevents avoidable adverse events by paying attention (as a discipline) to systems and interactions, including human interactions, and allowing learning by all parties from near misses and actual adverse events. Through a concerted, conscientious effort all those involved act to minimize the extent and impact of unavoidable adverse events by creating well-designed systems and well-motivated, informed, conscientious and vigilant personnel, and by seeking to honestly and respectfully repair damage when it occurs.

## Where does patient safety happen?

Slide 15

### Where does it happen?

- Microsystems  
where patient receives healthcare  
convergence of patient safety systems
- Microsystems can impact each other  
leads to unpredictable events

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The ultimate locus of patient safety is the microsystem. That is, the immediate environment in which care occurs – the operating room, the emergency department, etc. It is in the microsystem that the sharp end resides, where patient-caregiver interactions occur, where failures of safety emerge and patients are harmed. The breaches in safety may have occurred in many blunt-end components and, as described above, events constitute properties of interacting components of the overall system. Therefore, patient safety is irreducibly a matter of systems. Nonetheless, as the setting where the patient receives healthcare, the microsystem is the locus where the successes or failures of all systems to ensure safety converge.

At the same time, patient safety must simultaneously be concerned with the entire system. Importantly, patient safety recognizes that the microsystem is inherently unpredictable. Although it takes a mechanistic view of causation, patient safety

acknowledges that each microsystem is open in that it can be impacted by another microsystem. This may result in something unpredictable. So, for instance, the microsystem of concern in surgical safety may be the operating suite, but if a local emergency demands that two members of the surgical team leave the operating room, the microsystem has been unpredictably impacted.

## How is patient safety achieved?

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**How is it achieved?**

- High reliability design
  - reliable under complex conditions
- Safety science
  - application of safety knowledge
  - fail-safe systems
- Methods for change
  - rapid cycles of feedback
  - communication with patient and family

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### High reliability design

The fundamental mechanism by which patient safety can be achieved is high reliability design. Many components are part of the design; thus, the irreducible unit of patient safety delivery is multifaceted: all the components of healthcare delivery must be integrated into a system that is as reliable as possible under complex conditions.

A unique feature of high reliability design comes from complexity theory, which notes that open interacting systems will produce some level of chaos or inherently unpredictable events. High reliability designs are resilient even when unpredictable events occur.

Additional design features that guide health systems engineers include ‘lean process’ and, as noted above (A Property That Emerges from System Design), the notion of breaking through reliability boundaries in leaps from one safety level to another – these levels of reliability are often known as sigma levels – through the use of simplified and better processes.

The concept of a multi-layered system in which the failures within each of these layers must be aligned for a harm to occur is known as the “Swiss Cheese” model of accident causation. The components that make up the system include the institution and its organization, the professional team and the individuals that comprise it, and the technology in use.

Error traps, that is, unpredictable situations in which error is highly likely, are another vivid concept on which safety sciences focuses. The notion is that healthcare delivery is not only complex but is also an open interacting system in which illness is also a given,

so the opportunities for adverse events are many and endemic. Healthcare workers and health systems designers must therefore take this into account.

Safety systems design in healthcare is early in development. Practical approaches to design for safety have been pioneered by the Institute for Healthcare Improvement, the Agency for Health care Research and Quality, and the World Health Organization's World Alliance for Patient Safety (see also A patient safety model of health care).

For instance, as noted above, patient safety designs can be thought of as falling into two types:

1. those that are for types of routine care that vary little and can best be managed with protocols allowing little deviation, and
2. those that are for unique situations where on-the-spot innovation and significant deviation from protocol are required.

## **Safety sciences**

The term 'safety science' refers to the methods by which knowledge of safety is acquired and applied to create high reliability designs. The objective is to design systems that approach 'fail-safe' conditions, i.e. which ensure proper execution. The ideal design is one in which the operator cannot perform the function improperly. Short of that ideal, much of the effort in the past has been directed toward developing defenses, barriers that prevent an unsafe act from resulting in harm. Over the years, healthcare has developed many of these barriers, and usually several must be breached for patient harm to occur.

Acquisition of objective knowledge is a matter of science. Patient safety uses methods that are appropriate to the purpose and these can be drawn from a range of disciplines. Some – such as understanding human error – come from human physiology and psychology. Some – such as systems analysis and quality improvement – come from engineering and management. Some – such as organizational behaviour – come from social sciences. Other methods come from health services research.

However, the disciplines that contribute to safety use the methods that are appropriate to each field. These include controlled experiments, repeat tests and other traditional scientific methods. Human factors engineering is built on, as appropriate, randomized controlled trials of human performance, anthropometry, anatomy, physiology, physics and mathematics.

A strong claim can be made, as James Reason has, that while safety sciences are scientifically grounded, the fundamental drive to and the cutting edge of inquiry in patient safety uses the narrative; that is, it is the stories of adverse events that yield insights and drive adjustments. Stories provide pattern recognition for patient safety practitioners. Stories of patient safety – like other stories – are specific and yet have insights that can be applied to other settings. This feature is well suited to the need for dealing with events that may be either familiar or entirely unpredictable.

Importantly, however, one of the founding contributors to the safety sciences had a critical reason and unique standing to claim the term ‘science’ for the safety sciences. Philosopher Karl Popper, famous for his work in defining the scientific method, working with MacIntyre, identified error (and by extension one can include systems failures more generally) as analogous to the data that refutes a hypothesis in the scientific method. Sciences such as chemistry or biology use as their core method a cycle which is comprised of: observation, hypothesis generation, testing, and hypothesis verification or alteration, depending on the results of testing. Deviation from this method causes the knowledge to be unreliable and the deviant methods to be discarded as unsound. The patient safety discipline uses an analogous cycle - of observation, design, testing, and then use - as its method, and adjustment of the system is based on analyzing how adverse events came about. This in turn is based on the assertion by Deming that making a change is a key source of knowledge for systems. The rather close analogue of method warrants the use of the term ‘science’ in the safety sciences.

To understand how human performance slips up, psychology or physiology or social science must be used. To understand how a machine fails, engineering methods must be used. Each method must be used with its full insistence on rigor so that the new knowledge is as reliable and objective as possible. But by contrast with the application of the scientific method in the physical sciences, for ethical and practical reasons, there can rarely be in patient care a control or a repeat of the same event to check for reproducibility except in a simulated environment. Nonetheless, when the analytic method has yielded to the best of its capacity a new insight, then this – like the new data in the process of science – generates a new cycle of adjusted design, testing and use. In short, the analytic method must be unique to the adverse event, but then the safety sciences use the insight generated to create a new cycle of improved understanding and system design.

In short, patient safety applies many methods and techniques. However, two analytic methods have become widely associated with the field. One is retrospective: analysis of what went wrong when an adverse event has occurred is known as root cause analysis (RCA). Perhaps the close identification (probably excessively so) of patient safety with RCA is a result of heightened attention that occurs after a bad event. RCA is an approach to finding out what underlying features of a situation contributed to an adverse event. Adopting the idea that the immediate cause of an event is almost always the end result of multiple systems failures, RCA seeks, by review of data and interviews, to identify and understand all contributing causes in order to redesign the systems to make them safer in the future.

The RCA methodology was borrowed from the defense and manufacturing industries in the mid 1990’s and was gradually deployed across the industrialized world to investigate adverse events. The Joint Commission used the term Root Cause Analysis (RCA) in 1997 when they mandated this process for hospitals undergoing accreditation. In 1999, the US National Centre for Patient Safety (NCPS) of the Department of Veterans Affairs (VA)

piloted the use of RCA at four of its hospitals and then followed in 2000 with a full roll-out. The NCPS RCA methodology has been implemented on a large scale in many countries including the United States, Canada and Australia. A variety of other event analysis methodologies were subsequently developed and implemented in other healthcare settings.

RCA investigations of serious and less serious iatrogenic errors have played an important role in significantly reconfiguring clinical practices and how clinicians enact their relationships. The analysis is tri-focal and includes the technical details of the work, the interpersonal dimension, and the temporal staging that describes the socio-organizational activity. The process is difficult work and is not linear but rather fluctuates across multiple and contrasting concerns and positions.

There are now peer-reviewed studies in the literature that describe the effectiveness of RCA in reducing targeted adverse events. A systematic cost effectiveness evaluation of RCA has not yet been published.

As healthcare occurs in complex adaptive systems where unpredictability and paradox are ever present, some things will remain unknowable. Incorporating a dynamic, emergent, creative, and intuitive view of the world moves the RCA process beyond the traditional reduce and resolve approaches to clinical care and service organization.

Complexity science suggests trying multiple approaches and shifting time and attention to those strategies that appear to be effective. The Plan-Do-Study-Act cycle of quality improvement is one example of an activity that enables experimentation, autonomy, and working at the edge of knowledge and experience.

Given the complexity of their environment and the significant resource requirements of a comprehensive event analysis, healthcare leaders and patient safety experts have begun to look for a more “concise” method of event analysis to help meet the need for timely and accurate information on a larger number of adverse events. For example, a long-term care facility implemented “mini-RCAs”, an abbreviated version of the formal RCA process, when there was not enough time to do a full RCA on each fall. In 2008, the National Patient Safety Agency (United Kingdom) also recognized that various levels of investigation were appropriate and issued a root cause analysis tool with guidance on three levels: concise, comprehensive, and independent. Other abbreviated event analysis methodologies have emerged as case conferences, also known as modified mortality and morbidity or M& M rounds, or unit based safety programs.

The other characteristic method of patient safety is proactive and prospective: attempting to anticipate and prevent adverse events through safety design is known as failure mode effects analysis (FMEA). FMEA is an engineering approach – usually taken early in the development of a product – that seeks to imaginatively identify potential failures and their effects. Knowledge from past failures may contribute to a designer’s ability to foresee possible failures in their design. Designs are then adjusted to make failure less likely. FMEA is used in analyzing every aspect of a system’s design. This includes: the

system's global functioning, its components and their interactions, the equipment functioning, the programming of equipment, and the procedures for activities.

However, no one method is enough to produce the range of knowledge and types of understanding that is required for patient safety. By contrast to the clinical sciences in which the randomized controlled trial is the research method of choice, patient safety avoids the notion that there is a single gold standard in which the field can have confidence. In patient safety, contributions are sought from: engineering, social sciences, psychology, psychometrics, health services research, epidemiology, statistics, philosophy (theories of justice, accountability), ethics, education, computer sciences and more. Each discipline has particular methods that it uses; patient safety takes each on its own merits and selects the method most suited to the topic or question at hand.

Measurement remains an important area for development in patient safety. Many needed measures are not yet developed. The Institute for Healthcare Improvement talks of three types of measurement: process, outcome and balance. Process measure may need to be developed and validated for a complete bundle of carefully selected procedures for a given clinical setting. Outcome measures may need to be developed for the particular outcome in question, but they may also need to be used in a fashion that has been developed to allow for balance, that is, to look at the impact of intervention in one place in the system on other places in the system.

## **Methods for causing change**

G.R. Baker and P. Norton were among the first Canadians to publish nationally in Canada on the issue of patient safety. They recommended three key strategies.

“First, better information about the numbers and types of errors that occur is needed to help pinpoint change efforts. Non-punitive reporting policies must be put in place, to assist in altering the traditional culture of blame that has discouraged error reporting. Second, a set of strategies have to focus on developing more effective systems, including physician-order entry and medication administration systems which have been shown to have a dramatic impact in reducing errors. These systems are expensive, but their importance in reducing injury - and greatly reducing the costs of additional care that come from such injuries - make them an essential part of the answer.

Finally, healthcare organizations need to work to create more effective cultures oriented toward preventing errors and intercepting errors that inevitably occur. These cultures will require a new emphasis on teamwork, a continual focus on redesigning care systems, particularly in high risk areas such as operating rooms, intensive care units and emergency rooms. These are not easy tasks and will require investments in new equipment



and new skills. These steps are essential if we are to maintain public confidence in healthcare.”

With its emphasis on making changes in healthcare workers’ actions, patient safety seeks to engage methods to bring about improvements that go beyond transmission of knowledge and acquisition of skills to the effective implementation of appropriate skills. In this regard, patient safety builds on the insights and techniques of quality improvement. By its nature, separation between acquisition of new knowledge and service delivery is minimal.

Rapid cycles of feedback and response methods for institutional improvement were pioneered in healthcare by Berwick and others. These processes are derived from continuous quality improvement methods originally designed by Deming and others. The methods focus on the systems of healthcare delivery more than the medical issues, and the knowledge that the rapid cycles produce are of the specific local system. The methods are designed to improving services in areas where a gap between acknowledged standards and actual practices exists. Usually, a guideline or protocol that has already been endorsed by an expert medical body or bundle of established practices is to be applied. The rapid cycles tend to keep the guideline or protocol or bundle the same, altering its application only to optimize its full use in the local system. Once the implementation is done, quality indicators are monitored to maintain the new standards.

Patient and family voice is pivotal throughout the rapid cycle approach to quality improvement yet many healthcare systems continue to keep their input at a distance. Adverse events are subjected to analysis which feeds into redesign or adjusted design of the systems of care. More traditional health services research and other methods of acquiring understanding are also fed into the re-composition of the systems.

Dissemination of change is not a characteristic of the approach that uses rapid cycles or of quality improvement more generally. This is in great part because the methods are designed to be tailored to the local system and therefore they do not readily generalize and measures of success may also vary for the same reason. However, approaches that standardize measures and quality improvement methods are also being used; this will allow for better dissemination. Alternatively, more traditional campaigns to get individual healthcare sites to each do their own improvement work can be used, as has been done by the Institute for Healthcare Improvement.

# Who is a patient safety practitioner?

Slide 17

## Who is a practitioner?

- All members of health care can practice patient safety
- Skills and characteristics
  - experienced with patient safety
    - preventing adverse events
  - well-storied
    - provide real examples of adverse events
  - excellent team members

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Most health-related disciplines are characterized by having specialists who devote themselves to the full-time practice of the discipline. Similarly, patient safety is emerging as a specialty in which master's degree education is offered and there are patient safety offices and patient safety officers who devote their full-time effort to it.

But, patient safety requires that all members of the healthcare service delivery team, and where applicable the patient and significant others be 'patient safety minded.' It will also always depend on both hands-on patient safety practices and leadership within every discipline in healthcare. As quintessentially a collaborative activity, patient safety will always need leaders in each area of clinical administration and in each clinical discipline among physicians, nurses, pharmacists etc. as well as in information management, finance, human resources, equipment and plant management and so on. Patient safety practitioners truly include everyone in healthcare.

For those who have a higher degree in or a role determined by patient safety, patient safety may be a primary professional identity. For most, it will be a personal and professional commitment that is a part of, but not their primary identity, which will remain cardiology, or plant management, etc. Nonetheless, since all in healthcare should acquire the characteristics necessary for practicing safety, it is relevant to know what the characteristics of a patient safety practitioner (whether by primary or secondary identity) are.

## Skills involved in patient safety

What are the skills or unique characteristics of the patient safety practitioner? The professional who provides direct care needs to have a kind of wariness, or patient safety vigilance. This quality is most often informed by a rich knowledge about adverse events and how to help avert them or minimize their damage. This kind of practical wisdom or safety savvy is continuously grown from experience and an ability to recognize when something is not right. Often an adverse event that is about to unfold can be averted or its impact minimized if it is caught in action.

Patient safety practitioners are well storied. A leader in patient safety, James Reason, emphasizes the role of narrative in patient safety, both as a vehicle for acquiring safety-relevant knowledge or safety wisdom, and as a vehicle for becoming what Weick has called mindful or safety-wary. They understand that healthcare systems are full of ‘error traps’ and they are vigilant in foreseeing and preempting, mitigating and rescuing patients from them. Reason envisions a future for patient safety in which its practitioners include in their educational venues and habits the sharing of many, many true stories of adverse events. He sees this as the normative method for making members of the healthcare provider community optimally safety wise. Studies of pediatric cardiac surgeons found that those surgeons who were inclined to detect their errors and fix them even at the price of having a longer and less elegant operation had the best outcomes and reputations.

Patients and their families have a unique and invaluable story to contribute as well. They experience the complexity of an adverse event first hand and often have exceptional insights to causal factors and effective strategies for improvement.

Patient safety practitioners must also become excellent team members, whether they are natural leaders or better in other roles. They must be able to substitute for one another and appreciate the other’s perspective. Importantly, since vigilance is essential for patient safety and is also tiring, as Paul Schyve and others have pointed out, working in teams during shift-work is essential.

## A patient safety model of healthcare

Slide 18

**Patient safety model**

- Domains of health care
  - workers
  - recipients of care
  - systems for therapeutic action
  - methods for feedback and improvement



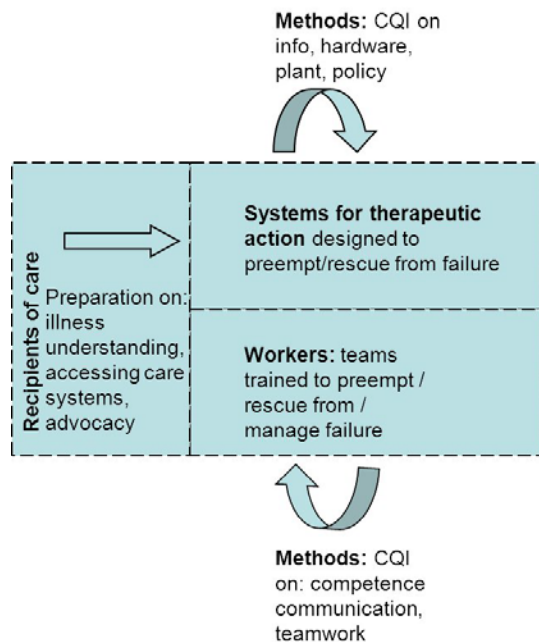
“With the above aspects of patient safety lined up, it is possible to see a simple model of patient safety. While good models of patient safety have been constructed, we seek an overarching model that is simple, fully authentic to the subject matter, and compatible with the good existing models. At the same time, it should be simple enough that it can be seen in a readily sketched diagram and stated in a simple, short sentence that can be easily recalled. Only such a simple model can ubiquitously permeate the interstices of daily thought among all the necessary people throughout healthcare.” (Emanuel et al, 2008)

We offer the following simple model with which to see patient safety. It divides healthcare systems into four main domains:

1. those who work in healthcare;
2. those who receive it or have a stake in its availability;
3. the infrastructure of systems for therapeutic interventions (healthcare delivery processes); and
4. the methods for feedback and continuous improvement.

These are represented graphically in Figure 1. Each domain interacts with each other one and with the environment, as depicted by the semi-permeable divisions (dotted lines) between them and at their outer edges. This provides a core, overarching model for patient safety.

**Figure 1: A patient safety model of healthcare**



The model is consistent with the descriptors above of patient safety ('What is the nature of patient safety?' and 'Where does patient safety happen?' correspond to the third domain, namely '*systems for therapeutic action.*' 'How is patient safety achieved?' corresponds with the fourth '*the methods.*' 'Who is a patient safety practitioner?' corresponds with the first and second, namely '*people who work in healthcare*' and '*people who receive it or have a stake in its availability*').

The model is also consistent with existing frameworks of thinking that underpin patient safety. Each of the frameworks define categories or elements that fall coherently within one or more of the four domains, as displayed below in Table 1.

Deming's notion of 'deep knowledge' of quality design required an understanding of: the system; variation in its performance; how to use change as a source of knowledge; and

the psychology of people in the organization. All of these elements drove the quality improvement field and they belong within the domain of ‘*methods*’.

Donabedian divided healthcare into structure, process and outcomes for the purpose of measurement. It is also a helpful way of categorizing the health system for the purposes of understanding how elements of the system interact. For this reason, the categories can be thought of as cutting across all four domains in the patient safety model.

Vincent identified seven elements that influence safety: organization and management factors; work environment factors; team factors; task factors; individual factors; patient characteristics; and external environment factors. These factors distribute among the three domains of: systems for therapeutic action; the people who work in healthcare; and the people who receive it or have a stake in its availability.

Carayon and colleagues proposed a Systems Engineering Initiative for Patient Safety (SEIPS) model for design in healthcare. In the SEIPS model, elements are helpfully depicted with interacting arrows that illustrate how the elements can interact with one another, so depicting the notion of emergent properties.

**Table 1: How domains and elements relate in the patient safety model**

Domain	Systems for therapeutic action	People who work in the healthcare system	People who receive healthcare or have a stake in its availability	Methods
Content areas	<ul style="list-style-type: none"> <li>• structure</li> <li>• process</li> <li>• outcome</li> </ul>			
	<ul style="list-style-type: none"> <li>• Organization &amp; management</li> <li>• Work environment</li> <li>• Task factors</li> <li>• External environment</li> </ul>	<ul style="list-style-type: none"> <li>• Team factors</li> <li>• Individual factors</li> </ul>	<ul style="list-style-type: none"> <li>• Patient characteristics</li> </ul>	<ul style="list-style-type: none"> <li>• System knowledge</li> <li>• Understand variation</li> <li>• Understand how change yields knowledge</li> <li>• Psychology</li> </ul>

The above eleven are not an exhaustive list of elements; others could be identified. Furthermore, elements can be subdivided into their content areas, something not attempted here. For instance, external environment has been divided into physical, social and biological areas. The elements can also be categorized in different ways. For instance, team factors could be considered within work environment. The purpose of this simple, broad model of domains is to capture the largest category of essential components in patient safety and their interaction with one another.

The fashion in which this or any patient safety model applies must vary by setting as dramatically as the settings vary. The nature of the illnesses and social setting, the nature of the therapies, the nature of the human resources, and the nature of the physical infrastructure will all contribute to defining the different systems. These systems must be

analyzed and options identified for improvement. However, the fundamental concepts in any good patient safety model are applicable to most settings.

What is the utility of this model, and of the other models with which ours is built to be compatible? It (and they) provide(s) a way of seeing the component elements involved in patient safety and how they interact. So, when designing a system, improving a system, analyzing an adverse event, researching an issue, or measuring a new intervention, it (they) provide(s) a ready map of matters that should be considered. Given the human tendency to limit the scope of focus, models provide a countervailing stimulus to include the whole universe of domains and their elements that may be involved in the patient safety issue at hand.

## Summary

Slide 19

### Summary

- Patient safety aims to:
  - eliminate preventable harm
  - redesign systems for high reliability and human factors
  - develop a culture change
    - reduce individual blame
    - be open about failure

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Patient safety aims to eliminate preventable harm in healthcare. It is a new discipline, but incorporates many important features from existing areas of science and engineering. Primarily, patient safety has shifted thinking from the traditional blame culture, to one in which adverse events are seen as resulting from an interplay of complex systems. By redesigning systems for higher reliability and human factors, rather than expecting trained perfectibility by clinicians, many types of adverse events can be reduced. Furthermore, developing a culture of openness and honesty about failure can help determine their causes, and as a result, prevent them and minimize their effects in the future.

In 2002, *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care* was released by The National Steering Committee on Patient Safety. The report outlined principles for action and specific recommendations that were designed to make patient safety a national priority ([http://rcpsc.medical.org/publications/building\\_a\\_safer\\_system\\_e.pdf](http://rcpsc.medical.org/publications/building_a_safer_system_e.pdf)).

Only a few of the nineteen recommendations have been fully implemented over the past eight years. Many aspects of the integrated strategy have only begun to be visible to healthcare providers and patients. There is so much more to know, understand, implement, and evaluate about patient safety in Canadian healthcare!

Now this is not the end. It is not even the beginning of the end. But it is, perhaps, the end of the beginning. - Sir Winston Churchill (British politician (1874 - 1965)), speech in November 1942

## Potential pitfalls

Slide 20

### Potential pitfalls

- Avoid blaming individuals
- Patient safety is not an exact science

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1. Avoid blaming individuals.
2. Patient safety is not an inexact science. Properly applied, safety sciences are as rigorous as the sciences that comprise it; together they can result in designs safe enough to put rockets into space.

## Pearls

Slide 21

### Pearls

- Everyone in health care should practice patient safety
- Adverse events can be prevented
- Designing systems with high reliability can reduce latent errors

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1. Everyone in healthcare should practice patient safety.
2. Adverse events can be prevented and minimized in an open and honest environment.
3. Designing systems with high reliability can reduce latent errors.

## Toolkits & outcome measures

- **Patient Healthcare Matrix:** Bingham J Quinn D Richardson M Miles P Gabbe S Using a Healthcare matrix to assess patient care in terms of aims for improvement in core competencies. Journal on Quality and Patient Safety 2005;31(2) 98-105 <http://www.ihl.org/IHI/Topics/HealthProfessionsEducation/EducationGeneral/EmergingContent/PatientHealthCareMatrix.htm>
- **Safer Healthcare**  
*Now!* <http://www.saferhealthcarenow.ca/EN/Pages/default.aspx> 
- **International Classification for Patient Safety (ICPS):** This conceptual framework for an international classification represents a consensus of international experts on what constitutes a reasonable understanding of the world of patient safety. [http://www.who.int/patientsafety/implementation/taxonomy/icps\\_download/en/index.html](http://www.who.int/patientsafety/implementation/taxonomy/icps_download/en/index.html) 
- **The Safety Competencies:** The Safety Competencies were produced in collaboration with The Royal College of Physicians and Surgeons of Canada (CanMEDS Office). This important work was spearheaded by the Canadian Patient Safety Institute's Education and Professional Development Advisory Committee and was guided and crafted by an interprofessional team of educators (Steering Committee). Each domain was further developed by theme-based working groups.  
<http://www.patientsafetyinstitute.ca/English/education/safetyCompetencies/Pages/default.aspx>   
<http://www.patientsafetyinstitute.ca/french/education/safetycompetencies/pages/default.aspx> 
- **Canadian Root Cause Analysis Framework:** In 2006, the Canadian Patient Safety Institute partnered with Saskatchewan Health and the Institute for Safe Medication Practices Canada (ISMP Canada) to co-author the Canadian Root Cause Analysis Framework. <http://www.patientsafetyinstitute.ca/English/toolsResources/rca/Pages/default.aspx>   
<http://www.patientsafetyinstitute.ca/french/toolsresources/rca/pages/default.aspx> 
- **Canadian Failure Mode and Effects Analysis Framework©:** ISMP Canada. (2006, December 23). Failure Mode and Effects Analysis: Proactively Identifying Risk in Healthcare. ISMP Canada Bulletin 2006, 6(8).  
<http://www.ismp-canada.org/fmea.htm> 



- **A Theory of Leadership for the Transformation of Health Care Organizations:** Reinertsen J. The Reinertsen Group. May 2003. (Unpublished manuscript, revised January 2004.) <http://www.ihl.org/IHI/Topics/Improvement/ImprovementMethods/Literature/ATheoryofLeadershipfortheTransformationforHealthCareOrganizations.htm>

## Resources

- **Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care:** National Steering Committee on Patient Safety. 2002 [http://rcpsc.medical.org/publications/building\\_a\\_safer\\_system\\_e.pdf](http://rcpsc.medical.org/publications/building_a_safer_system_e.pdf).
- **Safety and ethics in Healthcare: A Guide to Getting It Right:** Runciman B, Merry A, Walton M. Ashgate Publishing 2007.
- **Crossing the Quality Chasm: A New Health System for the 21<sup>st</sup> Century:** Committee on Quality of Health Care in America, Institute of Medicine, Washington, DC, USA: National Academies Press; 2001 <http://www.ihl.org/IHI/Topics/Improvement/ImprovementMethods/Literature/CrossingtheQualityChasmANewHealthSystemforthe21stCentury.htm>
- **The Canadian Adverse Events Study** 2004. <http://www.cmaj.ca/cgi/content/full/170/11/1678>
- **The Canadian Patient Safety Dictionary.** Davies, J., Hebert, P., Hoffman, C. Royal College of Physicians and Surgeons of Canada 2003. [http://rcpsc.medical.org/publications/PatientSafetyDictionary\\_e.pdf](http://rcpsc.medical.org/publications/PatientSafetyDictionary_e.pdf)
- **The Human Factor:** Vincente, K. 2003.

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## Plenary 3 Trainer's Notes

### Principal message

The single most important message your audience should come away with is that by redesigning systems for higher reliability and human factors, rather than expecting trained perfectibility by practitioners, *adverse events can be reduced*. Furthermore, developing a culture of openness and honesty about failure can help determine their causes, and as a result, *prevent them and minimize their effects in the future*.

### Plenary overview

This plenary explores the intellectual history, definition, description and model of patient safety. It is defined as a discipline in the healthcare professions that applies safety science methods toward the goal of achieving a trustworthy system of healthcare delivery; and also an attribute of healthcare systems that minimizes the incidence and impact of, and maximizes recovery from adverse events. This plenary outlines the following about patient safety: why it exists (the high prevalence of avoidable adverse events); the nature and properties of each component and its essential focus of action (the microsystem); how its essential mechanisms work (high reliability design, use of safety sciences, methods for causing change including cultural change); and who are its practitioners (all healthcare workers, patients and advocates). Finally, it identifies four domains of patient safety (recipients of care, providers, therapeutics, and methods) and elements that fall within the domains.

### 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
Trigger tape & discussion	5-7 minutes
Presentation	35 minutes

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

### 3. Number of slides: 21

### 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 Lucian Leape discussing the new culture of patient safety in healthcare. He highlights the need for reducing blame on individuals and creating an open reporting environment. Leape emphasizes that healthcare has become safer, yet perfectly safe care can be achieved.

## **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. Everyone in healthcare should practice patient safety.
2. Adverse events can be prevented and minimized in an open and honest environment.
3. Designing systems with high reliability can reduce latent errors.
4. Avoid blaming individuals.
5. Patient safety is not an inexact science. Properly applied, safety sciences are as rigorous as the sciences that comprise it; together they can result in designs safe enough to put rockets into space.

## **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.