

PHYSICIAN LEADERSHIP RESOURCE MANUAL

Module 6: Quality, Safety and Risk Management

Section 6.1: Quality Improvement and Safety

OVERVIEW

As discussed in Module 1, a variety of legislation has been enacted in recent years which impose new obligations on Ontario public hospitals with respect to quality, transparency, accountability and community engagement.

This module provides an in-depth discussion of expectations under the [Excellent Care for All Act](#) (ECFAA) which was enacted in 2010 with the purpose of ensuring that Ontarians receive health care of the highest possible quality and value. ECFAA and the complimentary amendments to Regulation 965 (i.e., [Hospital Management Regulation](#), as referred to in Modules 1 and 2) under the [Public Hospitals Act](#) (PHA) are the primary legislative vehicles for the province's "quality agenda."

Key Sources

[High Performing Healthcare Systems: Delivering Quality by Design](#) (Baker, Macintosh-Murray, Porcellato, Dionne, Stelmacovich, and Born, 2008)

This book provides a literature review offering recommendations for executing successful quality improvement (QI) initiatives. It also profiles a number of health systems across the world to provide benchmarking and inspiration.

[Case Study of Physician Leaders in Quality and Patient Safety, and the Development of a Physician Leadership Network](#) (Healthcare Quarterly, 2010)

This case study examines the roles of four physician leaders from hospitals in Ontario and describes their contribution to the design and implementation of hospital quality and patient safety agendas.

[Quality Improvement Guide](#) (Health Quality Ontario)

The objective of this guide is to help healthcare organizations start and support quality improvement initiatives, with a recommended process overview, and accompanying tools and support materials.

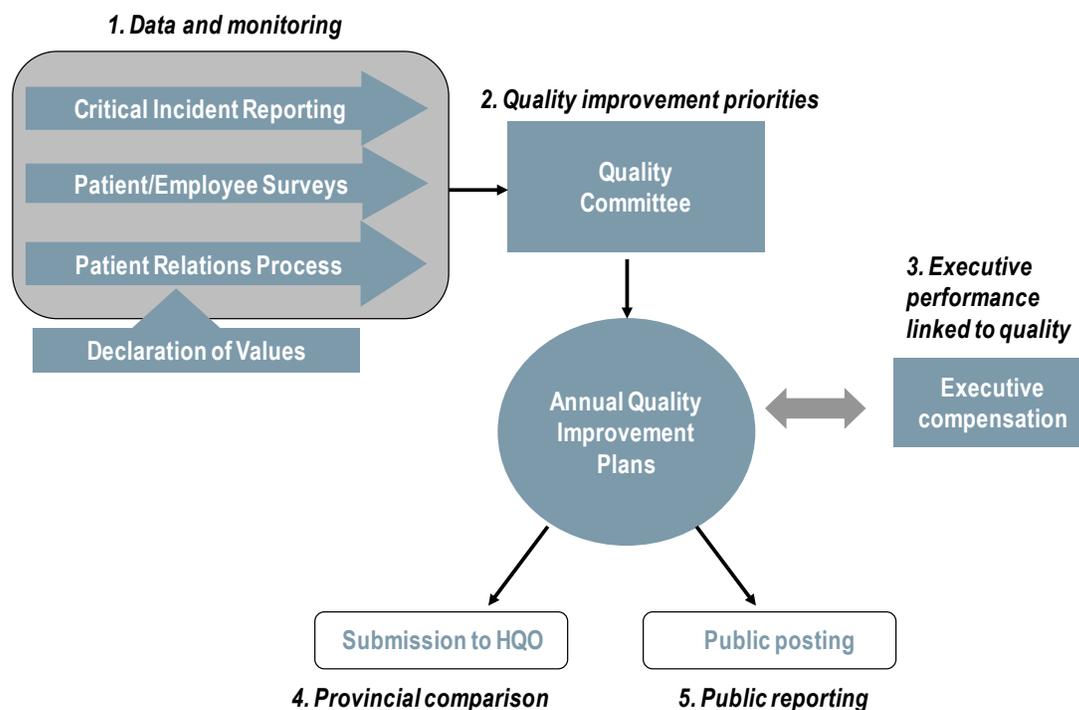
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ECFAA BACKGROUND AND CONTEXT

The diagram below provides an overview of all the key policy components under ECFAA.



ECFAA mandates that every health care organization must establish a Quality Committee that reports to the organization's Board of Directors. The Quality Committee is responsible for:

- monitoring and reporting on quality issues and overall quality of services;
- making recommendations for quality improvement priorities;
- ensuring best practices are shared with staff; and,
- overseeing the development of Quality Improvement Plans (QIPs).

ECFAA regulation also specifies the membership, composition and governance of Quality Committees.

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Further, related regulatory changes under the PHA establish an explicit link between the Quality Committee and the Medical Advisory Committee (MAC). Where the MAC identifies systemic or recurring quality of care issues, the MAC must make recommendations on these to the Quality Committee. The Quality Committee, in turn, must consider these recommendations in making its own recommendations to the Board.

Monitoring the patient experience and analyzing the relevant data is also a key requirement of ECFAA. Under ECFAA, hospitals are required to:

- Conduct patient surveys on an annual basis for patients and caregivers who received services from the institution within the past 12 months; the [Ministry of Health and Long-Term Care](#) (MOHLTC) provides some guidance and recommendations on how these surveys could be conducted.
- Conduct surveys of employees and persons providing services (e.g., physicians) within the organization every two years to measure provider satisfaction with their experience working at the organization, and their views about the quality of care provided by the organization.
- Develop a patient relations process that reflects the patient declaration of values. The [MOHLTC](#) states that the patient declaration of values will “help organizations continue to put patients first and move toward patient-centred care by clarifying what Ontarians can expect from their healthcare organizations.”

Under the PHA, hospitals are required to:

- Disclose individual critical incidents to the MAC, (Critical incidents are discussed in more detail in section 6.2.).
- Disclose aggregate critical incident data occurring at the hospital to the hospital’s Quality Committee at least twice a year. The aggregated data includes all critical incidents occurring at the hospital since the previous reporting period. Also, as described in Module 1, pursuant to agreements entered into by hospitals at the direction of the Ministry, public hospitals are required to report critical incidents related to medication/IV fluid occurring after October 1, 2011 to the National System for Incident Reporting (NSIR), a database which is administered by the Canadian Institute of Health Information (CIHI).

The data gathered through critical incident reporting, patient and provider surveys, and the patient relations process must be taken into consideration by the organization in the development of their annual QIPs.

ECFAA requires each institution to submit its annual QIP to Health Quality Ontario (HQO) for the purposes of provincial comparison and reporting on the performance improvement targets. In addition to being submitted to HQO, QIPs must also be made available to the public.

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QIPs are also directly linked to executive compensation. ECFAA requires that the compensation of the organization's CEO and other prescribed executives is linked to the achievement of performance improvement targets as set out in the annual QIPs ([MOHLTC, 2011](#)).

With these requirements, ECFAA equips the system with new tools and processes for achieving higher quality care. HQO – whose mandate was expanded through the ECFAA legislation – has been tasked with supporting many of ECFAA's requirements. Its mandate includes monitoring and reporting of key indicators to the public, supporting quality improvement priorities and initiatives within the healthcare sector, and translating evidence-based recommendations into practice.

For a more comprehensive discussion of each of the ECFAA components, please refer to OHA's guide on the ECFAA legislation.

Physician Leader's Roles and Responsibilities

As healthcare organizations increase their focus on quality improvement, patient safety, and risk management, strong leaders are needed to effectively manage change and build organization-wide commitment to high performance and safety.

ECFAA has created numerous opportunities for physicians to play a lead role in their organization's quality movement. These roles could include, among many others:

- Participating actively in their organization's Quality Committee and/MAC (Module 2 provides a detailed discussion of the role of the MAC and the responsibilities of physicians on the MAC);
- Developing a process and guidelines for critical incident reporting;
- Ensuring individual critical incidents are reported to the MAC and aggregate critical incident data is reported to the Quality Committee;
- Leading a team in the analysis of critical incidents and development of corresponding mitigation strategies;
- Providing input into the development and improvement of patient and provider surveys;
- Developing a mechanism for monitoring and analyzing patient and provider survey data;
- Identifying potential quality improvement opportunities through daily clinical responsibilities and interactions with other physicians and staff;
- Leading the design and implementation of quality improvement initiatives;

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- Providing input into the QIP development process;
- Setting an example for other physicians and staff by continuously promoting a focus on quality through daily activities and interactions;
- Developing excellent professional relationships with the organization's programs, thereby strengthening the inter-professional/multi-professional team approach to quality improvement, patient safety, and risk management; and,
- Using results from quality indicators to stimulate inter-professional dialogue about quality and safety.

The physician leader's role within any of these initiatives will depend greatly on the individual's role and leadership context. Those in senior leadership positions may be tasked with leading these initiatives themselves, or with selecting and overseeing dedicated individuals to manage them. The success of these initiatives often relies not only on local leadership, but also on all other physicians who will contribute to the implementation of the initiative, and continued compliance to procedures and guidelines that are developed.

The Need for Quality Improvement

Consistent with the ECFAA framework, improving the safety and quality of patient care is an increasingly important objective across all health systems. As improvements in science and technology have offered the promise of better healthcare and improved health, they have also increased complexity in the healthcare delivery system. The 2008 article, [High Performing Healthcare Systems: Delivering Quality by Design](#), notes "Many healthcare systems have been unable to cope with the acceleration of knowledge growth, thus creating a gap between the care that is possible and the care that is delivered".

Traditionally, excellence in healthcare has been defined in terms of individual physicians or caregivers. However, experts argue that improving quality and safety can only come from designing structures and processes that "reduce the likelihood of errors, make errors more visible, and provide the means to remediate before harm occurs" ([Baker et al., 2008](#)). Strong leadership is vital to all quality improvement and safety initiatives; physician leaders have important roles to play in their local clinics, care groups, and hospitals.

The following section provides an overview of quality improvement concepts, the quality improvement landscape in Ontario, and tools and resources for physician leaders managing and executing quality improvement initiatives.

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QUALITY IMPROVEMENT

A high quality healthcare system is defined by HQO as one that is accessible, appropriate, effective, efficient, equitable, integrated, patient-centred, population health-focused, and safe. The table below provides definitions of these attributes as they appear in HQO's [Quality Monitor](#).

Attributes of Quality	Outcomes
Accessible	People should be able to get timely and appropriate healthcare services to achieve the best possible health outcomes.
Effective	People should receive care that works and is based on the best available scientific information.
Safe	People should not be harmed by an accident or mistakes when they receive care.
Patient-centred	Healthcare providers should offer services in a way that is sensitive to an individual's needs and preferences.
Equitable	People should get the same quality of care regardless of who they are and where they live.
Efficient	The health system should continually look for ways to reduce waste, including waste of supplies, equipment, time, ideas and information.
Appropriately Resourced	The health system should have enough qualified providers, funding, information, equipment, supplies and facilities to look after people's health needs.
Integrated	All parts of the health system should be organized, connected and work with one another to provide high quality care.
Focused on Population Health	The health system should work to prevent sickness and improve the health of the people of Ontario.

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High-quality care results from effective practices and interactions of caregivers, patients, support staff, as well as the information they need to generate desired outcomes. The 2008 article, [High Performing Healthcare Systems: Delivering Quality by Design](#), notes that, “Quality improvement initiatives often include methods to analyze and improve (or design) work processes, techniques to collect and integrate patient information into the design of work, and methods to test and implement improvements.”

In its [Quality Improvement Guide for Long-Term Care](#), HQO presents a definition of healthcare quality improvement (QI) from the Hastings Centre in New York; “A broad range of activities of varying degrees of complexity and methodological and statistical rigour through which healthcare providers develop, implement and assess small-scale interventions, identify those that work well and implement them more broadly in order to improve clinical practice.”

A QI initiative is also defined by HQO as having the following features:

- Local interdisciplinary teams empowered and trained to set goals for improvement.
- Teams identifying causes of problems, barriers to quality or flaws in system design that lead to poor quality.
- Teams testing different ideas for improving how care is delivered in multiple brief, small experiments of change.
- Teams conducting frequent, targeted measurement of quality in a way that gives them instant feedback on whether the changes they are testing are heading in the right direction.

The Model for Improvement

The Model for Improvement is a simple and effective tool for accelerating improvement in healthcare organizations. The model, which was developed by Associates in Process Improvement and is endorsed by HQO as well as the [Institute for Healthcare Improvement](#) (IHI), aims to improve healthcare processes and outcomes using two basic components:

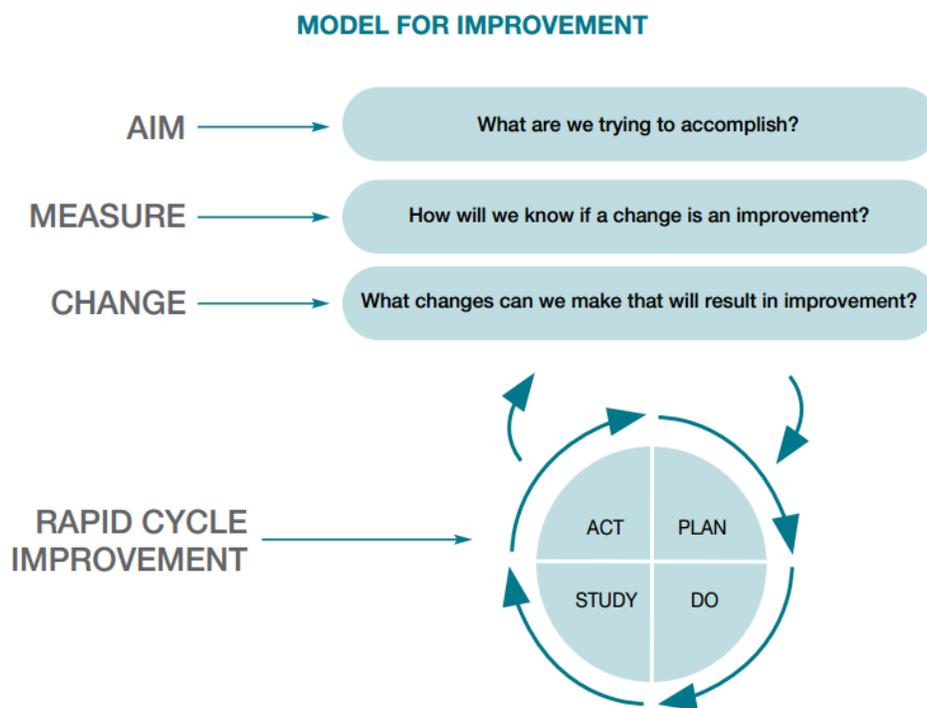
1. The first addresses fundamental questions about improvement goals, measurement, and possible changes; and
2. The second is a rapid-cycle, four-step process: Plan, Do, Study, and Act (PDSA), which allows organizations to develop, test, and implement changes for improvement.

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The following diagram offers a visual representation of this model:



HQO's Quality Improvement Guide offers step-by-step instructions for initiating and executing a quality improvement project, with tools and templates to help understand and analyze the process.

Leading Quality Improvement Initiatives

It is widely accepted that strong collaboration among physicians, nurses, and all other health professionals within the interdisciplinary team is critical to the success of quality improvement projects ([Reinertsen et al., 1998](#)). However, this remains a challenge in many hospitals. Reasons for this may include physician autonomy, administration approaching change from a systematic level without adequately considering service delivery implications, or insufficient formalized training in quality improvement.

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To overcome this challenge, healthcare institutions are developing formal physician leadership positions in quality and patient safety. A case study of physician leaders in Ontario hospitals observed the contributions leadership made to quality and patient safety agendas ([Hayes et al., 2010](#)): The following benefits were observed from having a physician in a quality improvement (QI) leadership role:

- The ability to incorporate clinical input into corporate initiatives.
- Greater credibility in the eyes of all health disciplines for having a physician in a leadership role.
- Increased involvement from the broader physician group in QI agendas.
- Improved adoption of the change initiative.
- More successful attitudinal and cultural change.

In a 2003 article, [Connections between Quality Improvement and Measurement](#), Bewick et al. states that leaders can influence the success of QI initiatives by ensuring that the organizational infrastructure necessary for improvement is in place, including:

- Leadership to guide and inspire improvement:
 - Leaders exemplify organizational values, and
 - Leaders celebrate and even participate in improvement initiatives.
- Alignment of strategic organizational incentives and improvement goals.
- Understanding of time and change management necessary to change core processes.
- Education and training for staff in improvement theory, methods, and techniques.
- Reliable flow of useful information.

Ultimately, the more that the individuals who will be implementing the change initiative are involved in the initial design and definition of the change, the more successful the initiative will be.

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IHI published a white paper, *Engaging Physicians in a Shared Quality Agenda*, which presents a framework hospital leaders can build upon to develop a written plan for physician engagement in quality and safety. HQO's *Improvement Map* also provides a helpful starting point for leading quality improvement projects, including an index of relevant resources and reference documents:

Additional Resources to Consult

[Tools for QI Teams; Links and Resources; MRP QIP Reference Guide](#) (Health Quality Ontario)

HQO is a government agency tasked with measuring and reporting to the public of Ontario on health system outcomes, in support of continuous quality improvement, and to promote healthcare supported by the best possible scientific evidence. HQO also offers tools for QI teams, and links and resources regarding QI in Ontario.

The *Most Responsible Physician Quality Improvement Program Reference Guide* provides quality improvement implementation supports that are aligned with the initiatives that 'Most Responsible Physician' (MRP) groups are pursuing in their Quality Improvement Programs, and a list of the initiative topics that each MRP has outlined in its program. The reference guide includes supports for a number of QI initiatives, including:

- Admission guidelines and policies,
- Patient flow, and
- Treatment protocols.

[Healthcare Quarterly Special Issue on ECFAA](#)

This special issue of *Healthcare Quarterly* highlights Ontario's healthcare system transformation with a special focus on ECFAA. The issue includes articles on patient-centred care, successful quality councils, leadership engagement, and perspectives on ECFAA.

[Quality and Patient Safety Governance Toolkit](#) (Ontario Hospital Association)

This online toolkit is designed as a set of practice templates and tools for hospital boards in Ontario. Topics covered include:

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- *Quality of the Board and its Practices*
- *Measurement and Reporting*
- *Board-Management Working Relationships that Support Quality Improvement*
- *Empowering Patients and Families*
- *Ensuring Strong and Effective Relationships with Physicians and Clinical Leadership*

[Education for Quality and Safety Leaders: A Needs Assessment and Program Review](#) (British Columbia (BC) Patient Safety & Quality Council)

This report describes the education and professional development needs identified by the BC health authority staff responsible for leading QI and patient safety initiatives, approaches to patient safety and quality training from 11 programs in Canada, the US, and the UK.

[Organizational Essentials for Quality Improvement Plans](#) (Baker & Baker, 2011)

This presentation from the National Health Care Leadership Conference discusses organizational essentials for high performance, key components of a quality plan, leadership requirements for performance excellence, and tensions between a quality plan and reporting requirements. It also provides a case study of creating and executing a quality plan at St. Joseph's Healthcare Centre, Toronto.

[Engaging Physicians in a Shared Quality Agenda](#) (Institute for Healthcare Improvement, 2007)

This white paper presents a framework on which hospital leaders might build a written plan for physician engagement in quality and safety. The paper includes tools to help hospital leaders assess organizational factors that can inform the degree of difficulty in engaging physicians, as well as to identify and prioritize initiatives for which physician engagement is essential.

[High Performing Healthcare Systems: Delivering Quality By Design](#) (Baker et al.)

This book provides a number of case studies of organizations and systems “that have made the pursuit of quality and safety a core element of their strategies, a part of everyone's work and the way they differentiate themselves from their competitors.”

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[Hospital Quality Improvement Plans](#)

As part of ECFAA, healthcare organizations are required to prepare annual QIPs for the following fiscal year, and to disclose the plan to the public. As part of the 2013/2014 QIPs, organizations are required to include a report on their progress against targets set out in 2012/2013.

[2012/13 Quality Improvement Plans: An Analysis for Improvement](#) (HQO)

For additional guidance on QIP development, physicians can consult HQO's 2012 QIP: An Analysis for Learning. This document identifies successful examples of plans that have a clear vision and strategy for improvement, with the aim of providing a learning opportunity for other organizations as they develop future QIPs.

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UNDERSTANDING PROCESS IMPROVEMENT

Process improvement is one aspect of broader quality improvement that organizations can undertake to help them achieve their priorities. In the healthcare context, process improvement techniques examine patient flow within the hospital or a particular ward/department from end-to-end, with the aim of identifying specific processes that can be redesigned to improve outcomes. These outcomes are often associated with improving efficiencies and/or the quality of care provided to patients.

Similar to their role in quality improvement initiatives, physician leaders can play a role in the identification, design and implementation of process improvement initiatives.

The remainder of this section provides a brief description of some commonly used process improvement techniques.

LEAN

“LEAN” is a management/production process that is essentially centred on increasing efficiency: preserving value with less work. Further, LEAN is a system that is designed to make the improvements work and be sustained. The expense of resources for any goal other than the creation of value for the customer/client is deemed wasteful, and thus a target for elimination. An application of LEAN can be observed in the ThedaCare business improvement system which recommends that standard work for leaders is a critical underpinning of program success.

Additional Resources:

- Healthcare Quarterly provides an overview through a 2009 article entitled, [Leading Lean for Canadian Healthcare Leaders](#) (Fine et al., 2009)
- The OHA offers an online certification course for [Lean Healthcare -- Greenbelt](#).

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LEADERSHIP QUOTE

In his Harvard Business Review essay on “Why Transformation Efforts Fail”, John Kotter points out that without a vision, transformation efforts can easily dissolve into a list of confusing and incompatible projects that take the organization in the wrong direction or nowhere at all. The tools of LEAN are not enough to deliver higher quality, safe care and improved morale. Sustainable improvement requires a system.

Whereas many organizations will take a project-based approach, North Bay Regional Health Centre plans to use a system that builds and supports a continuous improvement culture. This LEAN management process is designed after the Business Improvement System at ThedaCare. It has 10 elements:

1. Daily Unit Stat Sheet
2. Daily Huddle
3. Unit Leadership team
4. Monthly Scorecard
5. The monthly performance review meeting
6. Front Line Standard Work
7. Leader Standard Work
8. Visual Management
9. Unit waste removal activities including Rapid Improvement Events
10. PDSA (Plan, Do, Study, Act) – also known as the scientific method

One very exciting part of the system is the huddle board. Each of our units/departments will have a huddle board which supports the achievement of breakthrough goals and continuous daily improvement. This system will support frontline workers in solving problems every day and provide a way of translating strategy from the front line to the senior executives and back again.

Paul Heinrich
CEO, North Bay Regional Health Centre

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Six Sigma

Originating as a business management strategy, Six Sigma seeks to improve the quality of process outputs by identifying and removing the cause of defects (errors) and minimizing variability in business processes. Six Sigma projects carried out within an organization follow a defined sequence of steps with quantifiable targets. Many organizations also create a special internal infrastructure for organizational experts in these methods (known as “Black Belts”, “Green Belts”, etc.).

An article written in the Journal for Healthcare Quarterly provides an overview of how principles of Lean Thinking and Six Sigma can provide a framework for innovation in Healthcare ([de Koning et al., 2006](#)).

Root Cause Analysis/Corrective Action

Root cause analysis is a method for identifying and measuring problems or issues an organization is facing, then finding their root causes and understanding the relationships these root causes share. Steps are then taken to identify multiple potential solutions, test them through simulation, and implement them with control mechanisms to ensure the problem does not recur in the future.

Corrective action programs seek to eliminate the cause of a defect or error, and prevent its recurrence by ensuring its root cause is also eliminated.

Additional Resources to Consult

[Lean Hospitals](#)

Building on the success of the Shingo Prize-Winning first edition, [Lean Hospitals: Improving Quality, Patient Safety, and Employee Engagement, Second Edition](#), explains how to use the Lean management system to improve safety, quality, access, and morale while reducing costs. Lean healthcare expert Mark Graban examines the challenges facing today’s health systems, including rising costs, falling reimbursement rates, employee retention, and patient safety.

[Accreditation Canada](#)

Accreditation Canada is a not-for-profit, independent organization accredited by the International Society for Quality in Health Care (ISQua), providing national and international health care organizations with an external peer review process to assess and improve the services they provide to their patients and clients based on standards of excellence.

[What is Value in Health Care?](#) (Michael Porter)

This article from Michael Porter relates the concept of ‘value’ to a healthcare setting, and discusses the ways it can be better understood and measured.

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OVERVIEW

Advances in medicine over the years have substantially increased the complexity of care that many patients receive. This complexity – coupled with other factors such as an aging population, resource shortages, outdated models of training, and many others – has increased the likelihood of adverse events in the care that is provided to patients ([National Steering Committee on Patient Safety, 2002](#)). Patient safety continues to be an important topic for healthcare providers across Canada, as a number of media stories and legal cases on unintended adverse events have emerged over the years. Governments have continued to support the patient safety agenda, which has become tightly linked with the broader quality movement. As part of its patient safety strategy, the federal government established the Canadian Patient Safety Institute, which works with governments, health organizations, leaders, and healthcare providers to inspire extraordinary improvement in patient safety and quality.

Physicians must play an integral role in ensuring that the care provided to their patients meets the highest standards in safety and minimizes the potential for unintended adverse events. Physician leaders should take this responsibility further by providing a structure and mechanism to their peers and other health professionals, for reporting, analyzing, and resolving potential errors and adverse events. For example, morbidity and mortality rounds are mechanisms for reporting and discussing patient safety issues.

UNDERSTANDING ADVERSE EVENTS

Adverse events are defined in the [Canadian Adverse Events Study](#) (Baker et al., 2004) “*unintended injuries or complications that are caused by healthcare management, rather than by the patient’s underlying disease, and that lead to death, disability at the time of discharge or prolonged hospital stays.*” While some adverse events are unavoidable (e.g., unanticipated allergic reaction to a drug), estimates show that roughly half of all adverse events are potentially preventable.

The [Canadian Adverse Events Study](#) provided a starting point for developing strategies to minimize the incidence of avoidable adverse events. Among the key findings, the study notes that one of the most important factors in improving patient safety is ensuring the work environment of healthcare professionals encourages the development of initiatives for minimizing adverse events and their effects.

In this context, physician leaders must encourage the reporting of adverse events, continued monitoring, and improved communication and coordination among care providers.

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Additional Resources to Consult

[Canadian Patient Safety Institute](#)

The Canadian Patient Safety Institute (CPSI) is a not-for-profit organization that exists to raise awareness and facilitate implementation of ideas and best practices to achieve a transformation in patient safety. They develop evidence-informed products and resources that are customized for the frontline, middle managers, senior leaders, and boards.

[A Guidebook to Patient Safety Leading Practices: 2010](#) (Ontario Hospital Association)

The aim of this guidebook is to highlight and share innovative patient safety initiatives in Ontario hospitals, focused on four themes: boards and leadership, teamwork and communication, transparency of data and accountability, and patient and family and engagement.

[University of Toronto Centre for Patient Safety](#)

The Centre for Patient Safety creates, disseminates, and implements new knowledge in the field of patient safety at the University of Toronto and its affiliated hospitals. Examples of initiatives include:

- *Quality improvement workshops, including an annual symposium*
- *Publications on a range of patient safety-related topics*
- *A researcher database*
- *A broad range of consulting services*
- *Learning sessions in Patient Safety and Quality Improvement, including a certificate program course for clinicians and administrators*

[Institute for Safe Medication Practices Canada](#)

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent, national, not-for-profit organization committed to the advancement of medication safety in all healthcare settings and the promotion of safe medication practices. They offer educational events, publications, and medication safety tools and checklists for healthcare organizations.

Quality of Care Information and Protection Act

As described in Module 1, the [Quality of Care Information and Protection Act](#) (QCIPA) addresses the public interest in facilities engaging in quality of care and peer review activities by prohibiting disclosure of quality of care information generated for the purposes of a designated “quality of care committee”.

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Enacted in 2004, QCIPA was developed in response to the growing importance of patient safety. QCIPA promotes the patient safety agenda in Ontario by providing a legislative vehicle for hospitals and other health facilities to review adverse events with the assurance that the information resulting from the review is protected from disclosure. In short, QCIPA promotes increased information sharing and unfiltered collaboration among health providers, with the aim of understanding and resolving avoidable adverse events.

For more information on QCIPA, physicians are encouraged to consult OHA's QCIPA Toolkits (2004 and 2007).

Disclosure of Harm

Despite best efforts to ensure patient safety, patients may incur harm during the delivery of healthcare. Harm is not always preventable, nor is it necessarily an indicator of substandard care. Disclosure of harm provides patients with the information they need to make autonomous, informed decisions about their healthcare and promotes a culture of safety where openness, transparency and learning from adverse events are encouraged.

Physicians owe a common law legal duty to disclose errors to their patients. This duty arises from the doctrine of informed consent and the fiduciary relationship between a physician and a patient. The duty to disclose has been adopted in the codes of ethics of the majority of professional governing bodies, and is often addressed in institution-specific policies and procedures.

As described previously, hospitals are now also required by the Hospital Management Regulation to disclose all "critical incidents" to patients or family members, the hospital's administrator and the MAC. The hospital board is required to ensure that the hospital administrator establishes a system for ensuring the disclosure of critical incident as soon as practicable after the incident occurs. Disclosure must include:

- The material facts of what occurred;
- Consequences for the patient as they become known; and
- The actions taken and recommended to be taken to address the consequences to the patient.

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The Hospital Management Regulation defines a “critical incident” as any unintended event that occurs when a patient receives treatment in the hospital that results in death or serious disability, injury or harm to the patient, and does not result primarily from the patient’s underlying medical condition or from a known risk inherent in providing treatment. Many hospitals will have different definitions of critical/adverse events and/or errors, but the definition in the PHA will shape the hospital’s statutory disclosure obligations.

The Hospital Management Regulation (HMR) also requires that critical incidents be charted in the patient’s medical record. HMR further requires that the hospital board ensures that the administrator establish a system for analyzing the incident and taking steps to avoid or reduce the risk of further similar incidents occurring, and that there be disclosure of this information to patients or family members at an appropriate time following the initial critical incident disclosure.

In addition, ECFAA requires hospitals to develop QIPs that take into account, among other factors, “aggregate critical incident data as compiled based on disclosures of critical incidents”.

The HMR provides that the requirement to disclose these systemic steps is also subject to the requirements of QCIPA. The relationship between disclosure of critical incidents and QCIPA is complex. Additional guidance is provided in the [OHA’s December 2010 Legislative Update](#).

It is important to note that Ontario has adopted legislation that supports the use of an apology when an adverse event or critical incident occurs. Under the *Apology Act*, an apology made in connection with any matter will not be considered an express or implied admission or fault or liability in civil and administrative proceedings.

The following resources are also available to physicians for reference regarding policies and guidelines on the disclosure of harm.

Additional Resources to Consult

[*The Ministry of Health and Long-Term Care Guidelines for Critical Incident Reporting*](#)

This document provides Ministry guidelines for critical incident reporting, and refers to the World Health Organization’s International Classification for Patient Safety (ICPS) framework.

[*Canadian Disclosure Guidelines: Being Open with Patients and Families*](#) (Canadian Patient Safety Institute, 2011)

The purpose of these guidelines is to support and guide healthcare providers on communicating when harm occurs in healthcare, and to encourage organizations to develop policies and processes to effectively support communications.

[*The College of Physicians and Surgeons of Ontario Disclosure of Harm Policy*](#) (2010)

This policy articulates the College’s expectations of physicians for informing patients when harm is sustained in the course of receiving healthcare including, the legal basis for disclosure, what and when to disclose, whom to disclose information to, and who should disclose this information.

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[Learning from Adverse Events: Fostering a just culture of safety in Canadian hospitals and health care institutions](#) (The Canadian Medical Protective Association, 2009)

This booklet describes the requirements and processes for reporting adverse events and close calls, and the best approach for reviewing these events. It also explains how CMPA members and other healthcare providers can foster a culture of safety within a hospital/institution, whether they are in a leadership/management role or a participant in the reporting and review process.

[Communicating with your patient about harm; Disclosure of Adverse Events](#) (The Canadian Medical Protective Association, 2008)

This report offers definitions of the terms harm, adverse event and disclosure, a framework for understanding harm, an explanation of the different stages of disclosure, and a brief synopsis of no-harm events.

[Adverse Health Event Management: International and Canadian Practices](#) (Gregory)

This paper aims to facilitate an understanding of the international, national, provincial and organizational “leading practices” in adverse health event management.

[Ontario Guide to Disclosure: Implementing the Amendments to Regulation 965 under the Public Hospitals Act](#) (OHA)

Available for purchase via: This guide summarizes existing provincial disclosure legislation and provides resources to support the disclosure process.

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Section 6.3: Quality Improvement and Safety

OVERVIEW

While patient safety is one significant risk that hospitals must properly manage, there are many other risks that healthcare organizations encounter. For instance, hospitals may encounter financial risks in meeting overall financial budgets/commitments; human resource risks in the ability to attract, develop and retain the talent needed to meet its objectives; or privacy risks with regards to the safeguarding of personal information or data, to name a few.

Healthcare organizations are focusing more attention and effort on risk management, due to both external factors (such as public expectations for greater accountability and governance), and internal factors (such as better resource allocation).

The following section provides an overview of risk management strategies, and provides useful tools for physician leaders tasked with managing risk. Physician involvement in risk management activities will vary greatly from institution to institution and depend on the physician's role within the leadership structure.

At the very least, all physician leaders can expect to be involved in the patient safety aspect of risk management (as discussed in the previous section). With respect to other risks within the organization such as financial risks, human resource risks, privacy risks, and others, physician leaders may provide input into various aspects of risk management (identification, assessment, mitigation, etc.). Physician leaders are encouraged to consult with hospital administration to understand their hospital's model for risk management and their potential role in risk management activities.

Key Sources

[Integrated Risk Management \(IRM\) For Healthcare Organizations: Risk Management Resource Guide](#) (HIROC)

The purpose of this resource guide is to review the basic elements of IRM and, without prescribing an exact format or critiquing any particular approach, to offer sensible, efficient, and effective techniques and tips for IRM implementation.

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WHAT IS INTEGRATED RISK MANAGEMENT?

Risk Management is a function of the administration of a hospital or other health care organization that is directed toward the identification, evaluation, and correction of potential risks which could lead to injury for patients, staff members, or visitors, and result in property loss or damage (Mosby's Medical Dictionary, 2009). Many organizations manage large risks independently of one another, often within organizational silos, and this can lead to overlooking major risks. An alternative solution, IRM, provides a common framework for understanding and prioritizing very different types of organizational risks from all areas of the organization ([HIROC, 2011](#)).

The Emergency Care Research Institute (ECRI) defines IRM as:

“An approach for identifying critical risks, quantifying their potential impact and likelihood, prioritizing, and identifying risk management strategies to bring risks to acceptable levels”.

HIROC developed a risk management process for IRM that is built on the following eight steps: deciding on a simple framework, ensuring oversight and coordination, confirming organizational context, assessing risks, reporting risks, managing risk, and evaluating and improving the IRM program.

For additional information on this process, and accompanying tips and suggestions, physicians are encouraged to consult the *IRM Resource Guide* on HIROC's website.

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WHY MANAGE RISK?

A number of internal and external factors may influence healthcare organizations in Canada to implement integrated risk management strategies. The following examples were highlighted in the 2011 HIROC publication, [‘Integrated Risk Management \(IRM\) for Healthcare Organizations: Risk Management Resource Guide’](#):

External Drivers

1. Public accountability and reputation: expectations for public accountability in healthcare are increasing, including better fiscal responsibility for public funds. This is also becoming a more important factor for recruitment of competent staff, board members, and donors.
2. Governance: a call for better corporate governance is influencing the health system, as organizations and their boards are moving towards ensuring processes are in place to identify and manage risk.
3. Accreditation: Canada’s new [Qmentum](#) standards have articulated the need for leadership teams to implement integrated risk management strategies.
4. Provincial government uptake: IRM has been adopted by the ministries of health in British Columbia, Alberta, and Ontario.

Internal Benefits

1. To reduce the internal impact of surprises in the future.
2. To allocate valuable resources according to risk priorities.
3. To comply with relevant legal and regulatory threats and international norms.
4. To improve stakeholder confidence and trust.

Challenges to IRM

There are considerable challenges and costs associated with an IRM implementation. Coordinating IRM is extremely complex, as leaders need to have the organization- and system-wide view in mind at all times, while coordinating the multitude of stakeholders on the ground.

Among the most significant barriers to successful implementation are overly complicated structures and processes. The, [Ten common misconceptions about enterprise risk management](#), a Morgan Stanley publication, states that “failure to recognize that [IRM] is in fact an easier, simpler, and more logical undertaking than most people realize”. Risk management should follow a simple, well-understood process, with a dedicated coordinator role in place from the beginning.

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Another challenge occurs in acting upon the risks that were assessed. Often, a lack of clarity and accountability around objectives will lead to a failure to follow through on risk assessment findings. To overcome this challenge, objectives and action items should be clearly linked to an owner, with a timeline that is clearly defined ([PricewaterhouseCoopers, 2008](#)).

Additional Resources to Consult

[Healthcare Insurance Reciprocal of Canada](#) (HIROC)

HIROC is an insurance reciprocal (members insure themselves and each other, sharing the risk) that works in partnership with healthcare organizations across Canada to provide stable and cost-effective medical malpractice liability insurance, claims management expertise, and risk management services.

[A Practical Guide to Risk Assessment](#) (PricewaterhouseCoopers)

A practical guide defining risk assessment, offering key principles for effective and efficient risk assessments, and outlining essential steps for performing a risk assessment.

[Risk and Insurance Management Society, Inc.](#)

The RIMS Canada Council (RCC) is a standing committee of RIMS representing the Canadian chapters. The RCC addresses the strategic initiatives of RIMS and risk management issues in Canada.

[Canadian Healthcare Risk Management Network](#)

The Canadian Healthcare Risk Management Network (formerly Ontario only) is a membership-based forum for healthcare professionals to discuss current issues in risk management, patient safety, and quality, share information, and network.

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Section 6.4: Change Management Principles

OVERVIEW

Effective leaders are able to recognize that changing environments provide opportunities to introduce new innovations, improve efficiency, and strengthen the quality of the organization. Successfully managing change often requires concerted coordination of strategy, organizational buy-in, and the adoption of new behaviours. The following section provides leadership strategies and tools for managing change, that are specifically focused on the healthcare service delivery environment.

Key Sources

[Implementing strategic change in a health care system: The importance of leadership and change readiness](#) (Health Care Management Review, 2008)

This study explores how three variables—agreement with new strategy, leaders' actions, and groups' general orientation towards change—can influence members of physician teams to take actions supporting a strategic shift aimed at improving patient satisfaction.

[Strategies and Tools for Managing Change](#) (MacPhee, 2007)

This article describes major leadership strategies and tools for effectively managing change; observing traits of leaders, followers, and the organization; and offering relevant change management tools.

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KEY VARIABLES INFLUENCING EFFECTIVE CHANGE

A 2008 Health Care Management Review article titled, '[Implementing strategic change in a health care system: The importance of leadership and change readiness](#)', explored how three key variables influenced physicians to take actions to support a strategic shift aimed at improving patient satisfaction. The results can be applied to healthcare settings more broadly, and offer physician leaders insight into key variables they will face when initiating change:

1. Agreement with new strategy

When members of a team or organization have consensus about the direction of a strategic change, this has a positive influence on the success of implementing that change.

2. Actions of leaders

Leaders of a group or organization, specifically middle-level managers, have a strong ability to enhance or undermine the organization's ability to implement strategic change. Leaders who effectively demonstrate support for a new strategy are likely to see greater or faster improvements resulting from the change initiative, and mid-level managers specifically serve as an important gatekeeper of bottom-up change ([Woodbridge and Floyd, 2006](#)).

3. General orientation toward change

Group/network norms and capabilities can also influence the success of a change initiative, regardless of whether that group is supportive of the initiative or not. For example, norms determine whether people are rewarded or punished for embracing change. When group norms are not consistent with new behaviours, individuals may resist change for fear of informal sanctions. Alternatively, group norms that value innovation may see greater success from the change initiative.

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LEADERSHIP QUOTE

"Leadership is Influence, Nothing More, Nothing Less."

John Maxwell

Author, *The 21 Irrefutable Laws of Leadership*

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Combining variables

The combined effect of these three variables should be considered when implementing a new strategy. Individuals may agree with the new strategy, but lack the group norms or capabilities for successful implementation. Leaders may demonstrate support for the strategy, but may also need to provide direction and resources to ensure a group has the ability to implement the strategy. Ultimately, success of a change initiative hinges on two key factors:

1. The ability to understand the complexities of the change initiative; and
2. The willingness of individuals to change their actions to support the implementation of the new strategy (the aforementioned key factors can influence that willingness).

Change Model: Four Stages of Change in Healthcare Organizations

Healthcare organizations face unique challenges when implementing a change initiative. Often these organizations have multiple missions, such as providing healthcare, employing community members, and remaining financially steady. There are also many autonomous stakeholders to consider when managing the change, such as employees, funders, and patients. A 2006 [Healthcare Quarterly article](#) outlined a four-stage change management process for healthcare organizations.

Stage One: Determine Desired End State

1. Identify performance gap or opportunity (e.g., strategic or technical opportunities have emerged);
2. Create specific measurable goals;
3. Consider systems and activities required to measure these goals; and,
4. Discuss required new behaviours, capabilities, organizational structure, and systems.

Stage Two: Assess Readiness for Change

1. Conduct a broad situational analysis, considering:
 - a. Who are the key stakeholders, and do they recognize need for change?
 - b. Who are the likely supporters or opponents?
 - c. Are resources available to implement change?
 - d. Will new capabilities need to be developed?
 - e. Are there past examples of organizational change to learn from?

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2. Enlist appropriate change leader(s); they should be influential, motivated, connected, and skilled leaders:
 - a. This may take the form of individual leaders, or a steering committee of individuals who take on different responsibilities in the change initiative.

Stage Three: Broaden Support and Organizational Redesign

1. Develop and execute a communication strategy delivered by a credible source, with tailored messages for target audiences:
 - a. Communicate what the change is, why it is occurring and why now, how it will affect individuals in the organization, and why they should support it.
2. Ensure affected staff can appreciate the benefits of change by designing an organizational system that is aligned with the change:
 - b. Consider the Star Model when designing this organization. The following subsystems are 'points' of the star which must work together ([Golden and Martin, 2004](#)):
 - Goals and tasks
 - Structure
 - People and human resource policies
 - Rewards
 - Information and decision support

Stage Four: Reinforce and Sustain Change

1. Initiate performance monitoring efforts to:
 - a. Showcase successes and reward supporters;
 - b. Recognize and support any losses associated with the change process; and
 - c. Reconsider goals in light of new information or opportunities.
2. Reflect on the change process by asking:
 - a. What could have been done differently/more quickly/with fewer resources?
 - b. Have the right changes occurred?

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THE ROLE OF LEADERSHIP IN DRIVING CHANGE

Strategic change derives maximum positive impact when groups support the new direction that the organization is taking.

LEADERSHIP QUOTE

“Informed and engaged physician leaders working with the administration of the hospital is a successful recipe for organizations to remain current, patient-centred, and innovative.”

Dr. Gillian Kernaghan
President, St. Joseph's Health Care London

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Leaders can influence this support by:

1. Focusing on building support for the strategic changes with direct, consistent communication:
 - a. Help members of the organization understand both the benefits or outcomes of change, and the risks of continuing with the status quo (e.g., a safer work environment).
 - b. Outcomes should be realistic, valued, and manageable.
2. Looking for new ways to involve staff in identifying ways of implementing the strategy:
 - a. Allow individuals to take ownership of implementation to improve buy-in.
3. Modeling behaviours to build group norms that value change:
 - a. Approach mistakes as opportunities for learning and correction;
 - b. Reward team performance;
 - c. Be willing to try new things;
 - d. Convey energy toward reaching goals; and
 - e. Remain visible and positive to counter apathy or low morale.

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4. 'Chunking' complicated initiatives into more manageable parts that can be implemented locally:
 - a. Change happens more quickly when an initiative is simple and where local adaptation is possible.
 - b. Asking people to think and act outside their range of local influence can lead to discouragement.
5. Provide appropriate rewards for improved performance:
 - a. Rewards should be aligned with the pre-set, measurable goals of the change initiative.
 - b. Social recognition should be balanced with financial compensation.

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CHANGE MANAGEMENT TOOLS

The following tools from [Strategies and Tools for Managing Change](#) (MacPhee, 2007) can help facilitate a change management process:

The Vision / Mission Statement

A clear vision and mission can unify the values of stakeholders, leading to collaboration. The change process should begin with a vision/mission analysis, and a project plan for bringing the vision and mission to life. The following table offers a template for conducting a mission/vision analysis:

Step	Key Question	Explanation
1	What is the organization's basic purpose?	<ul style="list-style-type: none">• Consider priorities of the hospital, strategic partners, the ministry, and the community.
2	What is unique or distinct about the organization?	<ul style="list-style-type: none">• This is the "selling point" for stakeholders, especially external stakeholders.
3	What is the future orientation?	<ul style="list-style-type: none">• One to two sentences should summarize future strategy or organizational aspirations.
4	Who are the key stakeholders?	<ul style="list-style-type: none">• Some statements include examples of key internal and external stakeholders. This can be a powerful way to get "buy-in" from stakeholder groups -- include them in the vision/mission statement.
5	What are the key words or phrases?	<ul style="list-style-type: none">• Do these words represent the organizational culture's values, beliefs, and practices?• If they are enduring words, they should serve as a "thread" in departmental philosophy statements, and in project plan descriptions, goals, and objectives.

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Team Brainstorming and Pre-planning Exercises

- a. Identify the critical success factors of your new strategy, the “must have’s” and desired results.
- b. Conduct a stakeholder analysis: consider which groups will be impacted by the change, and their level of commitment to implementing the new strategy.
- c. Consider drivers and restraints in the ‘bigger picture’. Consider a SWOT analysis (strengths, weaknesses, opportunities, and threats) that examines the internal strengths and weaknesses, and the external opportunities and threats.

Teamwork and Project Management

Effective teamwork and project management are critical to the success of change projects. See Section 4.1 for recommendations for managing high-performance teams, and Section 5.2 for helpful project management tools.

Environmental Scan Tools

Two tools can be useful in conducting a quick environmental scan during the process of change management. One tool is referred to as the “SWOT” analysis described above, which encourages a leader to consider the “strengths”, “weaknesses”, “opportunities”, and “threats” for various contexts (e.g., an analysis of the organization, department or a particular initiative).

Another helpful preliminary tool is the “PESTEL”, which is often used in strategic planning processes. The “PESTEL” tool employs “political” (P), “economical” (E), “social” (S), “technological” (T), “environmental” (E), and “legal” (L) analyses of an issue. These tools are not meant to be exhaustive in their scan, but rather serve as a starting point for evaluation.

Additional Resources to Consult

[Leading Change: Why Transformation Efforts Fail](#) (Kotter, 2007)

In one of Harvard Business Review’s most popular change management articles, John P. Kotter identifies the eight largest errors that organizations can make that can doom their change management efforts (known as the Kotter 8-Step Model for Leading Change).

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Module 6: Quality, Safety and Risk Management

Section 6.5 - Resources for understanding clinical research in the hospital

OVERVIEW

The role that a physician plays in clinical research throughout their career depends greatly on his or her level of interest, and in the nature of the clinical trials conducted in their clinical environment or practice area. Participation in clinical trials can have significant benefits for physicians:

- It gives physicians a publishing opportunity, which brings significant credibility in the academic community.
- It can lead to opportunities for promotion.
- It allows physicians to strengthen their position as a key opinion leader and consultant, regardless of whether they are paid directly for their clinical trial services.

The Physician Leaders Role in Clinical Research

Research is conducted in hospitals by clinicians, but each institution has access to its own approval process (the Research Ethics Board), with which clinician research is required to comply before conducting research on the premises. Again, research and clinical discoveries at hospitals may be subject to an affiliation agreement with a university, and/or research policies and procedures which should be consulted and understood by physician leaders when considering research opportunities.

At the lowest level of participation, a clinician may be involved in a Phase III trial ([Health Canada, 2009](#)), where they would see the patient and follow a script. Ultimately, they are responsible only for seeing that nothing goes very wrong for that patient. The patient selection and data collection would only be carried out by a trial coordinator. Participation in Phase I/II research sees clinicians contributing to the development of the research protocol, where skill and speed are important success factors.

Clinicians who are active researchers and who understand the underlying pathophysiology of the conditions in question are invaluable to clinical trials. They are able to lift the performance of both the research and clinical components of the trial.

Hospital leaders improve leadership within the clinical research arena by putting more effort into identifying and nurturing these unique clinician scientists, perhaps through special remuneration and recognition packages.

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CLINICAL TRIALS: GOVERNANCE RESOURCES

The following documents provide useful information and policies that guide clinical research governance in Canada.

1. [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans](#) (2nd. Ed.)

A joint policy of Canada's three federal research agencies – The Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC), is a benchmark for the ethical conduct of research involving humans in Canada, and compliance with the policy is a requirement of federal funding.

2. [Clinical Trials Manual](#) (Health Canada)

This manual provides tools and relevant links to facilitate the successful filing of a Clinical Trial Application (CTA) to Health Canada, for clinical trials that involve the use of Pharmaceutical and/or Biological and Radiopharmaceutical drugs in human subjects. The manual is an administrative instrument, and where information is inconsistent with regulations, the regulations should take precedent. Topics include:

Background Information

- Publication: e.g., naming of authors, publishing results
- Intellectual Property: e.g., ownership and use of data, ownership and use of inventions
- Food and Drug Act, Regulations overview and key links
- Clinical Trials Application information
- Roles of Stakeholders (Health Canada, Sponsor, Research & Ethics Board, Qualified Investigators)
- Compliance to Regulatory Framework
- Classification of Clinical Trials (Phases I through IV)

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Clinical Trials

- Overview of the Application Process (preparation, submission, screening, evaluation, authorization/rejection, submission of amendments, and post-authorization requirements)
- Investigator/Institution Initiated Clinical Trials
- Accountability & Transparency
- Relevant Links
- Abbreviations and Definitions
- Frequently asked Questions
- Contact Info and Useful Links

3. [Statement of Principles to be Considered When Negotiating a Clinical Studies Agreement](#) (Council of Academic Hospitals of Ontario)

This document sets out the recommended minimum standard requirements for Ontario academic hospitals when negotiating a clinical study agreement. It is not meant to be interpreted as contract language, but rather to express the general concepts that should be included in contracts. Principles covered include:

- Publication: e.g., naming of authors, publishing results
- Intellectual Property: e.g., ownership and use of data, ownership and use of inventions
- Confidentiality: e.g., nature of confidentiality obligation, permitted disclosures, terms
- Privacy
- Indemnification: e.g., indemnitor obligations, exclusions, and conditions
- Limitation of Liability of Institution/Investigator/No Warranties
- Disclosure of Existence of Contract and Use of Name
- Parties' Rights and Obligations: e.g., compliance, conflict, force majeure
- Dispute Resolution and Governing Law/Jurisdiction
- Termination: e.g., termination events, survival of rights/obligations following termination

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4. [Law and Ethics in Biomedical Research: Regulation, Conflict of Interest and Liability](#) (Trudo Lemmens, Duff Waring)

Law and Ethics in Biomedical Research uses the Gelinger case as a touchstone, illustrating how three major aspects of that case -- the flaws in the regulatory system, conflicts of interest, and legal liability -- embody the major challenges in the current medical research environment. Editors Trudo Lemmens and Duff R. Waring, along with a host of top scholars in the field, demonstrate why existing models of research review and human subject protection are in need of improvement, and how more stringent regulatory and legal means can be used to strengthen the protection of research subjects and the integrity of research.

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CLINICAL TRIALS: ETHICAL AND LEGAL FRAMEWORKS

The following documents provide useful information and frameworks for conducting clinical trials in Canada, legally and ethically.

1. [Ethical Conduct for Research Involving Humans](#) (CIHR, NSERC, SSHRC)

This joint policy of Canada's three federal research agencies is a benchmark for the ethical conduct of research involving humans, and acts as a condition for individuals and institutions to be eligible to receive and administer funding from the Agencies. The site also offers companion documents, including highlights of the policy, and tables of concordance. Topics covered by the policy include:

Chapter	Topic	Sections
1	Ethics Framework	a) The Importance of Research and Research Ethics b) Core Principles c) How to Apply this Policy
2	Scope and Approach	a) Scope of Research Ethics Review b) Approach to Research Ethics Board Review
3	The Consent Process	a) General Principles b) Departures from General Principles of Consent c) Capacity d) D. Consent Shall Be Documented
4	Fairness and Equity in Research Participation	a) Appropriate Inclusion b) Inappropriate Exclusion
5	Privacy and Confidentiality	a) Key Concepts b) The Ethical Duty of Confidentiality c) Safeguarding Information d) Consent and Secondary Use of Identifiable Information for Research Purposes e) Data Linkage
6	Governance of Research Ethics Review	a) Establishment of Research Ethics Boards b) Procedures for Research Ethics Board Review c) Reconsideration and Appeals d) Research Ethics Review during Publicly Declared Emergencies

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7	Conflicts of Interest	<ul style="list-style-type: none"> a) Key Concepts b) Institutions and Conflicts of Interest c) Research Ethics Board Members and Conflicts of Interest d) Researchers and Conflicts of Interest
8	Multi-Jurisdictional Research	<ul style="list-style-type: none"> a) Review Mechanisms for Research Involving Multiple Institutions and/or Multiple Research Ethics Boards b) Review of Research Conducted Outside the Institution
9	Research Involving the First Nations, Inuit, and Métis Peoples of Canada	<ul style="list-style-type: none"> a) Key Concepts and Definitions b) Interpreting the Ethics Framework in Aboriginal Contexts c) Applying Provisions of This Policy in Aboriginal Contexts
10	Qualitative Research	<ul style="list-style-type: none"> a) Nature of Qualitative Research b) B. Research Ethics Review of Qualitative Research
11	Clinical Trials	<ul style="list-style-type: none"> a) Key Concepts b) Clinical Trial Design and Registration c) Assessing Safety and Minimizing Risk d) Financial Conflicts of Interest e) Analysis and Dissemination of Clinical Trial Outcomes
12	Human Biological Materials Including Materials Related to Human Reproduction	<ul style="list-style-type: none"> a) Types of Human Biological Materials b) Collection of Human Biological Materials c) Consent and Secondary Use of Identifiable Human Biological Materials for Research Purposes d) Storage and Banking of Human Biological Materials e) Research Involving Materials Related to Human Reproduction f) Research Involving Pluripotent Stem Cells
13	Human Genetic Research	<ul style="list-style-type: none"> a) Application of Core Principles to Genetic Research b) Plans for Managing Information Revealed through Genetic Research c) Genetic Counselling d) Genetic Research Involving Families e) Genetic Research Involving Communities and Groups f) Genetic Material Banks g) Gene Transfer

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2. [Canadian Bioethics Companion](#) - Chapter 8: Research Ethics (Unger, 2011)

This chapter from the Canadian Bioethics Companion provides a Roadmap of Canadian research ethics regulations and oversight, including grants and funding, and overview of regulations and guidelines, research ethics boards, and legal considerations. Topics covered include:

- Evolution of Research Ethics Guidelines
- Roadmap of Canadian Research Ethics Regulations and Oversight:
 - Grants and Funding
 - Overview of Regulations and Guidelines
 - Legal Considerations
- Research Involving Humans – the Tri-Council Policy Statement
- Research Involving Animals
- Responsible Conduct:
 - Conflicting and Competing Interests
 - Authorship and Publication
 - Research Misconduct
 - Liability
- Summary and References

3. [Good Clinical Practice \(GCP\): Consolidated Guideline](#) (Health Canada, 1997)

This guidance document is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. The document provides assistance to industry and healthcare professionals on **how** to comply with the policies and governing regulations. Topics covered include:

- Principles of Good Clinical Practices – International Conference on Harmonization
- Institutional Review Board/Independent Ethics Committee
- Investigator (qualifications and agreements, resources, compliance, reporting, etc.)
- Sponsor (quality assurance and control, trial design, financing, compensation, monitoring etc.)
- Clinical Trial Protocol and Protocol Amendment(s)
- Investigator's Brochure
- Essential Documents for the Conduct of a Clinical Trial (before, during, and after)

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4. [A Guide to the Personal Health Information Protection Act](#) (Information and Privacy Commissioner/Ontario)

This guide provides information about how the Personal Health Information Protection Act applies to the course of day-to-day activities and more specific scenarios. It also provides answers to frequently asked questions regarding the act. Topics covered include:

- Guide purpose
- Overview of the Act
- Does the Act apply to you?
- What information does the Act protect?
- Practices to protect personal health information
- Collection, use, and disclosure of personal information
- Access to personal health information records
- Correction
- How will the Act be enforced?
- Definitions

Additional Resources to Consult

[Clinical Trials Asset Map: A Showcase of Ontario's Excellence in Clinical Research](#) (Ministry of Research and Innovation, 2012)

This publication provides an overview of Clinical Trial activity in Ontario, demonstrating Ontario's advantages as they relate to research and innovation, showcasing key clinical trial activities, and spotlighting world renowned researchers in Ontario.

[Canada's Strategy for Patient-Oriented Research](#) (Canadian Institute for Health Research, 2012)

This document sets out a vision and strategy to improve health outcomes and enhance patient care through the lever of research. It observes and addresses strengths and weaknesses of the Canadian and International landscape, then provides a strategy for Canada.