

Healthcare
QUALITY & SAFETY
Management

A Framework for Alberta

July 2017

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Foreword

Effectively managing healthcare quality and patient safety is the goal of every healthcare system. Members of the HQCA's Health Quality Network saw the need in our province for a common understanding and description of how to lead and manage quality and safety. In collaboration with the organizations represented by the Health Quality Network, a working group was formed to complete this work. We commend the many individuals who contributed their expertise in developing a collective body of knowledge that demonstrates Alberta's leadership and dedication to quality and safety management.

The outcome of their efforts has resulted in this framework document, which describes three components of quality and safety management: two models that highlight the important conceptual elements required to effectively manage healthcare quality and safety, and a foundational set of enablers to facilitate success. One model represents the design of systems to provide optimal outcomes, and the second describes the appropriate response when a patient has been harmed in the healthcare system.

The ultimate goal of this work is to improve care for Albertans. In our document, for ease of reading, we consistently use the term "patients", but we acknowledge that Albertans receiving care in a variety of capacities will benefit from improved quality of care: whether it is residents of supportive living or long-term care facilities, patients receiving primary or acute care, or clients of home care services.

Like other HQCA frameworks, this document makes an important contribution to the tools available to organizations striving to excel in improving the quality of care. It is not intended to supersede existing healthcare quality and safety management models in Alberta that are already working well, but we encourage organizations to consider how this framework can be useful to them in enhancing what they already do. When we learn from one another, and when we share what works well across systems, we all move closer to achieving the standard of excellence in quality and safety to which we aspire.



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Executive Summary

The *Healthcare Quality and Safety Management: A Framework for Alberta (HQSMF)* outlines what healthcare providers, managers and executives need to do to effectively manage quality and safety. The HQSMF has two models that describe ‘*What to do*’: the **System Design Model** describes proactively managing to achieve optimal outcomes, and the **Harm Response Model** describes reactively responding when a patient has suffered serious harm. The third component of the HQSMF is a set of six enablers that represent ‘*What is needed*’ to ensure that quality and safety management efforts have maximum effect. ‘*How*’ to apply the HQSMF elements is described in a companion document, the *Healthcare Quality and Safety Management: Sample Scenarios*.

The first goal of quality and safety management is to improve one or more of the six dimensions of quality, as described in the *Alberta Quality Matrix for Health*, which in turn can contribute to the Triple Aim, as described by the Institute for Healthcare Improvement: (1) improve patient experience; (2) improve the health of a population; and, (3) reduce or control per capita spending. The second goal of quality and safety management is to limit the effect on patients, families and healthcare providers when patients are harmed.

System Design Model

PHASE 0: GOALS, VALUES AND GUIDING PRINCIPLES

The System Design Model is based on organizational goals, values and guiding principles used to influence decision-making. The model then involves five iterative phases:

PHASE 1: HEALTHCARE ENCOUNTERS (MEASURE, MONITOR, EVALUATE)

Continuous monitoring with valid and reliable data is an essential beginning to improving care; patient outcomes must be monitored, as well as measures of key processes and structural elements of the healthcare system.

PHASE 2: ISSUES/HAZARDS → OPPORTUNITIES

Safety management’s focus is to identify hazards that pose a risk to patients. Quality management focuses on issues that affect patients’ experience as well as the efficiency, accessibility, appropriateness and effectiveness of healthcare delivery. From these safety and quality opportunities, be they internal or external, organizations must prioritize a manageable number of opportunities on which to focus improvement activities.

PHASE 3: PRIORITY OPPORTUNITIES

Before starting a formal improvement project, a deeper understanding of the important factors contributing to the prioritized issues is required. This may mean additional measurement and evaluation or further analysis that provides insight about error-provoking conditions.

PHASE 4: IMPROVEMENT IDEAS

At this stage, formal improvement projects are created to develop and test ideas that are likely to address the issue or hazard that has been identified and analyzed. For the many ideas generated and tested in this phase, a process will be needed for selecting only a limited number to implement across healthcare delivery units to increase the likelihood of success.

PHASE 5: SYSTEM CHANGE (BY DESIGN)

Implementing, spreading (i.e., extending) and sustaining improvement ideas can be challenging, but chances for success will increase if three components are well planned: (1) project management; (2) change management; and (3) ongoing measurement with feedback loops that allow for further iteration.

Harm Response Model

PHASE 0: WAS A PATIENT HARMED?

The Harm Response Model is based on first confirming that a patient was harmed or nearly harmed and is not experiencing a progression of the underlying condition. The model then involves five phases:

PHASE 1: IMMEDIATE MANAGEMENT

The acronym RESPOND reminds and guides health providers and managers about important actions to consider as soon as it is recognized that a patient was harmed. **RESPOND** represents: **R**esuscitate the patient; **E**nsure the environment is safe; **S**ecure equipment; **P**rotect other patients, **O**ffer initial support to patient/family and healthcare providers; **N**otify and make a note in the chart; and, **D**isclose (at this stage meaning an initial acknowledgement of what happened).

PHASE 2: SITUATION ASSESSMENT

Someone within the organization or local unit (clinical microsystem) who has appropriate oversight and authority must decide whether phases 3 to 5 are required to effectively manage situations where a patient was harmed or nearly harmed. Decision-making is aided by having as much information about the case as possible at this stage.

PHASE 3: PATIENT(S) AND FAMILY

Patients and their families require timely information, often involving a formal disclosure process. An appropriate apology is part of disclosure. Support can include addressing psychological, spiritual, and financial needs.

PHASE 4: HEALTHCARE PROVIDERS

Healthcare providers require support to lessen the trauma they can experience when a patient is harmed. A fair assessment of healthcare providers' actions, respecting the principles of a just culture, will help to ensure they are not unjustly blamed and/or disciplined.

PHASE 5: HEALTHCARE SYSTEM

When a patient has experienced serious harm, the healthcare providers, managers and executives of the responsible healthcare system have a duty to learn from what happened and to make improvements aimed at reducing the likelihood of a recurrence. Reporting what occurred, followed by a methodical analysis that uncovers the contributing system factors, leads to effective recommendations for improvement. A process of informing both internally and externally should be considered so that other patients can be protected from possible harm and the learnings are shared with other organizations across the health system.

Structural Elements (Enablers)

While many factors have been suggested as enablers for managing quality and safety, the HQSMF highlights six that are considered essential for the framework's process elements to be effective.

LEADERSHIP

Leaders provide the vision for what a health system needs to accomplish and thus are critical for promoting and advancing the quality and safety agenda as well as 'setting the table' for an organization's culture.

FOLLOWERSHIP

Continuous quality and safety improvement requires change, which does not happen without effective followership. Followership refers to people understanding how to support an organization's vision and strategy, and is felt to be a more critical success factor than leadership because effective followers encourage others to adopt changes.

GOVERNANCE AND ACCOUNTABILITY STRUCTURE

For effective improvements to be implemented and sustained, organizations need to have clear organizational accountability for results. This requires a formal organizational structure that supports quality and safety management. When the accountability chain is obvious there is no doubt who is responsible, and what is required, for achieving results.

CAPACITY AND CAPABILITY

Successful quality and safety management requires numerous people with a diverse set of skills at all levels of the organization. Capacity also refers to having the appropriate time and the necessary infrastructure to support quality and safety management.

SUPPORTIVE INFORMATION SYSTEMS

Monitoring, measurement, and evaluation are critical at all stages of quality and safety management. Data need to be systematically captured and stored in linked, accessible databases.

VALUES AND GUIDING PRINCIPLES

Values and guiding principles provide the moral and ethical compass that places and keeps the quality and safety management efforts focused and moving forward.



Background

The business of any healthcare system is that of helping people. When people think about their healthcare experience, they reflect on the care they received and what happened to them, or the outcomes of that care; these are the core features of healthcare quality. The Institute for Healthcare Improvement (IHI) describes the need for healthcare systems to focus on three targets referred to as the Triple Aim¹: (1) improve the patient experience; (2) improve the health of a population; and, (3) reduce (or at least control) the cost of healthcare for each person.

The Triple Aim is an integrated and interrelated health system design strategy where care delivered in the community, communication between sectors, and continuity of care drive results. The Triple Aim promotes five high-level design strategies: (1) involve individuals and families when designing care models; (2) redesign primary healthcare services and structures; (3) improve population health management (which includes addressing the social determinants of health); (4) control cost per capita; and, (5) support system integration and execution.¹ In this context, inter-healthcare sector relationships are not merely encouraged; they are required to achieve the Triple Aim by design. Achieving the Triple Aim requires that healthcare decision-makers and providers share a common understanding of quality and how to manage it.

The concept of healthcare quality is better understood by describing its 'dimensions' as was originally done by the Institute of Medicine (IOM).² The IOM's quality dimensions have been adapted and incorporated into the *Alberta Quality Matrix for Health* (Appendix I).³ The six dimensions are acceptability, accessibility, appropriateness, effectiveness, efficiency, and safety. These dimensions can be used to describe and evaluate healthcare practices.

Members of Alberta's Health Quality Networkⁱ saw the need for a common understanding and description of how to lead and manage quality and safety in the healthcare system. In collaboration with the HQCA's Health Quality Network member organizations, a working group was formed to complete this work (Appendix II).

Although safety is among the quality dimensions described in the Alberta Quality Matrix for Health, the working group members saw a need to isolate safety as a discrete construct. This has been done by high-hazard, non-healthcare industries, which use unique, well-described, safety management systems based on the science of human factors.⁴ In these industries, safety management systems are used to manage risk of harm, including death, ill health, and injury; damage to property or environment; and, loss of production, assets, or reputation. In healthcare, the major goal of safety management is to mitigate the risk of patients being harmed.

Quality management concepts such as efficiency, reliability, and waste reduction are well described in non-healthcare industries. Application of these concepts to healthcare could be described as ensuring the value of services provided to patients is optimal, including that of the direct experience patients have with healthcare providers.

Conceptually, there is overlap between functional aspects of safety management and quality management. For example, common to both is the use of measurement and evaluation, the need to prioritize and understand improvement opportunities (quality issues or safety hazards), developing and testing improvement ideas and

ⁱ The Health Quality Network is a voluntary group of Alberta healthcare delivery organizations, universities, government agencies, professional colleges and associations, the HQCA's Patient/Family Safety Advisory Panel, and is chaired by the HQCA's CEO.

managing system change. This document describes each of the elements of the quality and safety management framework; where there are nuanced differences between quality and safety management elements, a description of these differences is included.

The framework is made up of three components: two models that highlight the important conceptual elements required to effectively manage healthcare quality and safety, and a foundational set of enablers. The two models represent the design of systems to provide optimal care and the appropriate response to an adverse event. These elements emerged from a search of both published healthcare literature and grey literature. After developing an outline for the models and then for the enablers, the working group consulted with a broad group of stakeholders before seeking external expert review from healthcare and non-healthcare quality and safety management experts.



Introduction

Three decades ago, Arthur Jones, a human resources expert at Proctor & Gamble, stated that “All organizations are perfectly designed to get the results they get.”⁵ The maxim was then restated by Paul Batalden as “Every system is perfectly designed to get the results that it gets.”⁶ Jones followed his first statement with a second: “To get better results, you need to improve the design of the organization.” The corollary of this theory is that if healthcare systems want to achieve the IHI’s Triple Aim, then the people responsible for them must be intentional about their design of healthcare delivery.

The **System Design Model** is one of the HQSMF’s two models (Figure 1 and Table 1) and reflects the goal of *proactively managing* healthcare to optimize patient outcomes. These outcomes, together with the processes undertaken to deliver the care, and the structures that allow or support care delivery, were proposed by Donabedian as the three elements of healthcare delivery that reflect the quality of care.⁷ Thus, when considering the design of healthcare delivery improvements, it is useful to consider both structure and process elements. Often improvements in quality are considered to be synonymous with process control and improvement, which had its origins in the concept of statistical process control, one of the many contributions of Shewart and Deming to the science of quality improvement and management. Structural improvements, however, must also be considered in the management of quality and safety.

Despite the best design of quality and safety structures and processes, and the best intentions of healthcare providers, some patients receive inappropriate or inadequate healthcare, which contributes to poor outcomes. The management of such situations is an important component of healthcare safety management. Based on that premise, the **Harm Response Model** (Figure 2 and Table 1) is the second construct of the HQSMF. This model proposes a *reactive approach* for managing instances of patient harm.ⁱⁱ The three aims of the model are to: (1) minimize ‘second harm’⁸ to patients and their families by providing support and disclosure, including an appropriate apology; (2) support and assess healthcare providers fairly; and (3) learn from these events, and redesign and implement system improvements.

ⁱⁱ Harm is defined as a situation where patients are injured primarily as a result of either the healthcare they received or did not receive, but should have. It is acknowledged that in addition to suffering physical harm, people can suffer psychological harm when they are not treated in a respectful, dignified or culturally sensitive manner. The response to harm described in this framework primarily considers the situation of a person suffering serious physical harm but health system providers, managers and executives could follow the same approach in situations where someone has suffered psychological harm.

Managing implies 'doing'. Accordingly, the two models that form the basis of the HQSMF use verbs that name process elements required for managing the framework's major concepts (Figure 1, Figure 2 and Table 1). For example, the System Design Model requires people to "identify issues, hazards and opportunities," while the Immediate Management phase of the Harm Response Model is made up of seven clearly defined steps to be followed. The framework was designed to be functional and pragmatic rather than abstract.

The third component of the HQSMF is a set of six '**enablers**' (Figure 1, Figure 2 and Table 1) that represent the core structural elements that healthcare systems require to effectively manage quality and safety. The enablers are common to both the System Design Model and the Harm Response Model.

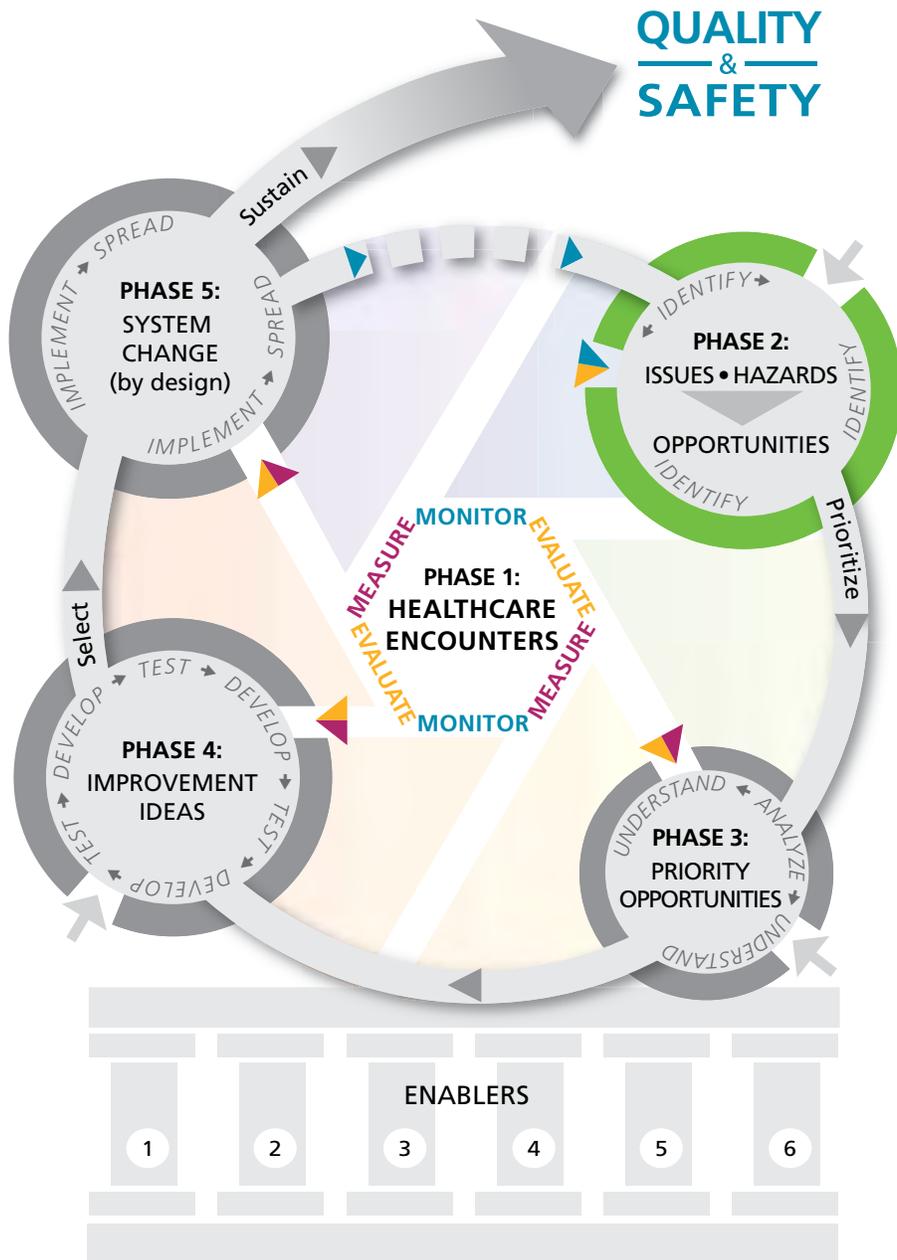
Planning and delivering healthcare is complex, involving many 'layers' of accountability. These layers may be more recognizable in some settings (e.g., a hospital) than others (e.g., a community-based doctor's office). Describing an organizational hierarchy helps to bring clarity to the question of '*who*' is accountable for quality and safety management, and thus for completing the tasks within each phase of the models. The IHI describes five layers in a 'high-performance management system',⁹ a concept similar to the System Design Model. The first two layers – patients and families and frontline staff/frontline leader (FL) – represent the healthcare encounter, where care is delivered. The other three layers reflect an organizational hierarchy: Tier 1 (T1) – unit manager; Tier 2 (T2) – department manager or director; and Tier 3 (T3) – executives. Governance could be included in Tier 3 or represented by an additional tier. The three tiers, from T1 to T3, roughly correspond to micro-, meso- and macrosystem-level accountability, respectively. Clinical microsystems are small groups of people who regularly work together to provide care to discrete subpopulations of patients.¹⁰ These microsystems are 'the essential building blocks' of the healthcare system. Many patients require services from multiple microsystems to receive the comprehensive care they need for their health problem. A mesosystem is a collection of interrelated microsystems that provide care to a shared population of patients.¹¹ A macrosystem is the larger healthcare system whose job is operating and coordinating its meso- and microsystems.⁹

Effective, proactive quality and safety management (System Design Model) requires coordinated monitoring, planning, execution and accountability, both within and among the management hierarchy, from FL to T3. Leading change at all levels is important; however, T3 leadership in particular is critical. Similarly, effective, reactive safety management requires clear accountability from FL to T3 for coordinating and conducting the five phases of the Harm Response Model. The HQSMF should be used by all organizational levels to ensure coordinated and integrated quality and safety management in the healthcare system.

Healthcare providers, managers, directors and executives have to partner with patients and public stakeholders to co-design and co-produce healthcare. This is a key HQSMF guiding principle because it is critical that patients and the public are considered full partners not only in the delivery of their own care but also in system design; this includes goal setting, measuring, prioritizing, improving and implementing/spreading of interventions.

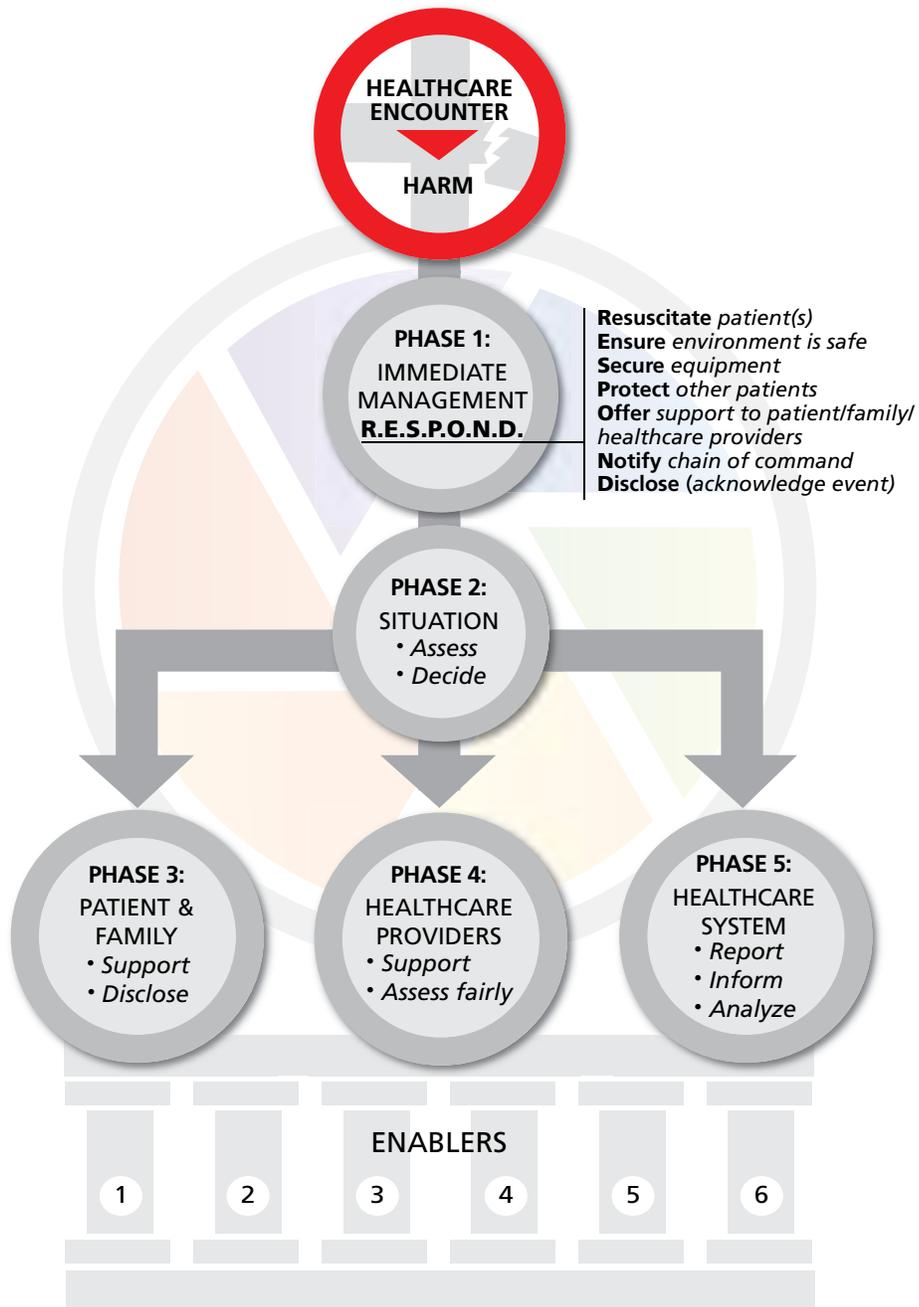
If a patient suffers harm then they and their family should be the main focus of the response by healthcare providers and organizations.

Figure 1: SYSTEM DESIGN MODEL



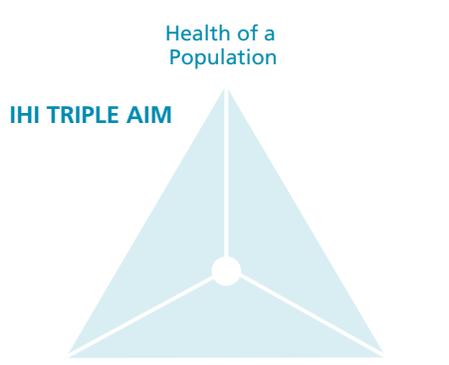
1. Leadership 2. Followership 3. Governance and accountability structure 4. Capacity and capability 5. Supportive information systems 6. Values and guiding principles

Figure 2: HARM RESPONSE MODEL



1. Leadership 2. Followership 3. Governance and accountability structure 4. Capacity and capability 5. Supportive information systems 6. Values and guiding principles

Table 1: HEALTHCARE QUALITY AND SAFETY MANAGEMENT FRAMEWORK

	Construct	Concept/Phase	Action Elements
<p>1. Positively influence one or more quality dimensionsⁱⁱⁱ</p> <ul style="list-style-type: none"> ▪ Acceptability ▪ Accessibility ▪ Appropriateness ▪ Effectiveness ▪ Efficiency ▪ Safety <p>So as to:</p> <ul style="list-style-type: none"> ▪ Improve patient experience ▪ Improve health of a population ▪ Reduce cost per capita 	<p>SYSTEM DESIGN</p>	Healthcare Encounters	<i>Measure, monitor, evaluate</i>
		<p>Issues / Hazards ↓ ↓ Opportunities</p>	<p><i>Identify:</i> <i>Issues/Hazards → Opportunities</i> → <i>Internal inputs</i> → <i>External inputs</i> (<i>monitor/evaluate</i>)</p> <hr/> <p><i>Prioritize</i></p>
		Priority Opportunities	<i>Analyze → understand</i> <i>(measure/evaluate)</i>
		Improvement Ideas	<p><i>Develop ideas</i> → <i>Internal sources</i> → <i>External sources</i></p>
			<i>Test ideas (measure/evaluate)</i>
			<i>Select the best solutions</i>
		System Change (by design)	<i>Implement solutions</i>
<i>Spread solutions</i> <i>(measure/evaluate)</i>			
<i>Sustain improvements</i>			
<p>IHI TRIPLE AIM</p> 	<p>HARM RESPONSE</p>	Immediate Management	<p>Resuscitate patient(s) Ensure environment is safe Secure equipment Protect other patients Offer support to patient/family/healthcare providers Notify chain of command Disclose (acknowledge event)</p>
		Situation Assessment	<i>Assess → decide</i>
		Patient(s) and Family	<i>Support</i>
			<i>Disclose</i>
		Healthcare Providers	<p><i>Support</i> <i>Assess fairly</i></p>
		Healthcare System	<i>Report</i>
			<i>Inform</i>
<i>Analyze</i>			

ENABLERS

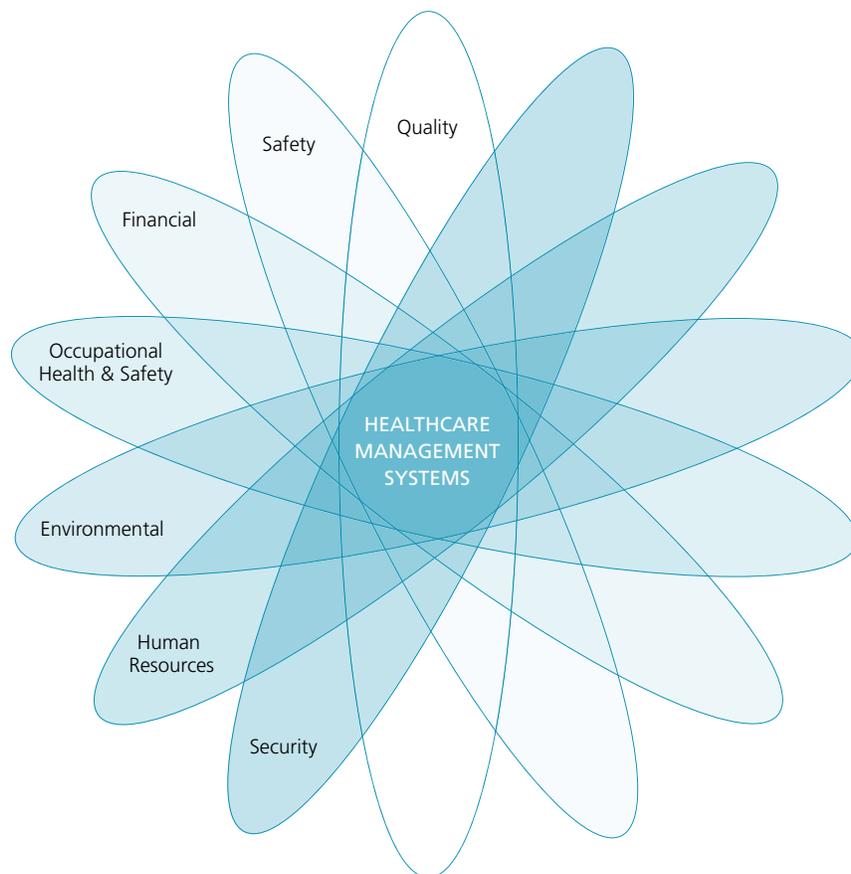
- Leadership
- Followership
- Governance and accountability structure
- Capacity and capability
- Supportive information systems
- Values and guiding principles

ⁱⁱⁱ Six quality dimensions as defined in the Alberta Quality Matrix for Health³ – see Appendix I.

The HQSMF describes *'what is required'* (enablers) and *'what to do'* (the models), and links these to the *'why'* (Table 1). It does not describe the *'how'*. Sample scenarios have been developed to show *'how'* to apply the safety and quality management concepts outlined in the HQSMF; these cases can be found at: www.hqca.ca.

Finally, the premise that managing quality and safety is the first and most important responsibility of healthcare systems is reasonable; however, several other important parts of the system need to be well managed, including financial, occupational health and safety, human resources, environmental, and security considerations (Figure 3).^{iv} These overlap with quality and safety management.

Figure 3: OVERLAPPING AND INTERACTING HEALTHCARE MANAGEMENT SYSTEMS



^{iv} Adapted from the International Civil Aviation Organization (ICAO), Safety Management Manual, 3rd Edition; 2013.⁴

System Design Model

The System Design (SD) Model (Figure 1) features high-level conceptual process elements that are common to both quality and safety management. An important pre-step for effective quality and safety management is for a microsystem, mesosystem, and macrosystem to explicitly specify and ideally align their goals. The six quality dimensions should underlie the quality and safety management cycle.⁵ The SD Model shows the relationship between five phases (bold text) and the action, or process elements (italics) related to the phase. The five phases and corresponding process elements include:

Phase 1:	Healthcare Encounters	<i>measure/monitor/evaluate</i>
Phase 2:	Issues/Hazards → Opportunities	<i>identify → prioritize</i>
Phase 3:	Priority Opportunities	<i>analyze → understand</i>
Phase 4:	Improvement Ideas	<i>develop → test and select</i>
Phase 5:	System Change (by design)	<i>implement → spread → sustain</i>

The SD Model is continuous and iterative, which makes it similar to other continuous improvement models; for example, the Model for Improvement (MFI) and its Plan-Do-Study-Act (PDSA) cycle.¹²

The three MFI questions are applicable to the SD Model (Table 2). The SD Model expands the quality improvement concepts of the MFI into a management model that links action elements to required enablers, and includes other management functions in addition to improvement. The SD Model's unique features include:

- Starting with monitoring and evaluation to initially identify candidate issues or hazards; the MFI assumes the issue needing improvement has already been identified, thus it begins at the phase of developing and testing improvement ideas.
- Having a deliberate prioritization step and an analysis step to ensure that limited resources are applied to the most important issues, and that additional understanding is gained about candidate issues/hazards before moving into an improvement phase.
- Having a deliberate phase of system change recognizing that this requires detailed attention so that positive change is sustained; the MFI includes the 'Act' step of the PDSA cycle, which implies that a plan for implementation, spread, and sustaining change is required, but it isn't stated explicitly.
- Recognizing that managing requires the need for monitoring, measurement, and evaluation at multiple phases of the management cycle rather than as a single step in an improvement cycle.

The MFI's three important questions keep users focused on the improvement process. These same questions should be applied at various times in the 'life cycle' of the SD Model, as outlined in Table 2.

Table 2: APPLYING THE MODEL FOR IMPROVEMENT QUESTIONS TO THE SYSTEM DESIGN MODEL¹¹

System Design (SD) Model Phases where the MFI questions should be used	Model for Improvement (MFI) Questions
Phase 0: Define and use goals, values and guiding principles to guide decision-making Phase 4: Improvement ideas – develop and test	What are we trying to accomplish?
Phase 4: Improvement ideas – develop and test	What changes can we make that will result in improvement?
Phase 4: Improvement ideas – develop and test Phase 5: System change	How will we know that a change is an improvement?

Because the SD Model includes phases that precede the improvement phase, a fourth question has been added: *“How do we know an issue or a hazard, and its solution(s), is high priority?”* This question, about prioritizing, is relevant at Phase 2 (Issues/Hazards → Opportunities – identify and prioritize) of the SD Model. It is also relevant at Phase 4 (Improvement ideas – develop → test and select) of the SD Model when the focus is selecting solutions. Many potential improvement ideas may be developed and tested to solve a prioritized opportunity, but only some of these will actually create the value intended once spread at a system level; hence, re-asking the question in Phase 4 is required.

Phase 0: Goals, Values and Guiding Principles

DEFINE AND USE TO INFLUENCE DECISION-MAKING

Before starting to establish a quality and safety management system, it is important that leaders of an organizational macrosystem, its microsystems and mesosystems clarify their goals. Goals should be focused on patient populations and on the six quality dimensions,⁵ which relate to, and overlap with, the IHI Triple Aim.¹ A well-defined set of goals helps micro-, meso-, and macrosystems accomplish a crucial management function of prioritizing improvement efforts, thereby guiding decision-making about resource allocation. Asking “What are we trying to accomplish?”¹¹ will help to keep goals focused.

Clearly enunciated, widely understood values will clarify and justify difficult decisions. Similarly, a set of principles that guide quality and safety decision-making at all levels of a healthcare organization are important guideposts.

Phase 1: Healthcare Encounters

MEASURE, MONITOR, EVALUATE

In the System Design (SD) Model, quality and safety management begins with continuous monitoring of patient outcomes that are the result of healthcare delivered during *healthcare encounters*, and that are identified as important to patients and to the health system (as defined by its goals). Outcomes can be classified as one of three types: (1) clinical (e.g., mortality, morbidity, complications); (2) functional (e.g., quality of life, functional status, symptoms); or (3) patient experience (experience of care, perception of benefit).^{13, v} Monitoring the key processes and structural elements of the healthcare system (e.g., the number of workers, amount of equipment, number of treatment spaces, etc.) that most contribute (sometimes referred to as drivers) to the outcomes of interest is also essential.



Measurement is an important quality and safety management function in all five phases of the SD Model. For measurement to play an effective role in managing quality and safety, healthcare leaders have to understand what they are trying to accomplish for a given patient population (which dimensions of quality they are targeting), the processes by which healthcare encounter data are collected, validated, stored and analyzed, and by whom.

Monitoring is often quantitative and is best shown in a statistical process control chart that allows data variation to be classified as common cause (random variation) or special cause (non-random variation).¹⁴ Monitoring may also be qualitative in nature and result from periodic evaluations of healthcare delivery. Evaluation of a healthcare encounter could arise as the result of an adverse event, close call or complaint. It could also involve surveys or focus groups that capture people's experiences with their healthcare system. Some healthcare systems perform regular audits/evaluations (e.g., accreditation) of the care that is provided to patients.

In the SD Model distinct colours are given to measure (fuchsia), monitor (blue) and evaluate (gold). To show how these action elements are important in all phases of the model, coloured arrowheads (in some cases bicoloured arrowheads) are shown as 'inputs' into each of the other four model phases.

Data quality is an essential component of Phase 1: healthcare encounters. Data used for decision-making should meet the following seven quality criteria, as proposed by the International Civil Aviation Organization (ICAO): (1) validity; (2) completeness; (3) consistency; (4) accessibility; (5) timeliness; (6) security; and, (7) accuracy.⁴

^v These outcomes are adapted from the Clinical Value Compass that includes cost as an outcome.¹³ Cost has not been included here based on the premise that it could be considered an input and not an outcome for an individual patient.

Phase 2: Issues/Hazards → Opportunities

IDENTIFY

Safety management is concerned with identifying hazards that pose a danger to patients where the probability of patients suffering harm is moderate to high.^{vi} Quality and safety management focuses on issues that affect patient experience (acceptability, accessibility, safety) and the effectiveness, efficiency, and appropriateness of healthcare delivery and its effect on patient outcomes. Health systems that systematically pay attention to quality and safety management *identify* issues and hazards through the regular *monitoring* of key (patient) outcome, process and structure indicators. Monitoring may also involve measurement and evaluation of previous and ongoing work to improve healthcare design and delivery. If results of those improvement efforts do not meet set goals, these findings can identify additional improvement opportunities.



All of these inputs into the process of identifying issues and hazards can be regarded as *internal*. In the SD Model these inputs are represented by blue arrowheads [▶] (monitoring). In this context the blue arrow refers to monitoring previous attempts at improvement that may not have reached stated goals. The blue/gold arrowheads [▶] (monitoring/evaluation) represent key structure, process, and outcome indicators. Indicators can flag an important issue or hazard when there is special cause variation, or when the mean, median or a percentile rank result (e.g., 90th percentile) are incongruent with the system's stated goals.

Other examples of internal inputs include:

- an *evaluation* of safety reports (e.g., observed hazards, errors, adverse events, close calls) submitted to a health organization by individuals who work for it or an affiliate organization, or by some other type of stakeholder
- ad hoc or routine program or standards *evaluations* (e.g., accreditation or standards compliance)
- analyses of adverse events
- patient/family concerns/complaints reporting and analysis system

Inputs into this process of identification may also be external (represented by the gray arrow [↘] in the model). Examples of external inputs include reports or research studies from other healthcare organizations, regulatory authorities or professional associations, published in either peer-reviewed or grey literature. Collectively, internal and external inputs highlight *opportunities* for the system to improve its healthcare delivery performance.

PRIORITIZE

Given the many opportunities to improve, healthcare organizations and units within those organizations must be able to select a small number of those opportunities on which to focus if they want to move effectively through the quality and safety management cycle. When organizations/units fail to prioritize effectively and by default decide that 'most things are important', then often there is little actual effective improvement of any issue or hazard. Successful prioritization usually involves making difficult choices

^{vi} ICAO defines a hazard as a condition or an object with the potential to cause death, injuries to personnel, damage to equipment or structures, loss of material or reduction of the ability to perform a prescribed function.⁴

based on an organization's values and principles, its pre-established goals, and the evidence of current performance reflected by measured outcomes. In a safety management context, hazard prioritization involves decisions based primarily upon hazard assessment balanced against productivity, and the cost of mitigating a hazard's risk of causing harm.

Decisions about quality issues are often based on concepts like controlling variability, cost effectiveness, removing non-value-added activities that free up limited resources, and/or reduce the need for resources. The likelihood of legal liability can be a safety or a quality management consideration. Prioritization decisions should incorporate stakeholders' perspectives, in particular those of patients and a representative sample of the public that a healthcare system serves.

Asking, "How do we know this issue or hazard is high priority?" will help units and organizations make reasonable prioritization decisions.

Quality Management

Procedures for prioritizing quality issues should be based on pre-stated goals and an assessment of the extent to which an identified issue contributes to achieving or not achieving those goals. Pareto charts^{vii} show cumulative percentages and can be useful for presenting the relative contribution of many factors to the outcome of interest, highlighting those that most contribute (and are therefore worthy of prioritizing). For example, assume the goal of an organization is to reduce hospital inpatient bed occupancy rates so as to reduce wait times for admitted patients in its emergency department. Prioritizing analysis efforts on the hospital inpatient services that have the largest number of beds may result in the greatest impact on the stated goal if they also have inefficient bed use practices. A Pareto chart that highlights these opportunities is shown in Figure 9, Appendix III.

If efficiency (i.e., cost efficiency) is a stated goal, then expenditures may be an important consideration when prioritizing. Demonstration of variation in any quality metric is often used as a method for prioritizing based on the philosophy that unexplained variation often represents suboptimal quality and therefore an improvement opportunity. Other methods for prioritizing that use a more qualitative approach can be used. This might involve obtaining multi-stakeholder feedback, such as formal multi-vote approaches that establish predefined criteria to judge the estimated impact of candidate issues/hazards for their impact on quality and safety.¹⁶

Safety Management

Risk is the possibility or probability of something unwanted happening. ICAO defines safety risk as the projected likelihood and severity of the consequence or outcomes from an existing hazard or situation.⁴ The process of prioritizing identified hazards involves estimating:

1. The probability (likelihood/frequency) of occurrence (a hazard resulting in an adverse outcome). This estimate could be based on past organizational experience, other organizations' experience, published reports or expert advice. A safety probability table may be helpful to categorize likelihood of occurrence (Table 3, Appendix III).
2. The severity of possible consequences related to a hazard. A safety severity table, similar to the probability table, can be used to summarize the level or degree of severity (Table 4, Appendix III).

A hazard's risk probability and severity can be combined into a safety risk assessment matrix that identifies levels of 'safety risk' assessment that an organization deems unacceptable, tolerable or acceptable (Table 5, Appendix III).⁴ In keeping with the principle of patient/public engagement, healthcare decision-makers

should incorporate patients' and the public's perspective when establishing what criteria are used to make these assessments. The decision-making process and its outcome should be transparent to a healthcare system's stakeholders. Hazards with a safety risk assessment in the unacceptable category are high priority and need to be managed using the other phases of the SD Model. Hazards in the tolerable range may similarly require some safety risk mitigation strategies to be developed and managed using the model, but may be less urgent for an organization to address.

A related approach, Failure Modes and Effects Analysis (FMEA) developed from reliability engineering, can be used to proactively and systematically study possible ways that processes (or structures) can fail, the likelihood of failure and the possible impact.¹⁵ FMEA can be used at this stage of prioritization or in the analysis/understanding of Priority Opportunities (Phase 3) to gain additional insight into a specific hazard or hazardous activity.

Phase 3: Priority Opportunities

ANALYZE → UNDERSTAND

As a health system moves into the phase of working on prioritized opportunities, there is a need to further understand what the important contributing factors are because they will be the focus of improvement in the next phase. This need for more in-depth understanding usually involves additional analysis. Quality management and safety management will use different tools for this analysis.



Quality Management

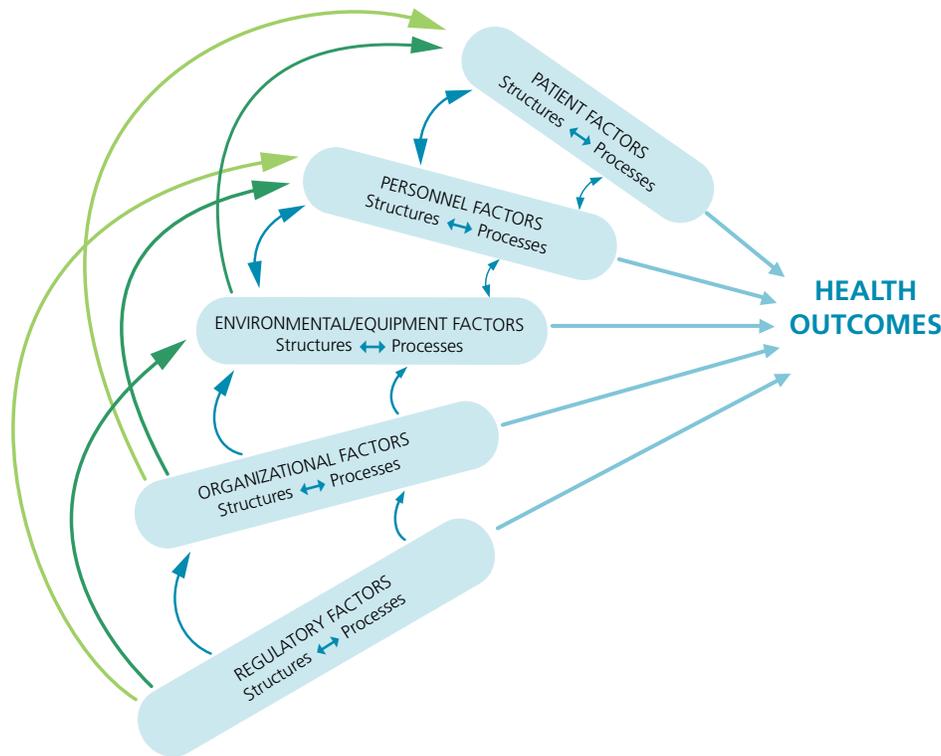
Where the opportunity for improvement is related to how patients move from one microsystem to another or the actual process of care delivery, a flow, process or value stream map is often required to better understand what is being done to or for groups of patients. Completing this detailed analysis will increase the likelihood that the correct issues will be addressed. Measurement and evaluation may be required at this stage to better understand the relative importance of factors contributing to the identified issue (gold/fuchsia arrowhead [▶]). Pareto charts can be helpful, as can statistical modelling, to further understand the relative contribution of several factors to the prioritized issue. This type of analysis can increase the likelihood that improvement efforts will focus on the most important factors and hence increase the opportunity for measurable improvement at the next phase.

Safety Management

An analysis process is a component of an effective risk management system. When a safety risk assessment identifies that the risk from a hazard is unacceptable or tolerable with risk mitigation strategies, then a more formal human factors analysis can provide additional insight about how best to plan the mitigation strategies. A model that identifies the various types of factors (and their interplay) that contribute to patient outcomes is helpful for understanding the complexity of healthcare delivery. The Winnipeg Model is one such model.¹⁷ It is an adaptation of Reason's Organizational Accident Model¹⁸ (often referred to as the 'Swiss cheese' model) and Helmreich's consideration of the human factors aspects of the Air Ontario crash at Dryden, Ontario.¹⁹

^{vii} Pareto charts are based on the Pareto principle – the observation that in many systems a small number of factors contribute disproportionately to the outcome of interest. Displaying data as a cumulative distribution can highlight the difference between the vital few and the trivial many.

Figure 4: AN ADAPTATION OF THE WINNIPEG MODEL, showing the five system-level components^{viii} and their interactions that affect health outcomes



The Winnipeg Model also incorporates Donabedian's quality triad of structure, process and outcome.⁷ The Winnipeg Model identifies five system levels and considers the structures and processes of each level to characterize factors and hazards that influence patient outcomes (Figure 4).²⁰ The five levels of the Winnipeg Model are: (1) patient; (2) personnel; (3) environmental and equipment; (4) organizational; and, (5) regulatory. The arrows in Figure 4 highlight how each system level can influence other system levels in a complex interplay of factors that ultimately can impact the outcome for a patient. This perspective makes it more likely to consider system factors and their effects on human behaviours, decisions and actions. Ultimately, this important human factors perspective makes it more likely that recommendations for mitigating the risks associated with identified hazards are comprehensive and effective.

Another approach increasingly being used in high-risk industries for improving understanding and proactively managing hazards is critical control management using the BowTie model (Figure 7, Appendix III).^{21,22} The BowTie model guides users to identify hazard-specific threats and consequences, where threats are defined as a possible direct cause of a state where control over a hazard has been lost, resulting in an unwanted event that could have potentially serious or catastrophic consequences, such as loss of life. These unwanted events are designated 'top events' in the BowTie methodology. A top event – the administration of an incorrect drug, for example – might lead to a catastrophic consequence, such as the death of a patient.

^{viii} Adapted from Davies, JM.¹⁷

In the BowTie method, hazards are defined as physical energy sources (e.g., electrocautery), materials, conditions or anything that has the potential to cause either one, or a combination, of:

- Harm, including death, ill health, and injury
- Damage to property or environment
- Production losses
- Loss of assets
- Loss of reputation
- Increased liabilities

Examples of healthcare hazards are an infectious disease, concentrated electrolyte solutions or the need to transport critically ill patients between facilities. A single hazard can result in a top event as the result of failing to adequately control one or more different threats. These threats may need to be managed differently, with different sets of preventive controls to stop the top event from occurring. To illustrate: a toxic chemical is a hazard, and the top event would be a spillage of the chemical – the point at which control of the hazard is lost. Threats represent the ways in which control of the hazard could be lost. For a toxic chemical, the threats that could cause the spillage are corrosion of the container, incorrect handling procedures, and failure of the valve delivery system. Each of the threat pathways leading to the spillage needs to be managed by different sets of preventive controls to stop the spillage occurring.

A BowTie model provides a clear visualization of two major concepts associated with any particular hazard by illustrating: (1) structures and processes designed to reduce the probability of threats resulting in a top event – these are referred to as preventive controls in the BowTie model; and, (2) structures or processes designed to reduce the likelihood that a top event, once it occurs, will result in serious, or catastrophic consequences. These are referred to as recovery controls in the BowTie model.

Both preventive and recovery controls are subject to escalation factors. Escalation factors can compromise or reduce the effectiveness of these controls. For example, for controls that are procedural, typical escalation factors include non-compliance with the procedure, poor training, poor documentation, and ambiguous procedures.

Consequently, escalation controls need to be put in place to prevent escalation factors from reducing the effectiveness of the primary preventive and recovery controls. To illustrate, if the primary control is a standard operating procedure, an escalation factor would be non-compliance with that procedure. The escalation controls for this may be improved training, clearer documentation of the procedure, improved ergonomics of a piece of equipment – or all three.

In a single diagram, a BowTie analysis allows a visual representation of hazards, top events, potential consequences, the types of threats presented by each hazard, preventive controls for each threat pathway to the top event, recovery controls following the occurrence of the top event, as well as escalation factors and escalation controls for both preventive and recovery controls (Appendix III). Probability estimates of preventive and/or recovery controls failing allows an assessment of the likelihood that events could unfold that would result in harm. Statistical analysis of adverse events that have already occurred can provide objective empirical measures of the effectiveness of the controls involved.

Once a hazard is better understood following this type of control analysis, strategies can be developed and tested to determine which controls appear to be the most important, and to develop ideas to improve the

effectiveness and reliability of controls; this would correspond to Phase 4 of the System Design Model. The success of implementing interventions designed to improve the effectiveness of critical controls (corresponding to Phase 5 of the System Design Model) can be empirically assessed by the ongoing monitoring and evaluation of these controls.

In a safety management system, the processes of proactive safety management and reactive investigation should be fully integrated with each other, as both consider the same sets of controls, one before the event and one after.

For both safety and quality management, the use of evidence to forecast the impact of current practice into the future can be beneficial (i.e., the risk of doing nothing). Quantifying decisions to do nothing at this stage can help teams further prioritize issues, hazards and opportunities, relative to how resolution may affect the achievement of goals.

Phase 4: Improvement Ideas

System improvements that are intended to positively influence outcomes for populations of patients or the public can be targeted at either the structures that support healthcare delivery, or the processes used to deliver care. Although there is overlap between quality management and safety management in their approaches for improving systems, some distinctions can be made. Quality management is more often process focused; indeed, the term ‘process improvement’ is often considered synonymous with ‘quality improvement’. In contrast, safety management, with its analysis and understanding grounded in human factors science, is more often focused on assessing processes to make structural improvement. Human factors studies (e.g., task analysis) analyze the steps within a process (including manual and mental activities), the structures that support these processes and how they affect human performance (Figure 4), and then identify opportunities to improve performance (including error reduction/mitigation strategies) through better-designed equipment, environments and human interactions. A study of human factors should be considered as one approach for improving the delivery of care.^{ix}



DEVELOP

“What changes can we make that will result in improvement?”¹¹ The MFI’s second question, is the emphasis of this part of Phase 4. Improvement often is not an ideas problem, however. Improvement, like innovation, is hampered not by an organization’s lack of ideas on what to do or how to solve a problem, “but rather a lack of noticing the good ideas already there.”²³ Important improvement ideas are often generated by people who work within a unit or organization and by people who have experienced the care delivery issue of concern. Leaders should recognize that the talented people in their organizations can be a robust source of improvement ideas. This recognition can often be difficult given a natural human bias against new and creative ideas when decision-makers are faced with even small amounts of uncertainty of success.²⁴ Creating internal markets for idea tracking, and sharing and creating environments where frontline staff are allowed

^{ix} Consider, for example, the design of medication storage and administration. How drugs are stored and labelled can influence the probability of errors being made. A human factors design would incorporate structural methods using elements like colors, lettering on labels, and separating similar sounding high hazard medications, as well as the actual layout and organization of the storage areas themselves.

to dedicate a portion of their work time to supporting testing, can be an effective means to democratize recognition and to foster enhanced creativity. To do this effectively, organizations are encouraged to regularly make the time for employees to participate in the quality improvement process. This is often referred to as ‘creating slack’, allowing for active participation in the initial testing and later, the dissemination of innovation.²⁴ Some teams make this a requirement of the workplace, rather than a voluntary ask.

Organizations should consider experienced patients/family members (and the public that it serves) as excellent sources of improvement ideas. When it is truly appreciated that the patient/client/consumer is at the centre of every healthcare encounter, it becomes more obvious that real design is co-design or co-production.²⁵ Additionally, other improvement teams may be a valuable source of improvement ideas, especially if a local team is participating in a collaborative improvement project as part of a larger community-of-practice group.

Sources of improvement ideas can also be found external to an organization (represented by the grey arrow [↖] in Phase 4 – Improvement Ideas in Figure 1). Published, peer-reviewed literature and grey literature should be considered. Teams should not feel their ideas must be novel or unique. Often priority issues have been solved, or attempted to be solved, elsewhere in the world. Accreditation standards and best practices from other organizations are useful sources of information. Accreditation Canada maintains a database of best practices of client organizations to help spread these ideas across organizations.²⁶ Even though local context and constraints may be different (e.g., different political or governing rules) key learning ‘from away’ can often add tremendous value locally.

Initial improvement team discussions should be forward looking, and facilitators should minimize the “we’ve tried that before” perspective that can dampen creative thought. Thinking of potential solutions allows a team to project or forecast what effect it thinks can be achieved locally; it does not need to be an academic process. Indeed, this idea generation should be grounded in the reality of the frontline. Experienced frontline workers can often make an informed guess of future outcomes. When such best-guess efforts are done independently and then collated, a ‘wisdom of crowds’ approach can be reasonably accurate when compared with more data-driven approaches.²⁷ This can also speed up the quality improvement process.

TEST

Teams are motivated to solve problems, so there is a tendency to jump to solutions (move directly from Phase 1 to Phase 4 in the System Design Model and from Plan to Act in the PDSA cycle) before adequate testing is completed. Much like the prioritization process that is required in Phase 2 of this model, a rigorous prioritization process for selecting solutions to implement should begin by testing many potential solutions to avoid pre-judging the outcome. Staying focused on the issue at hand can be helped by team members re-asking the MFI’s first question, “What are we trying to accomplish?”¹¹ Testing many solutions at once, knowing that not all will work in helping teams achieve their goals, requires a culture that permits trial and error. Allowing for this encourages teams to be vested in the process rather than vested in a solution prematurely.

A measurement/evaluation-driven approach (as represented by the gold/fuchsia arrowhead [▶] in the SD Model) should be used to assess improvement ideas. Asking the MFI’s third question, “How will we know that a change is an improvement?”¹¹ will remind improvement teams to incorporate measurement and evaluation into this phase. If local data are not readily available, data routinely captured as part of day-to-day healthcare encounters and stored in organizational information systems should be explored. Clinical documentation (electronic or paper based) may be an additional source of information that could be used

for analysis. Chart reviews, though valuable, can be time-consuming and therefore less cost-effective than other data-collection strategies. Sometimes, local, short-term data-collection strategies (either quantitative or qualitative data) can be used to judge the effectiveness of possible solutions. Measurement is a key part of testing improvement ideas and is often iterative until the evidence is relatively clear that tests of change are successful under several conditions.

If a potential solution comes 'from away', (e.g., from a peer-reviewed publication), a two-pass approach should be applied: on first pass, assume similar gains can be achieved locally as if culture, process, and people were the same; on second pass, adjust or take into account the local context, culture, people, and existing process. This two-pass approach can better establish realistic forecasts of improvement gains.

SELECT

From many potential solutions that are rigorously tested, a short list of proven, value-creating solutions can be derived. Although teams tend to want to choose only one final solution at their own clinical microsystem level, if the team doing the local testing is doing so on behalf of a network of similar clinical microsystems, it is important to acknowledge that differences may exist between microsystems, and therefore teams shortlisting a few select solutions is recommended. Final selection can then be based on a balance of local priorities, constraints, and goals relative to organizational priorities, constraints, and goals.

Then, like the gardener who plants many seeds (ideas), or who creates fertile ground knowing that many seeds find their way into the soil, it is possible that many seeds will blossom. Leadership is then required to selectively prune the garden, allowing the highest-value crop(s) to emerge. This concept of 'how to let 999 flowers die' in order to find the highest-value flower(s) is the final step before scaling solutions across a system.²⁸ Asking the question, "How do we know this solution creates important value for patients and is therefore a high priority?" can help guide the final selection process. Value in this context can be assessed by a mix of local staff, patient, and community perspectives on how to achieve defined quality improvement goals.

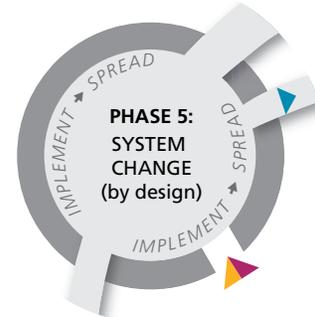
Having selected a few high-value solutions, and having created a filter that can be applied in context to local unit cultures, patient population, and community inputs, organizations are in a position to fully implement, and then spread/scale solutions.

Some improvement work will be focused within a single clinical microsystem, so the idea of selecting solutions that can then be spread and scaled may not be top of mind. A team that has developed local improvements that positively impact patient care in one microsystem, however, should consider how to share that information with other, similar microsystems so more patients can benefit.

Phase 5: System Change (by design)

IMPLEMENT

Improvement ideas can fail at this stage without three components in place: (1) a project management plan; (2) a change management plan; and (3) a plan for ongoing measurement with feedback loops that allow for further iteration. Collectively these components ensure a focus on results-based execution. All of this needs to be considered together within a healthcare provider's ability to apply key organizational design principles. This is as true for local implementation as it is for spreading across multiple system layers. Commitment to make the 'new way the new normal' is needed.



Being fully committed to this 'new way' of practising requires first and foremost an understanding of human behaviour. There are many methods, models, and tools to support change management, such as ADKAR (Awareness – Desire – Knowledge – Ability – Reinforcement) from ProSCI,²⁹ IHI's Framework for Going to Full Scale,³⁰ and Kotter's 8-step change model.³¹ Although change management models can help with change management planning, effective leadership is a critical factor for successful implementation.³²

SPREAD

To ensure the greatest effect on healthcare delivery and patient outcomes, changes have to be implemented across as many microsystems as appropriate. Each microsystem may need to adapt the improvement idea to its local context. The goal at this phase is to move beyond having filtered a few high-value-creating solutions to implementing across systems in a staged manner to create exponential value. Teams must ensure ongoing measurement and evaluation (represented by the gold/fuchsia arrow head [▶]) once solutions are implemented locally to prevent regression to previous practices. Measurement/evaluation of the implementation should be iterative, and performed at pre-defined stages of scaling or spread.^x

As with implementation, spreading and/or scaling an initiative requires considerable planning and focus on project and change management. An enabler of this work (see section on Structural Elements (Enablers)) is an obligation for the manager of a microsystem, the director of mesosystems and the executive of a healthcare organization to accept accountability for improvement and therefore ensure effective implementation.

Dissemination of solutions is hard. There are many barriers to adoption, including the lack of required resources. The discipline of Knowledge Translation (KT) or knowledge2action (K2A) and "implementation science" is dedicated to studying and supporting dissemination of research and innovation. Like quality and safety improvement experts, KT experts struggle to support spread/scale unless organizational-level goals and metrics are clear. To achieve sustainable change, as solutions are disseminated, it is critical that local teams are allowed to adapt (or slightly modify) as they adopt the changes, based on local culture and ways of doing things.²¹ Focus needs to be on achieving the goal, not being constrained too precisely by process. Success will be more likely when everyone is trying to change behaviour so as to support the Triple Aim. Market or system forces have to 'pull' high-value initiatives into use; quality improvement teams merely 'pushing' (promoting) them does not create sustainable change. Phase 5 is critical for achieving health system impact.³⁵

^x Differentiating scale and spread is important. Scaling up refers to doing the same thing in multiple, similar places. Spread means moving beyond the original targets of implementation and applying an improvement approach to different types of units that may be distinctly different from the original site of implementation; often spread requires local adaptation of the solution.

The IHI's Framework for Going to Full Scale is based on the concept of a scalable unit and includes four phases: (1) set-up; (2) developing the scalable unit; (3) test of scale-up, and, (4) going to full scale.⁵⁰ The IHI approach identifies four adoption mechanisms: (1) leadership, (2) communication, (3) social networks, and, (4) culture of urgency and persistence. Their list of 'support systems' required for scaling up interventions is similar to the HQSMF's set of Enablers (see Structural Elements).

SUSTAIN

Longer-term sustained improvement will require ongoing monitoring and measurement that should be planned as part of the implementation phase, combined with accountability for sustained improvement. Asking the MFI's third question, "How will we know that a change is an improvement?"¹¹ again during Phase 5 will aid the planning of measurement and monitoring. Monitoring should be transparent so that all stakeholders can evaluate whether effective change is taking place and that improvement gains are not eroded over time. During this monitoring phase a health system may determine that additional efforts are needed to achieve the gains that were originally planned. This monitoring (blue arrow [▶]) may become an input into Phase 2 of the SD Model.

In preparing to maintain and sustain gains, teams must ensure integration of the changes into routine practice. "To build a foundation for lasting change, messages should shift from creating a sense of urgency (important for initial engagement) to encouraging institutionalization of the change." Similarly, "Without integration into the culture, structure, and processes of an organization, initial clinical improvements can be lost when organizational attention shifts to (another, or the next) new priority."⁵⁴

Securing new processes into routine practice is more likely when ongoing measurement is combined with both individual and team performance management and accountability. In creating a culture of accountability, the responsibility that healthcare providers share with middle and senior executives, as well as board members includes moral responsibility to continually improve the safety and quality of care delivered to patients. This is key to aligning and sharing health stewardship. An organization's culture reflects the ethical value it places on the health-related interests of the patient: "You can't assume that culture aligns with ethical values; you have to make sure it does."⁵⁵

Sustaining the incremental value created from testing, selecting, then implementing at scale, quality and safety management efforts require courage and executable plans, as described above. Incorporating ongoing measurement into daily practice is vital to teams' successes. Performance should be measured, reported and shared to maximize continuous learning. Much like PDSAs are meant to be an iterative process over time, and not a one-off event, so too is the SD Model. Comparison of forecasted gains relative to actual gains achieved over a period following implementation will assist in the assessment of whether there has been measurable improvement. To sustain gains, new investments in ongoing measurement and evaluation will likely be required, incorporated as part of the 'operational production system', rather than having them considered as linked to improvement projects.

Opportunity cost, a term often used in economic circles, refers to the cost of taking limited resources and investing them in one solution rather than another. In healthcare it is important to consider value (or outcome) relative to what would have otherwise happened if teams did nothing to solve an issue. Researchers and analytical teams refer to this forecast of a baseline measure as the 'counterfactual'. Organizations should consider including the counterfactual in their measures in addition to forecasted and actual outcomes achieved from various tested solutions before determining if the improvement process has been successful. They should also openly share these findings with stakeholders so they can evaluate for themselves the rationale and the results of investments made in improving the delivery of care.

Harm Response Model

The Healthcare Quality and Safety Management Harm Response Model (Figure 2) was created to highlight the important process elements that need to be addressed to optimally manage situations where patients have been harmed by the healthcare they received (or by healthcare they should have received, but didn't).

As with the System Design Model, it is important to ground this work in understanding values and using guiding principles (see section on Structural Elements (Enablers)) to inform decision-making. The goals of harm response are to avoid second harm⁸ to patients and their families, limit the impact an event has on healthcare providers, and identify system learning and improvement, thereby reducing the likelihood of future occurrences (Table 1).

The five process elements include: (1) immediate management; followed by (2) assessment of the situation to determine if ongoing management (the other three elements) is required; (3) support and disclose to a patient and their family; (4) support and assess fairly the healthcare providers involved in an adverse event; and, (5) report, inform and conduct a system analysis of the healthcare system.

Phase 0: Was a Patient Harmed?

When a patient's condition deteriorates, it is reasonable to ask whether the deterioration was primarily related to: (1) progression of the patient's underlying condition; (2) the delivery of healthcare, which might or might not have been optimal; or (3) not receiving healthcare that likely could have slowed deterioration and/or effectively improved the patient's condition. If the deterioration was likely the result of the second or third points, then it is reasonable to assume that a patient was harmed. Additional information can be helpful in establishing if a patient was harmed: a patient summary and chronology of events, sometimes referred to as a timeline, usually abstracted from a patient's chart and then supplemented with more information (e.g., descriptions from interviews with the patient or family member, or a healthcare provider). Sometimes, harm to a patient can be anticipated (e.g., side effects from chemotherapy). Harm response protocols are implemented when a patient's poor outcome was unexpected. This protocol can also be followed in some situations where a patient was nearly harmed or when the patient/family's perception differs from that of the healthcare team.



Phase 1: Immediate Management

The acronym RESPOND^{xi} can be used to highlight seven procedures that should be considered as soon as it is recognized that a patient has been seriously harmed.³⁶



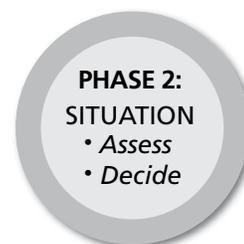
Resuscitate patient(s)
Ensure environment is safe
Secure equipment
Protect other patients
Offer support to patient/family/healthcare providers
Notify chain of command
Disclose (acknowledge event)

- **Resuscitate the patient:** attending to the basics of life preservation (airway, breathing, circulation), which is usually the main focus of healthcare providers.
- **Ensure the environment is safe:** whatever hazard injured the patient could still be present in the immediate environment and pose a hazard for anyone still in that environment.
- **Secure equipment:** any equipment that was part of the patient's care should be seized and examined for two reasons: first, so that other patients are not exposed to the equipment if it was a factor causing the harm; second, to determine if it was functioning properly or not. A detailed review of the equipment's function may need to be undertaken by a member of the clinical engineering staff in the organization.
- **Protect other patients:** other patients might have been exposed to the same hazard or hazardous situation. For example, if a patient was misdiagnosed with cancer because of a mix-up in the processing of pathology slides, it is possible that a patient who does have cancer was given a wrong non-cancer diagnosis.
- **Offer initial support to patient/family/healthcare providers:** as will be discussed below, it is crucial that a patient and family be offered psychological support when harm has been discovered. The sooner and more readily a patient/family is offered support, the more effectively they will be able to handle the repercussions of being harmed. It is also important to provide initial support to healthcare providers involved in the patient's care.
- **Notify chain of command/note in chart:** ensuring that people with organizational authority are told in a timely fashion about the circumstances of the event. A note in the patient's chart about the facts of what happened is critical; this is the only legal document that is available in which to describe what happened while the details are still fresh in the minds of the healthcare providers involved in the patient's care.
- **Disclose (acknowledge event):** disclosure is the process in which factual information (without speculation) is provided to a patient who has suffered harm. Initially it may not be obvious exactly what happened, how it happened or why until a thorough review is completed. Disclosure, especially in more serious events, is often a multi-step process. Thus, during the immediate phase of management it is likely that the only factual thing that can be shared is the acknowledgement that harm has occurred and a promise that additional information will be shared as it becomes available.

^{xi} The RESPOND acronym and the description of associated actions was created in collaboration with B MacLeod, G McRae and JM Davies. Some of the procedures in RESPOND were adapted from Davies JM, Risk assessment and risk management in anaesthesia.³⁵

Phase 2: Situation Assessment

After the seven-step immediate management has occurred, someone within the organization or clinical microsystem who has appropriate oversight and authority will need to decide the degree and the number of phases (detailed below) that will be required to effectively manage the situation. Decision-making will be aided by having as much information as possible. Often the primary source is the patient's chart, from which a timeline can be developed. Assessing this information forms the basis for determining what supports are needed by patients/families and providers; whether additional disclosure is required; and if there is any benefit to other individuals or organizations in knowing about the event. Also important is to ensure that the organization's safety information system captures the important information, usually done through the reporting system.



Phase 3: Patient(s) and Family

SUPPORT

Patients who have been harmed (and, in some situations, nearly harmed) need to be supported so they are not harmed a second time by the feeling (real or perceived) that their needs are not being met by the organization and/or their caregivers where the harm occurred.⁸ Patients need information and answers. Most of this is covered under 'Disclosure' (below). When disclosure is delayed, patients and family members understandably sense a lack of transparency. This usually leads to additional stress, frustration, anger and mistrust. A timely and transparent response is particularly important in situations where it is clear that a patient was harmed by care that did not meet an acceptable professional standard.



The harm that patients suffer may lead to a need for psychological and/or spiritual support. Healthcare organizations should know where this support is available before it is required so it can be offered immediately. Often patients also need additional support from family or friends who may not currently be with them; when travel is involved, financial support or compensation for patients or family becomes an issue.

Three types of compensation can be considered as part of the management of serious or fatal harm events: (1) out-of-pocket expenses (may include travel and accommodation costs for family members, special equipment, psychological counselling, etc.); (2) loss of income; and, (3) pain and suffering.³⁷ Out-of-pocket compensation could be offered very soon after a harm event as a goodwill gesture, without prejudicing future decisions about the quality or standard of care provided. The latter two types of compensation will usually need to wait until all investigations are completed and the facts are known before any commitment can be made. This may, but does not need to, involve formal legal proceedings.

DISCLOSE

Disclosure entails open and honest discussions with patients/families when patients have suffered harm. Much has been written about the reasons why disclosure is important. The provision of healthcare occurs in the context of relationships; trust is a foundational requirement for this to be effective, and trust is eroded or lost when a patient has been harmed or nearly harmed. Disclosure makes it possible to rebuild trust and therefore rebuild a relationship. The basic elements of effective disclosure include:

1. An apology for what happened to the patient. It is critical that appropriate accountability is taken for the actions and decisions taken (or not taken) by healthcare providers and organizations and to specifically apologize for not providing the correct care.
2. Empathy: person(s) involved in disclosure (healthcare providers and/or administrators) have to demonstrate that they understand the suffering the patient/family experienced.
3. An explanation of the facts about what happened and why it happened, based on what is currently known, and a commitment for timely updates as more facts become known.
4. What the patient can expect in the future about how they will or could be affected as the result of the inappropriate care they received.
5. How the patient will be cared for in the future, including by which healthcare providers and in what facilities (if required).
6. Information about what efforts will be made to change the system of care delivery that might reduce the risk of the same or similar event happening to patients in the future.

Disclosure may, at the simplest end of the spectrum, involve a single conversation between a healthcare provider and a patient about the patient being nearly harmed or suffering minor harm. At the other end of the spectrum, in complex cases involving several healthcare providers and/or in which a patient was seriously or fatally harmed, disclosure may take place repeatedly over several weeks or months. This type of disclosure usually involves many conversations and several individuals using a 'team' disclosure approach.

Phase 4: Healthcare Providers

SUPPORT

Healthcare providers directly involved when a patient suffers harm may be profoundly affected. This has been described as the 'second victim' syndrome.⁵⁸ Healthcare providers require support so that they do not assume undue responsibility for a patient's outcome; counselling and peer support should be made available to them. It is also important to consider whether they are emotionally capable of providing care to other patients, and when.



ASSESS FAIRLY

Organizations that strive to improve the safety of patient care recognize the need to learn from patient harm events, but it is important to consider what type of structured analysis is appropriate. Although humans are inextricably linked to the provision of care, they represent only one part of a complex healthcare system.³⁹ At first it may appear logical to analyze in detail the decisions and actions of each healthcare provider who was directly, or even indirectly, involved with the patient's care. It is important, however, to separate a formal detailed systems analysis from an assessment of an individual's decisions and actions. An organization has an opportunity to make a strong statement about its culture when things go wrong for patients by making it clear that the organization's primary focus is a system-level understanding of what happened and why (functioning/interactions of the different parts of the system that created the context for the care environment), rather than a critical analysis of an individual's decisions and actions. If anyone with line-authority for individuals involved in a patient harm event participates in a formal systems analysis of the event and then is perceived to use that information to make judgments about the decisions and actions of individuals, it will undermine safety culture.

A fair and just assessment of an individual's decisions and actions in a patient harm event requires that the person performing the assessment has enough of a system perspective to place the decisions and actions of that individual in proper context. The goals of individual assessment are threefold: (1) to establish if there are important knowledge or skill-based deficits that should be addressed to improve overall performance; (2) to consider any underlying medical or psychological conditions a healthcare provider may be suffering from that were, and still could be, affecting performance; and, (3) to determine if there were noncompliant actions (violations) that would warrant sanctions. In healthcare, not all noncompliant actions warrant sanctions. The types of decisions, actions and behaviours that are sanctionable should be clearly outlined in an organization's just culture policy and in general be limited to those that involve any willful intent to harm or that show a clear disregard for the best interests of a patient. It is important for organizations not to confuse knowledge or skill deficits with sanctionable actions.

Phase 5: Healthcare System

REPORT

Reporting involves sharing information with appropriate responsible individuals or organizations for the purpose of system improvement.⁴⁰ Reporting systems can be created for one of two primary objectives: accountability or learning.⁴¹ Accountability systems usually employ mandatory reporting. In contrast, when learning is the primary purpose, reporting is voluntary and without repercussions to the reporter. Completing a report should be easy for reporters, involve as few tick-boxes as possible, and be primarily narrative-based so that reporters can tell 'the story' of what happened.⁴⁰



INFORM

Informing is the sharing of safety-related information by an organization, or an individual healthcare provider, with stakeholders who are not responsible for the care of a particular patient or patient population.⁴⁰ There are four reasons to inform:

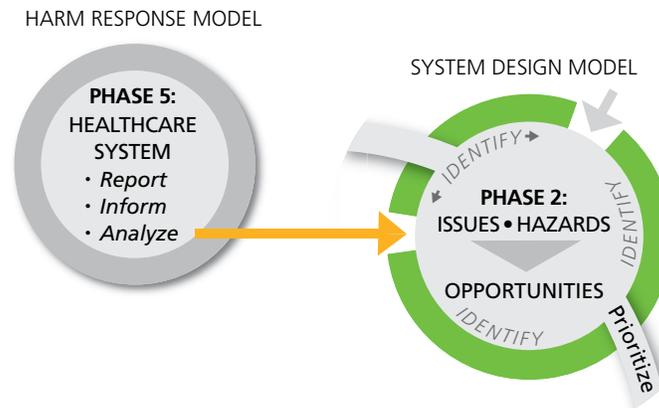
1. Protecting other patients. Following a patient harm event, it could be important to alert other healthcare organizations and providers about the system vulnerabilities that contributed to the event. Informing provides an opportunity for other healthcare organizations and providers to take steps to mitigate any risks to patients in similar settings.
2. Reputation management. It is important for a healthcare organization to maintain the trust of the patients and public it serves. This is accomplished when leaders are seen to be accountable for the performance of their organization, including when patients suffer serious harm. A lack of openness about the circumstances surrounding a serious event fuels speculation that something is being ‘covered up’, further damaging reputation and trust. Trust is rebuilt or maintained through transparency.
3. Empowering patients and the public to make informed decisions. Healthcare organizations may become aware of situations that pose a risk of harm, such as an outbreak of a highly communicable disease in one of its facilities. In these circumstances, people have the right to be informed of the risk in a timely manner.
4. Normalizing open discussions of system vulnerabilities and failures, and encouraging others (healthcare providers, other employees, patients) to be open and share their observations and stories about potential or actual breakdowns in care is an important element of building a safety culture.

ANALYZE

A structured and systematic approach for evaluating the components of a healthcare system and how they interact is important for learning about breakdowns in healthcare delivery and in the structures and processes that are designed to support it. ICAO’s safety management system⁴ is largely based on Reason’s organizational accident causation model¹⁸ which has been used to develop an investigative approach. This approach has been adapted for use in healthcare.¹⁷ Several other system-focused methods are used in healthcare to analyze situations where patients have been harmed or nearly harmed. Whatever method is used, it should not identify the individual providers involved in the care of a patient by name, and should not form judgments about their decisions, actions or behaviours. The output of a system analysis includes a report of findings and usually recommendations for improvement. This information should be stored securely in an organization’s safety information system.

The outputs of the Harm Response Model’s Phase 5 reporting of, and any analysis of, hazards, patient harm events or close calls can identify opportunities to improve and thus be an internal input to Phase 2 of the System Design Model (Figure 5). Informing other units and organizations provides useful information, as an external input, into their system design models.

Figure 5: THE LINK BETWEEN THE HARM RESPONSE MODEL (PHASE 5) AND THE SYSTEM DESIGN MODEL (PHASE 2)



Structural Elements (Enablers)

Quality and safety management work occurs in the larger context of a health system that must provide the supporting structures or enablers if the Triple Aim is to be achieved. Enablers direct and drive performance. Whether system change is focused on large-scale spread or local improvement efforts, outcomes are made possible through the positive influence of many different system enablers. The HQSMF highlights six that are necessary for the framework’s process elements to be effective.^{xii}

Leadership

Leaders provide the vision for what a health system needs to accomplish. They are critical for advancing the quality and safety agenda and ‘setting the table’ for an organization’s culture. A key responsibility is constancy of purpose – or, ‘stick-with-it-ness’.⁴² The IHI High-Impact Leadership Framework proposes six domains through which healthcare leaders focus their actions:⁴⁵

1. Driven by persons and community: engage patients and the public in the process of improvement.
2. Create vision and build will: pay attention to priority efforts; be transparent about measures and results.
3. Develop capability: teach basic improvement at all levels; integrate improvement with daily work at all levels; invest in needed infrastructure and resources.
4. Deliver results: use proven methods and tools; frequently review results; devote resources and skilled leaders to high-priority initiatives.
5. Shape culture: communicate and model desired behaviours; take swift and consistent actions against undesired behaviours.
6. Engage across boundaries: model and encourage systems thinking; partner with other providers and community organizations in the redesign of care.

^{xii} Several types of legislation can also facilitate quality and safety management. For example, the *Alberta Evidence Act* includes provisions for the work of quality assurance committees and for identifying the effect of apology on liability by indicating that evidence of apology made by a person connected with the matter is not admissible as evidence of fault or liability. Similarly, the *Alberta Health Act* identifies the principles guiding the health system and the requirement for the minister to establish a health charter to guide the actions of those providing healthcare as well as the actions of Albertans.

Followership

Continuous improvement requires change. Followership, which refers to people understanding how to support an organization's vision and strategy, is felt to be a more critical success factor than leadership. Effective followers encourage others to adopt changes. Four qualities of effective followers have been described:⁴⁴

1. Self-management: the ability to think critically and work independently.
2. Commitment: share the same values and common purpose of the organization and actively engage in the work of continuous improvement.
3. Competence: possessing above average skills and knowledge.
4. Courage: holding strong beliefs, maintaining high ethical standards and being prepared to challenge superiors when necessary.

At times, followers need to take over as leaders; formal leaders need to be generous in sharing power and authority.⁴²

Governance and Accountability Structure

Although most users of the HQSMF will see their role as influencing at a micro- or mesosystem level, all micro- and mesosystems are interconnected and contribute to larger macrosystem-level goals. Effecting change is hard work. It requires continuous decision-making at multiple levels within an organization. Alignment at all levels with an accepted and shared strategy for improvement is a critical success factor. This strategy starts at the level of organizational governance and it must be made explicit: everyone must understand the organizational accountability structure. When accountabilities are obvious, there is no doubt who is responsible for achieving results and where the dependencies for success lie. When progress in a clinical micro- or mesosystem depends on change that is beyond its scope of control, that group must know where to turn for assistance. Having a clear strategy for improvement, and an equally clear organizational accountability chain, requires a formal organizational structure that supports quality and safety management.

Capacity and Capability

People at all levels in a healthcare organization require particular skills to manage quality and safety. Some of the required skill sets include measurement (e.g., statistics, statistical process control), database creation and management, analytics, improvement methodology, and effective quality and safety leadership (including change leadership). It has been recommended that healthcare leaders master the theory and methods of improvement as a core competence to increase the uptake of improvement strategies and manage costs.⁴⁵ These skills are not yet part of the core training of healthcare providers, managers or executives. Thus, an education program is a fundamental enabler for most units and organizations.

Capacity also refers to having the appropriate and necessary infrastructure to support quality and safety management. This should include electronic systems to capture valid source data, database management systems, reporting software, strong analytical support and effective working relationships between data analysts and frontline providers/managers to define useful measures for monitoring that support decision-making. Capacity also refers to people who have the necessary skill sets and sufficient time to do this important work.

Supportive Information Systems

Measurement, monitoring, and evaluation are critical at all stages of quality and safety management. Data need to be systematically captured and stored. In most cases, the relevant data exist in multiple databases. Thus effective data management includes the ability to link person-specific data across databases and create data tables to support ongoing reporting of quality and safety measures. Effective measures require data definitions created jointly by clinicians and data analysts. For data linkages to be valid, an organization needs a robust process for managing person-specific unique identifiers. For sustainability, and to support timely access and decision-making, the process of data retrieval, storage, linking, and reporting must be automated as much as possible.

Reporting systems and analyses of adverse events and close calls require a data storage strategy that includes a classification system to identify trends in contributing factors. This implies that an adequate number of people are trained and available to monitor these data trends. Analyses of reports and adverse events generate recommendations for improvement; these also need to be classified and stored so they can be retrieved and tracked for understanding implementation status as well as 'lessons learned and lessons shared'.

Values and Guiding Principles

Values and guiding principles provide the moral and ethical compass that places and keeps the quality and safety management efforts in the correct perspective. Values are defined as one's judgment of what is important in life. When leaders and followers have shared values, a state of continuous improvement is more achievable. Values should not be assumed; they should be clearly stated so that leaders, followers and the people they serve can hold each other to account for their actions and behaviours. Principles are fundamental truths or propositions that serve as the foundation for a system of beliefs or for a chain of reasoning.^{xiii} Therefore, principles guide decision-making by leaders at all levels of an organization and, if followed, can help standardize prioritization of initiatives and investments in improvements.

In 2010 the HQCA led a multi-stakeholder group that described the following foundational principles believed important in shaping decisions in organizations that are committed to improving quality and safety of care:⁵⁹

- *Patient engagement* (increasingly referred to as co-production). This means that patients and families are included as equal partners in the decisions made about their care and are involved in the design of structures and processes that support improved patient outcomes.
- *Respectful, transparent relationships*. Effective communication among all people involved in healthcare delivery is essential for optimal patient outcomes; communication is enhanced in high-trust environments; trust is gained through mutual respect and transparency.
- *Healthcare as a complex adaptive system*. Humans and human interactions are a fundamental component of healthcare delivery systems. These interactions can be unplanned and feature unfamiliar sequences and characteristics, which contribute to the complexity of healthcare. This complexity must be taken into account when designing, or analyzing the failure of, healthcare delivery.

^{xiii} Oxford Dictionaries online.

- *Just and trusting culture.* Human fallibility is both universal and inevitable, but improvements to the design of healthcare delivery can reduce the likelihood of errors. Treating providers fairly if they make errors is a critical first step in supporting a reporting culture, which is necessary to have a learning culture.⁴⁰
- *Responsibility and accountability.* For any system to improve, the person or team responsible for the implementation of improved processes or structures must be clearly identified and therefore accountable for results.
- *Continuous learning and improvement.* At its core, quality and safety management is about continuously striving to improve. This implies ongoing monitoring of key performance metrics and the willingness and competence to draw the correct conclusions from this information as well as the will and capability to implement changes when the need to change is indicated.¹⁷

Conclusion

The Healthcare Quality and Safety Management: A Framework for Alberta (HQSMF) consists of two models, the **System Design Model** and the **Harm Response Model**, and a set of six **Enablers**. Each model describes five phases that take a user through a proactive approach for managing quality and safety or a reactive approach for managing an adverse event where a patient has suffered serious or fatal harm. The goal of the System Design Model is to improve one or more dimensions of the Alberta Quality Matrix for Health and ultimately to contribute towards achieving the Triple Aim.¹ The goals of the Harm Response Model are to avoid second harm for patients and their families, limit the impact that serious or fatal adverse events have on healthcare providers, and enable health systems to learn and improve so as to reduce the likelihood of similar adverse events occurring in the future. The learning or output from the Harm Response Model, generated from an analysis of factors contributing to an adverse event, serves as an input to the System Design Model, which provides the opportunity to improve.

This framework was developed first and foremost to guide managers of clinical microsystems and directors of clinical mesosystems in the work required to manage the quality and the safety of care provided to patients. The HQSMF also has utility for healthcare executives and governors who have macrosystem accountability for this care. The six enablers provide the foundation for quality and safety management. They are essential at all levels of the healthcare delivery system. Patients and the public need to be involved in the design of the healthcare services they receive if a healthcare system hopes to be responsive to users' needs and expectations and therefore achieve the Triple Aim.

Finally, the actions that are specified in the System Design Model and the Harm Response Model provide the basis for a quality and safety management curriculum. Building quality and safety capability through education and training should be a key strategy of healthcare systems and organizations. Investing in this way will help healthcare systems evolve a culture where its major preoccupation is the high-quality and safe delivery of healthcare services to the people they have been entrusted to serve.

Appendices

Appendix I: The Alberta Quality Matrix For Health

The *Alberta Quality Matrix for Health*⁵ has two components:

1. Dimensions of quality, which focus on aspects of the patient/client experience.
2. Areas of need, which divides the range of services provided by the health system into four distinct, but related, categories.

Figure 6: THE ALBERTA QUALITY MATRIX FOR HEALTH




DIMENSIONS OF QUALITY AREAS OF NEED	ACCEPTABILITY Health services are respectful and responsive to user needs, preferences and expectations.	ACCESSIBILITY Health services are obtained in the most suitable setting in a reasonable time and distance.	APPROPRIATENESS Health services are relevant to user needs and are based on accepted or evidence-based practice.	EFFECTIVENESS Health services are based on scientific knowledge to achieve desired outcomes.	EFFICIENCY Resources are optimally used in achieving desired outcomes.	SAFETY Mitigate risks to avoid unintended or harmful results.
BEING HEALTHY Achieving health and preventing occurrence of injuries, illness, chronic conditions and resulting disabilities.						
GETTING BETTER Care related to acute illness or injury.						
LIVING WITH ILLNESS OR DISABILITY Care and support related to chronic or recurrent illness or disability.						
END OF LIFE Care and support that aims to relieve suffering and improve quality of living with or dying from advanced illness or bereavement.						

Adopted June 2005 by the Health Quality Network, an HQCA collaborative. Adapted from the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services under contract to the Institute of Medicine.

www.hqca.ca

The *Alberta Quality Matrix for Health* provides a way of organizing information and thinking around the complexity of the health system. It enables the public, patients, providers, and organizations to see how dimensions of quality and areas of need might intersect. It has been used in numerous ways, including policy development, strategic and service planning, and as a way to educate the public about quality in healthcare. More information is available at <http://hqca.ca/about/how-we-work/the-alberta-quality-matrix-for-health-1/>

Appendix II: Working Group Terms of Reference and Membership (August 2015)

PROJECT SPONSOR

The development of a provincial quality and safety management framework will be sponsored by the Health Quality Network (HQN). The final framework document will be brought to HQN for endorsement.

PROJECT GOAL

To develop a provincial quality and safety management framework that supports a consistent approach for improving and managing the delivery of healthcare services in Alberta.

PRINCIPLES OF ENGAGEMENT

- The HQN member organizations will be asked to nominate their content experts to participate in a working group.
- HQN member organizations and other key stakeholders will also be asked to participate in a broader stakeholder consultation group.
- Framework development will be a collaborative process, building on pre-existing work in the province.
- The framework will provide clarity on the topics/functions that support a provincial quality and safety management framework.
- The process will engage national or international experts to review the work.

TARGET AUDIENCE FOR THE QUALITY AND SAFETY MANAGEMENT FRAMEWORK

- This product will inform healthcare organizations/programs of the key functions required to support quality and safety management within their own organizations.
- This framework will not be mandatory but is designed to provide guidance for healthcare organizations looking to enhance quality and safety management in the delivery of healthcare services.

ROLE OF THE HQCA

The Health Quality Council of Alberta (HQCA) will lead the project to develop the provincial quality and safety management framework on behalf of the HQN.

Project Plan

PROJECT STRUCTURE

The project will convene a core working group and a larger stakeholder group.

- The core working group will provide the operational direction for the project to inform and respond to the work of the HQCA team.
- The stakeholder group will be convened to identify elements that would be of value to them to be addressed in the framework. This group will also provide feedback to the final draft, following the expert review and prior to publication.
- The HQCA team will provide administrative and content support to develop the framework.

PROJECT METHODOLOGY

- The project will use a collaborative model of engagement to develop the framework.
- The core working group will be convened approximately five times during the course of the project; the stakeholder group will be convened approximately two times.
- External content experts will be contracted to review/validate the final draft of the quality and safety management framework document.
- The project team will report to HQN on the progress of the project.
- HQN will be asked to endorse the final quality and safety management framework product.

DELIVERABLES

- There will be several work products throughout the course of the project (draft documents or components) that will be shared with the working group and selected others for the purpose of reporting, soliciting feedback or validation.
- The project will develop a final document in electronic and hard copy format. The document is expected to include, at a minimum, the following sections:
 - background or 'white paper' (approx. 10 pages) related to the study of quality and safety management
 - principles of Q & S management as defined by the project
 - a framework/model of Q & S management for Alberta
 - a discussion of the framework
 - guidance for using the framework

BUDGET AND FUNDING

- The project will be funded by the HQCA. This includes expenses related to HQCA staff time, travel, meeting expenses, contracting needed resources, document design and production.

HEALTHCARE QUALITY AND SAFETY MANAGEMENT FRAMEWORK WORKING GROUP MEMBERS

Ward Flemons	Health Quality Council of Alberta
Peter Campbell	Alberta Health
Owen Heisler	Covenant Health (previously with the College of Physicians & Surgeons of Alberta)
Jon Popowich	Covenant Health
Deborah Prowse	Office of the Alberta Health Advocates
Jim Silvius	Alberta Health Services
Peter Fenwick	Consultant
Jonas Schultz	Health Quality Council of Alberta
Carmella Steinke	Health Quality Council of Alberta
Anette Mikkelsen	Health Quality Council of Alberta

Appendix III: Safety Management Risk Assessment and Quality Prioritizing Tools and Method

Table 3: EXAMPLE – SAFETY PROBABILITY TABLE⁴

Likelihood	Meaning	Value
Frequent	Likely to occur many times (has occurred frequently)	5
Occasional	Likely to occur sometimes (has occurred infrequently)	4
Remote	Unlikely to occur, but possible (has occurred rarely)	3
Improbable	Very unlikely to occur (not known to have occurred)	2
Extremely improbable	Almost inconceivable that the event will occur	1

The estimated probability (likelihood/frequency) of occurrence (a hazard resulting in an adverse outcome) could be based on past organizational experience, other organizations' experience, published reports or expert advice.

Table 4: EXAMPLE – SAFETY SEVERITY TABLE (ADAPTED FROM ICAO⁴)

Severity	Meaning	Value
Catastrophic	Multiple deaths	A
Major	Serious harm ^{xiv} / single death or urgent intervention required to avoid this degree of injury	B
Moderate	Permanent or long-term partial loss of organ or limb function	C
Minor	Transient loss of organ or limb function	D
Negligible	No recognizable harm	E

The severity of possible consequences related to a hazard is shown. A safety severity table, similar to the probability table, can be used to summarize the level or degree of severity.

^{xiv} Serious harm – loss of major organ or limb function transiently or permanently

Table 5: EXAMPLE – SAFETY RISK ASSESSMENT MATRIX (ADAPTED FROM ICAO⁴)

Probability of Occurrence		Severity				
		Catastrophic A	Major B	Moderate C	Minor D	Negligible E
Frequent	5	5A	5B	5C	5D	5E
Occasional	4	4A	4B	4C	4D	4E
Remote	3	3A	3B	3C	3D	3E
Improbable	2	2A	2B	2C	2D	2E
Extremely Improbable	1	1A	1B	1C	1D	1E

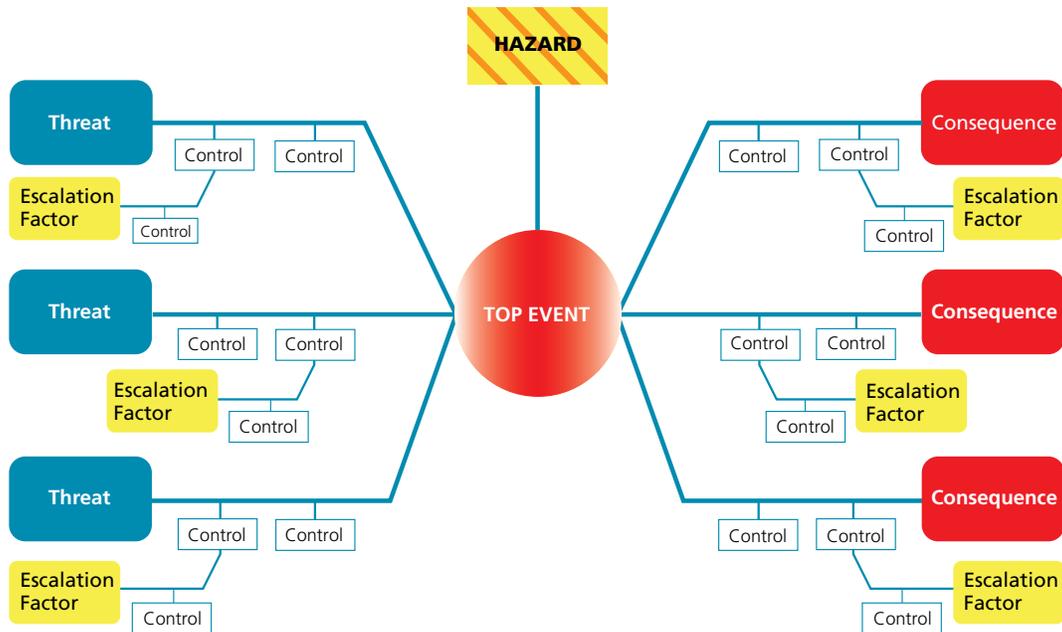
A hazard’s risk probability and severity can be combined into a safety risk assessment matrix that identifies levels of risk assessment that an organization deems unacceptable (in red), acceptable (green) or tolerable (orange). In keeping with the principle of patient/public engagement, healthcare decision-makers should incorporate that perspective when establishing what is red, green and orange in a matrix such as is presented here. Hazards with a risk assessment in the unacceptable category are high priority and need to be managed through the other safety management steps in the cycle. Hazards in the tolerable range may require some risk mitigation strategies to be developed (the safety management cycle may still be useful to guide task completion) but are less urgent for an organization to address.

THE BOWTIE METHOD

The BowTie method is a risk management methodology that focuses on controls rather than events (Figure 7).^{21,22} It links causes, referred to as *threats*, with *consequences*. A BowTie model is created for a specific *hazard*. In non-healthcare industries where this methodology was developed, a hazard is defined as energy sources, materials, or conditions, or anything that has the potential to cause either one of, or a combination of: harm, damage to property or environment, production losses, loss of assets, loss of reputation or increased liability. The following are healthcare examples of: an energy source – electrocautery; a material – chemotherapy; a condition - pneumonia or atrial fibrillation. A healthcare definition of hazard includes anything that has the potential to lead to patient harm.

The link between the left side of the model (threats), and the right side of the model (consequences) is the middle of the model – the *top event*, also referred to as an ‘unwanted event’. A top event is an undesired state resulting from the loss of control over a hazard. It has not necessarily resulted in undesired consequences but it could if *recovery controls* (located on the right side of the model between the top event and consequences) do not interfere with the accident trajectory of the top event. On the left-hand side of the model, threats represent direct causes of top events; the barriers that are in place to keep threats from leading to top events are *prevention controls*. A unique feature of the BowTie model is the inclusion of *escalating factors*, defined as a condition that leads to increased risk by defeating or reducing the effectiveness of prevention controls. Finally, the model also includes *escalating factor controls* – strategies for managing or controlling escalating factors.

Figure 7: THE BOWTIE MODEL^{xv}



A simple example of a BowTie model for patients taking anticoagulants (Figure 8):

Hazard – anticoagulant (warfarin)

Top event – excessive anticoagulation (INR > 5)

Consequence – gastrointestinal bleeding

Recovery Control – Vitamin K

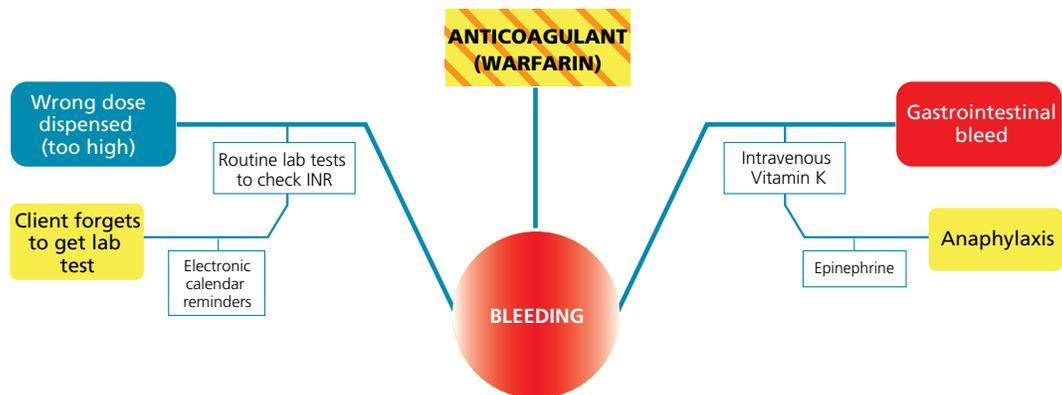
Threat – wrong dose

Prevention Control – Frequent monitoring of INR

Escalation Factor – patient forgets to go for laboratory test

Escalation Factor Control – reminder notices in electronic calendar

Figure 8: EXAMPLE – BOWTIE MODEL FOR AN ANTICOAGULANT

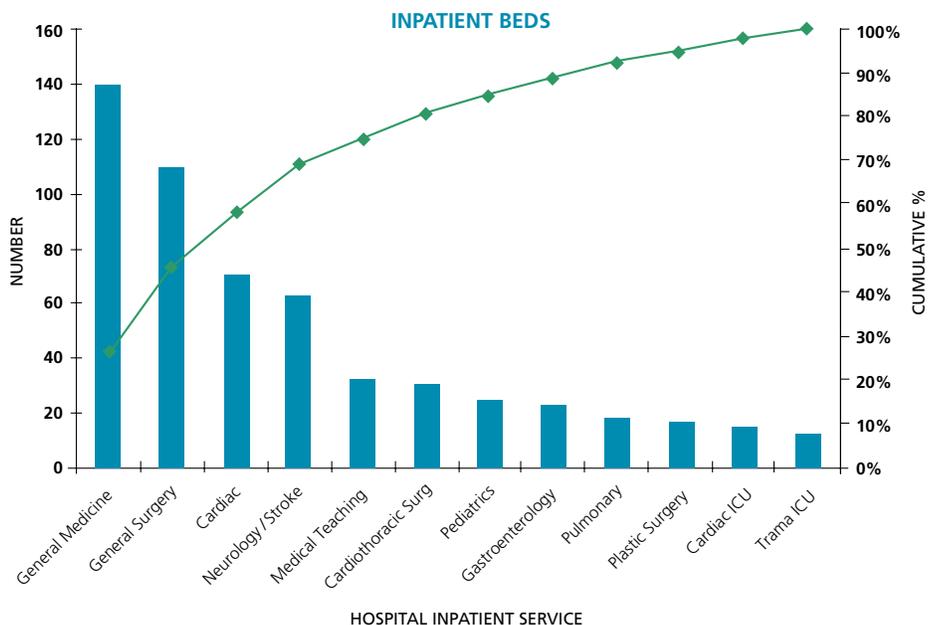


^{xiv} Adapted from the United Kingdom Civil Aviation Authority.²⁰

For any 'Hazard – Top event' combination many threats and consequences would be identified. Similarly, for each consequence several recovery controls, and for each threat several prevention controls, could be specified. Several potential escalation factors and the corresponding control(s) could be relevant for each prevention control. Systematically building a BowTie model that explores potential combinations of threats, consequences and various types of controls provides a comprehensive picture of where serious threats to patients' safety exist and what controls are in place to reduce the likelihood of harm. Quantifying risk still depends on estimating the likelihood of threats 'releasing a hazard' so that a top event occurs and the likelihood of that event translating into a patient being harmed (consequence). The severity of harm also needs to be estimated in similar fashion to Table 2. However, unlike the approach outlined by ICAO, the BowTie model specifies evaluating the criticality and the effectiveness of controls; elements of effectiveness include adequacy (the extent that a particular control will interrupt a particular scenario) and assurance or reliability – the level of confidence that a control will function the way it is intended to when it is needed. Specification of accountability for controls is important so that they are managed and resourced appropriately.

BowTie models have been used to analyze medication safety. Insights from adapting the BowTie approach for healthcare included the need to be specific about the hazard and threats that were analyzed so there was direct relevance for the stakeholders who were engaged to develop the BowTie model.⁴⁶

Figure 9: EXAMPLE – PARETO CHART: HOSPITAL INPATIENT SERVICE BED NUMBERS
(any service > mean 95% occupancy)



In this example assume the goal of an organization is to reduce hospital inpatient bed occupancy rates (as a mechanism for improving patient flow in emergency departments thereby reducing wait times (improving access) and improving patient experience). Prioritizing improvement efforts on the hospital inpatient services that have the largest number of beds will result in the greatest impact on the stated goal – in this example that would include General Medicine, General Surgery, Cardiac and Neurology/Stroke beds.

Appendix IV: Quality Improvement Methods

MODEL FOR IMPROVEMENT – RAPID CYCLE IMPROVEMENT (PDSA CYCLES)

Probably the most accessible improvement approach, PDSA (Plan-Do-Study-Act) cycles use rapid test cycles to evaluate improvement ideas in a specific setting on a limited basis then make adjustments accordingly. In contrast to more formal clinical trials, PDSA cycles use learning from each cycle to adjust and adapt the intervention before deciding its overall utility. The Plan stage includes generating a hypothesis and then planning a small test of change to test it (including data collection). Following the completion of the mini-experiment (Do), the Study stage focuses on analyzing the data to decide whether the test was successful, whether it needs to be repeated (and possibly modified), or whether the idea should be abandoned. Collected data can be quantitative and/or qualitative. The Act stage involves making a decision about next steps (additional tests, modify or abandon an idea or move forward with implementation). Training can be primarily experiential. However, despite the appearance of simplicity, many teams fail to legitimately use PDSA methodology to adequately test ideas; a disciplined approach is recommended.⁴⁷ It is important that improvement ideas are studied with iterative tests of change over various conditions to ensure that an idea actually accomplishes what is intended and opportunities to uncover unintended consequences have not been missed. Connecting multiple PDSA cycles together, properly analyzing the data and deciding when there is enough evidence to declare success can be complicated, hence the need for experience and rigor in conducting PDSA cycles. Under pressure to ‘get on with it and improve’, improvement teams may prematurely select and implement an idea before adequate testing is completed.

LEAN PRODUCTION

Adapted from the Toyota Production model (an industrial process improvement methodology), the focus of Lean is to uncover and eliminate wasteful process steps that do not contribute value to the customer (patient). Lean defines value based on the lived experience of the patient, not on what a healthcare organization or unit believes the patient experiences; therefore it requires legitimate engagement and inclusion of patients by healthcare teams. Lean also engages frontline staff who are ‘process owners’ using their experience along with that of patients to redesign process. Examples of Lean improvement tools include value stream mapping, the 5 S’s (Sort, Set in order, Shine, Standardize, Sustain) and Kaizen events, but more than a set of improvement tools, Lean is a fundamental change in management approach based on a set of principles that, when implemented successfully, is described as resulting in a cultural transformation.

SIX SIGMA [DMAIC, DMADV]

The focus of Six Sigma improvement is to design highly reliable processes by eliminating defects; it is based on statistical modelling of manufacturing processes. Therefore, it relies on very rigorous data analysis and follows a cycle of Define-Measure-Analyze-Improve-Control (DMAIC) to uncover and error-proof processes. Define refers to project scope, resources, and schedule; Measure means quantifying the process to determine current performance; Analyze refers to data analysis with the goal of identifying causes of defects, which will guide decisions about what to improve; Improve focuses on eliminating defects; and Control refers to maintaining improvements through measurement and monitoring. A related activity, DMADV (Define-Measure-Analyze-Design-Verify), involves initial product design rather than improving an existing manufacturing process.

LEAN SIX SIGMA

Some organizations combine the rigorous DMAIC approach of Six Sigma and its focus on eliminating defects with the Lean approach of eliminating wasteful steps that cost money but do not add value.



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Glossary

Co-produce: Healthcare is not a product manufactured by the healthcare system, but rather a service, which is co-created by healthcare professionals in relationship with one another and with people seeking help to restore or maintain health for themselves and their families. This co-productive partnership is facilitated or hindered by many forces operating at the level of the healthcare system and the wider community.²⁵

Enablers: Core structural elements that healthcare systems require to effectively manage quality and safety.

Followership: Followership is the ability to take direction well, to get in line behind a program, to be part of a team and to deliver on what is expected of you.⁴⁸

Harm: A situation where a patient is injured primarily as a result of either the healthcare they received or did not receive but should have. It is acknowledged that in addition to suffering physical harm, people can suffer psychological harm when they are not treated in a respectful, dignified or culturally sensitive manner.

Hazard: A condition or an object with the potential to cause death, injuries to personnel, damage to equipment or structures, loss of material or reduction of the ability to perform a prescribed function.⁴

Healthcare encounter: A situation where people/teams providing healthcare interact with the recipients of healthcare – patients, their families and/or supporters.³⁹

Human factors: A body of knowledge about human abilities, human limitations, and other human characteristics that are relevant to design. Human factors engineering is the application of human factors information to the design of tools, machines, systems, tasks, jobs, and environments for safe, comfortable, and effective human use.⁴⁹

International Civil Aviation Organization (ICAO): A UN specialized agency, established by States in 1944 to manage the administration and governance of the Convention on International Civil Aviation (Chicago Convention). ICAO works with the Convention's 191 Member States and industry groups to reach consensus on international civil aviation Standards and Recommended Practices (SARPs) and policies in support of a safe, efficient, secure, economically sustainable, and environmentally responsible civil aviation sector.⁵⁰

Just culture: An atmosphere of trust in which people are encouraged, even rewarded, for providing essential safety-related information – but in which they are also clear about where the line must be drawn between acceptable and unacceptable behavior.¹⁸

Macrosystem: The larger healthcare system that operates and coordinates its meso- and microsystems.¹⁰

Mesosystem: A collection of interrelated microsystems that provide care to a shared population of patients.¹¹

Microsystems: Clinical microsystems are the small, functional, frontline units that provide most healthcare to most people. They are the essential building blocks of larger organizations and of the health system. They are the place where patients and providers meet. The quality and value of care produced by a large health system can be no better than the services generated by the small systems of which it is composed.¹⁰

Model for Improvement (MFI): Developed by *Associates in Process Improvement*, is a tool for use in accelerating improvement. The Model for Improvement consists of two parts:

- Three fundamental questions.
- PDSA cycle to test changes in real work settings. The PDSA cycle guides the test of a change to determine if the change is an improvement.¹²

Multi-vote approach: Multi-voting narrows a large list of possibilities to a smaller list of the top priorities or to a final selection. Multi-voting is preferable to straight voting because it allows an item that is favored by all, but not the top choice of any, to rise to the top.¹⁶

Safety risk: Risk is the possibility or probability of something unwanted happening. ICAO defines safety risk as the projected likelihood and severity of the consequence or outcomes from an existing hazard or situation.⁴

Spread/Scale: Spread – the adoption and replication (with little modification) of an intervention within a health system. Scale – addresses the system/infrastructure issues that arise during full-scale implementation.³⁰

Second harm to patients and their families: Occurs when a patient or family perceives a lack of action on the part of individuals associated with the healthcare system (healthcare providers and administrators) in response to an experience of harm. Second harm is the result of what healthcare providers and administrators do and say, or fail to do and say, that contributes to the patient and/or family from not moving through a grief process.⁸

Second victim: A healthcare provider involved in an unanticipated adverse patient event who is traumatized by the event.³⁸

System factors: Characteristics that exist within the various components of the healthcare system that may positively or negatively contribute to an outcome. These components can be related to patients, personnel, equipment/environment, organization and regulatory agency.²⁰

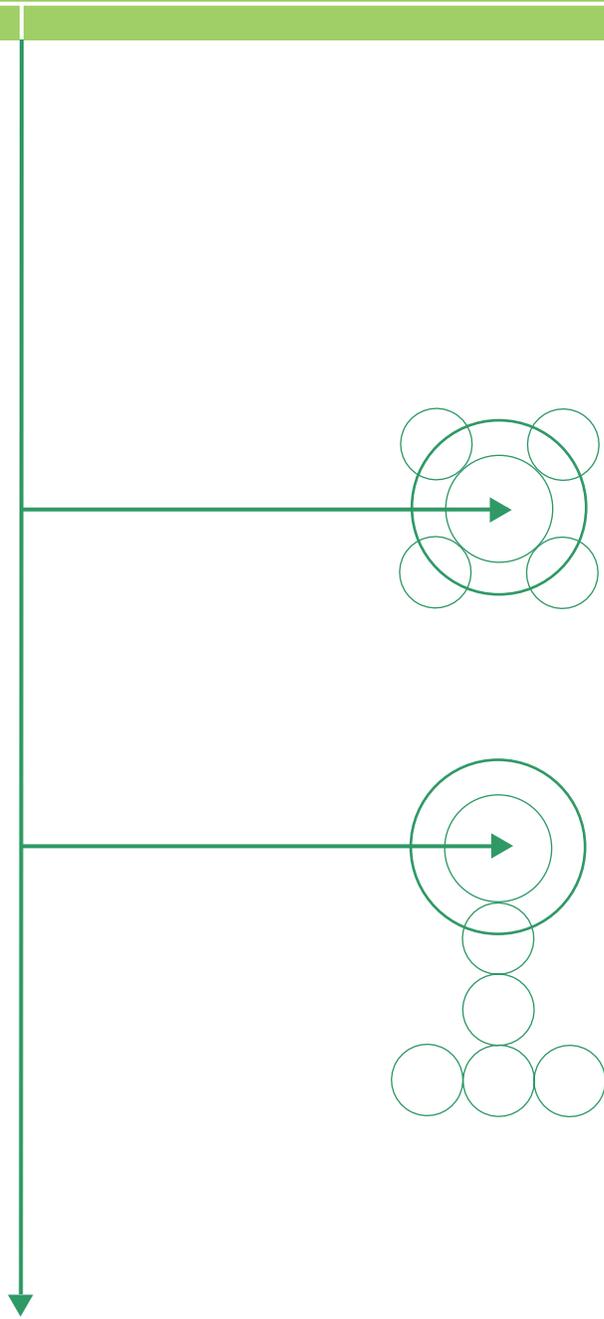
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