



Canadian College of
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Fellowship Program – Special Project

**Pursuing Enterprise Risk Management: A Local Roadmap for Canadian Health Care
Leaders**

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Executive Summary

In the broader business community, organizational risk management programs have been shown to be a highly effective way for senior leadership teams to capture, assess, and manage risks across the breadth of an enterprise. By taking a coordinated approach to managing risks, organizations are able to detect risks earlier, devote time and expertise to understanding the nature of issues, and promote timely and informed strategic decisions in line with the overall values and mandate of the organization. Successful organizational risk management involves the combined skills and talents of not only the senior leadership team, but also (and more importantly) the pooled expertise and abilities of individuals throughout the organization within a defined enterprise wide risk management framework. The enterprise risk management framework is the underlying methodology that serves as the shared approach to treating risk throughout the organization. When applied strategically, organizational risk management provides senior executives with the ability to: align risk appetite and strategy, enhance risk response decisions, reduce operational surprises and losses, identify and manage multiple and cross-enterprise risks, and improve deployment of resources (human and financial). Overall, an enterprise wide approach to managing risks expressly demonstrates a commitment to effective governance and stewardship of resources.

Looking beyond the broader business context, Canadian health care leaders have long sought ways to address the many facets of risk present within a health care organization. These efforts have traditionally focused on specific services or functions of the organization and in many cases (and for understandable reasons) emphasized patient care situations. While providing health care leaders with a general awareness of potential risks, these traditional risk strategies have the inherent weakness of failing to recognize the interconnection of risk and decision-making between or amongst the multiple functions of the organization. In absence of a unifying approach to assist senior leaders manage risk across the organization, strategic decision-making and effective outcome generation becomes extremely problematic, especially as health organizations become increasingly more complex in terms of size and scope.

An in-depth analysis of organizational risk management in health care, and in particular the concepts of Enterprise Risk Management (ERM), has identified a five part model that can be used by local health care leaders as an evidence supported approach to successful organizational risk management. The *Model for Organizational Risk Management* has been developed as a basis for linking the components of an ERM framework into the existing processes of a health organization in order to overcome the barriers that commonly disrupt strategic risk management within health care. The Model addresses how an ERM framework can fit within an existing multifaceted health organization by building off of and/or enhancing existing processes and resources in order to ensure familiarity, acceptance, and ultimately sustainability of the risk management program. By approaching the Model in a stepwise fashion (based on individual organizational context) health care leaders are provided with a road map from which to initiate or advance their own organizational risk management program. Through the investigation of what has worked broadly in the business community, and studying what is required in order to make ERM relevant to a health care organization, an effective approach to managing risks across the complexity of a health care organization is achieved.

Introduction

In March 2007, the Medical Officer of Health (MOH) of the East Central Health Region issued a Public Health Order affecting St. Joseph's General Hospital (Vegreville, Alberta) that closed the Central Sterilization Room and ordered that admission of inpatients cease. The MOH had reason to believe that inadequately sterilized medical equipment had been, and up until that point continued to be, used in St. Joseph's, thereby potentially exposing patients to blood borne pathogens (Health Quality Council of Alberta, 2007). Considerable public fallout ensued, and a third party Root Cause Review was initiated. Findings from the review identified a) wide spread awareness of these issues by senior hospital and regional officials, and b) the existence of a critical inability by those in accountability roles to address these risks despite knowledge thereof. The aftermath of this situation culminated with the dismissal of the Health Region Board and many senior administrators, including the CEO; as well as some erosion of confidence in the local health system.

As the above example suggests, there seem to be problems at play between the mechanisms of risk awareness, informed strategic planning and decision-making. Examples such as this are unfortunately more prevalent in health organizations, as health leaders continually grapple with how to identify, manage, and avoid all types of risks in and amongst a very complex (and increasingly unforgiving) public social structure. While the primary goal of senior leadership should not be to simply 'stay off of the front page' when it comes to risks, it is not difficult to understand the frustrations that exist for health leaders who already devote considerable resources towards planning, quality improvement, patient safety, financial accountability and general risk management. This leads health leaders to question whether these processes are working, or even whether modern health organizations are capable of anticipating or preemptively heading off seemingly obvious issues. Unfortunately, the reality faced by Canadian health organizations and their leaders is exceedingly more complex, requiring carefully considered and targeted solutions if improvements are to be achieved. Enter the concept of *Enterprise Risk Management*.

With its origins in the financial world (and considerably renewed in this context with the recent international financial collapse), Enterprise Risk Management (ERM) at its core is the combination of *“planning, organizing, leading, and controlling the activities of an organization in order to minimize the effects of risk on an organization. Enterprise or organizational risk management expands the traditional risk function to include not just risks associated with accidental losses, but also financial, strategic, operational, and other risks”* (Steinberg, 2004, p. 17). While defined in a logical manner, *ERM* should more accurately be seen as the intended destination or outcome rather than strictly the transport vehicle to that objective. In other words, ERM is most properly viewed as an organizational goal that deliberately incorporates the sum total of its risk management activities with intentional and strategic coordination so as to encompass the entire business.

Over the last number of years, numerous approaches to ERM have been developed and commercialized in the broader business context. However, given health care’s complexity and constant context of change, off the shelf or broader business approaches to organizational risk management do not appear to necessarily fit or adequately address the needs of the public health system in a way that is meaningful. Where attempts at ERM have been introduced into health care, common approaches have tended to impose a pre-packaged solution into the management process. While this may in some cases lead to positive outcomes, this pre-packaged type of program implementation is considerably less successful than one that intentionally recognizes that a health organization is distinctive and built on the unique personal talents and skills of staff. Evidence from the Canadian health system has shown that where organizational risk management has been successful, it is due in large part to a program developed within the organization instead of for the organization. In this way, local processes, talents, challenges and expectations remain foremost, with knowledge and sustained commitment to the risk management process intentionally fostered into the ERM approach. The key is to find the correct balance between risk management as a function versus an integrated organizational destination.

Best available evidence to date suggests that Canadian health care is at a precipice in terms of ERM, either ready to climb the rock face – or barely hanging on. Many organizations realize that their risk strategies no longer address the mounting pressures now openly being placed on boards

and senior executive teams who are expected to demonstrate a comprehensive risk strategy as stewards of the public purse. It is no longer acceptable for organizations to merely purport to manage risks, as the tolerance for crisis leadership – or the appearance of unpreparedness – has evaporated. Health care based ERM must look beyond program silos and not only provide a snapshot of the current challenges, but rather a portrait of emerging trends, likely pressure points, and strategic opportunities. Common sense, supported by leading research, prescribes that truly comprehensive risk management practice needs to be built-up from within the organization based on tested methodology that (in a practical way) contemplates the common barriers that often derail efforts at organizational risk management. Overall, it cannot be overstated that the most effective risk management processes acknowledge the unique idiosyncrasies of the organization, tap into existing programs and techniques, understand and address key management challenges to risk program success, and most of all, build on the strengths of its own people.

Project Objectives

The aim of this project is to better understand the barriers that prevent health executives from making informed and timely decisions related to identified risks and provide specific guidance on how organizational risk management can be implemented in healthcare. This study is premised on the belief that: 1) risk can be both detrimental and opportunistic in nature and therefore needs to be managed, 2) current risk methods can be improved by understanding and addressing common organizational challenges, and 3) there is value in working towards an organizational risk model that purposefully links risk management processes with timely strategic planning and decision-making.

The main issues of this study relate to the following key study questions regarding the barriers to effective risk management and informed strategic planning in health care:

1. *What causes identified risks to be ignored in healthcare?*
2. *How is perceived inaction justified?*
3. *What information and risk management process is required to strategically manage identified organizational risks?*
4. *How should the awareness of risk be translated into the strategic planning process?*

The objectives of this project are to:

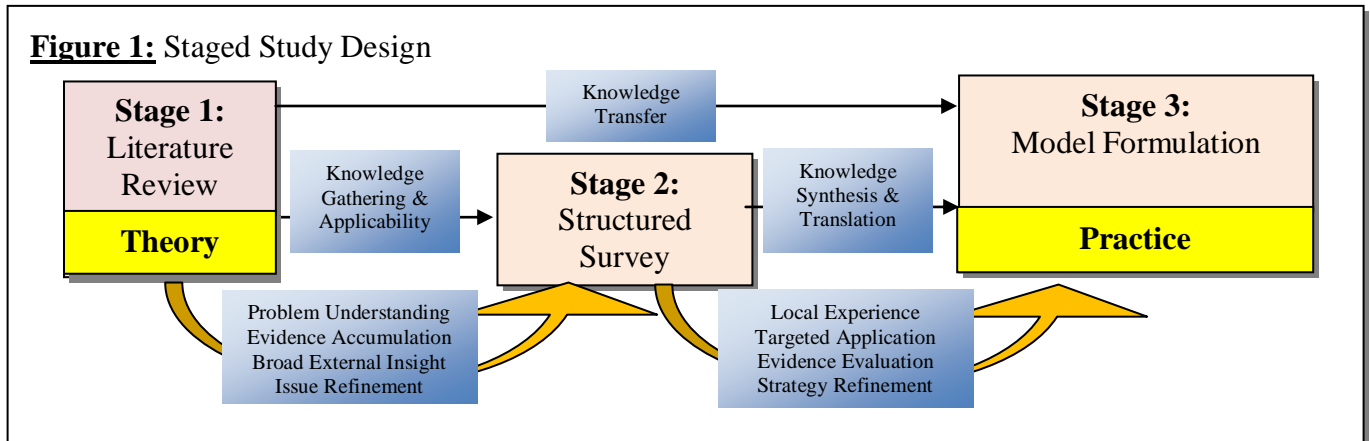
- Identify the common barriers to effective risk management and informed strategic planning in health care.
- Evaluate and critically assess how risk management and strategic planning initiatives can be more effectively linked to the decision-making process.
- Assemble a clear methodology for critically assessing and comparing the viability of various risk management frameworks (or other defined approaches for managing risks as part of an overall health organization risk management strategy).
- Develop an overarching organizational risk management model that addresses identified barriers, links together existing processes and stakeholders, and provides health care leaders with an approach from which to foster strategic risk decision-making.

Methodology

The philosophical basis of this study is that of a pragmatic approach, which maintains that outcomes arise out of actions, situations, and consequences, with a focus in particular on what works in a practical setting. With a pragmatic view, emphasis is placed on the research problem (or contextual issue) and the use of all approaches and information available to understand the problem (Creswell, 2008). With this premise, a mixed methodological approach was selected to study and better understand the barriers to effective risk management and informed strategic planning in health care. This process of research is characterized by emerging questions and procedures, data collected in the participants setting, data analysis inductively building from particulars to themes, and the researcher making interpretations of the meaning of all available information (Creswell, 1998). Use of mixed methods offers an attractive means to study local health organization processes, gather perceptions from stakeholders, make comparison to broader literature findings, and synthesize resulting learnings into an approach that equips health leaders with information on what will work in a practical health care setting (Creswell, 1998). The strength of a mixed methods approach in this study is that it allows contextual real world experience of the challenges facing health care leaders to be captured, thereby contributing to the broader engagement of individuals in the study of this issue, which, if maintained throughout the

process, serves as a key interface to any future change management or coordinated implementation that is built on key learnings.

This mixed study design consisted of three key stages (see Figure 1).



In Stage 1, a comprehensive literature review was conducted to determine a) what the prevalent barriers are to effective risk management and strategic planning, b) what evidence exists concerning effective risk management and strategic planning (and the most common gaps in implementation), and c) current knowledge of strategic planning and risk management governance models. This stage involved the use of a research librarian as well as predetermined search methodology developed to find peer reviewed literature and related case study organizational documents. Key word searches utilizing condensed search terms (or MeSH Terms) of broad electronic sources (including grey literature), were undertaken and assessed against preselected criteria that ranked the findings based on: 1. Relevance to Problem, 2. Study Design, 3. Setting (Context / Applicability to Problem / Transferability), 4. Flaws or Limitations, 5. Relevance of Findings, and 6. Overall Quality of the Study. This approach provided insight into what causes identified risks to be ignored as well as perspectives of how awareness of risks can be translated into the strategic planning process. Using the above, 71 (out of 357) citations found were reviewed in depth. Of the 71 primary sources, consultation with project mentors (chosen based on their familiarity with risk and planning process assessment and expertise in health system modeling) and review using the criteria above, refined the literature to 15 key papers; the strongest evidence being a systematic review by Jardine et al. (2003). Other strong

evidence came from literature on broader business experiences, as well as the local survey responses from health leaders.

The findings from Stage 1 served as the foundation of Stage 2, which consisted of a structured investigation into the perceptions and experiences of a group of senior health care leaders from an integrated health organization (termed ‘Study Organization’ – see Appendix 4). In this stage, a 45 question survey consisting of a mixture of numerical and open ended questions was administered to the Study Organization. Questions within the survey were directly linked to the underlying problems and issues identified in the study, with each question supported by observations reported in the literature. In this way, the survey tested both the local experiences within the Study Organization and the findings from existing research. The survey was administered to: 1) the senior management team of the Study Organization (n=15), and 2) senior personnel within the Study Organization identified as having primary responsibility for oversight of risk management or strategic planning activities (n=10). This combined group (n=25) was contacted via email and asked to participate in an electronic survey in accordance with an approved research ethics protocol. The email included a link to a confidential web-based survey. The survey, collected data, and data analysis was supervised by health care researchers familiar with this study design and type of analysis from the University of Alberta and University of British Columbia (see Appendix 5).

In the final stage of the study (Stage 3), the evidence from the first two stages served as an informed basis for constructing an organizational risk management model. Specifically, the data were characterized according to major conceptual constructs derived from the literature and compared thematically to identified challenges, barriers, sustainability, positive/negative effects, and viability of organizational risk management models for strategic decision-making within a Canadian health care setting (see Appendix 3). The resulting Model translates the key findings of the preceding stages and uses the accumulated evidence to construct a roadmap for health care leaders to follow when considering ERM.

Throughout the three stages, the importance and critical nature of stakeholder engagement was expressly built into the methodology; as it is the individual health care leaders who are the key

contributors to not only the nature of the problem, but also the primary means of implementing change. (Note: Implementation and formal program evaluation of the Model is intended to be the basis of further research work and is outside of the scope of this current project).

Evidence Review

The assessed collective findings from the peer reviewed literature, organizational documents, grey literature, and the survey of senior health care leaders, generated some key main messages relating directly to this problem and key study questions (in *italics*) which are now discussed (see also Appendix 3).

Why are identified risks ignored in healthcare?

How is perceived inaction justified?

a) General Management / System Barriers

Main evidence messages:

1. Complexity of the health system fosters considerable opportunity for gaps in risk management processes to occur.
2. It is not intentional management inadequacy that causes risks to be ignored, but rather the combined effect of multiple system barriers that result in failed strategic risk management execution.
3. Translation of strategy into operations is an essential component of effective risk management.
4. Data, role uncertainty, reactionary leadership, political interference, competing interests on health leader time, and financial constraints/uncertainty, explain in general what leads to inaction/ineffectiveness of health leaders on identified risks.
5. Clarity within a defined framework, dedicated resources, targeted education and focused organizational strategy, should be the underlying premise of a risk management program.

Kaplan and Norton (2008) describe how an organization's management system (i.e. the integrated set of processes and tools that a company uses to develop its strategy, translate it into operations, and monitor and improve the effectiveness, quality and risk) is the main source of breakdown or barrier to effective organizational functioning. Further, Kaplan and Norton (2008) point to the management system, not a manager's lack of ability and effort, as a critical factor leading to unexplored opportunities and risks. Looking into the specific management processes where barriers exist, Kaplan and Norton (2008) found that strategy (and the strategic process) at many companies is almost completely disconnected from execution. This creates a considerable gap, as the employees who are closest to customers and who operate processes that create value are unaware of the strategy and thus cannot help the organization implement it effectively or mitigate risks as they arise. These findings, as they relate to system impediments to the strategic process, are supported by the findings of Adams (2005), who also found that in many cases leaders have difficulty translating their strategic plan into specific actions (operations) because of a lack of clarity in what a strategic plan is and what it should do for the organization.

Barriers within the management system are described by other research as well. Brazeau (2008) found that questionable data integrity, unpredictable human performance, system financial impediments, un- or under-specified responsibility, over quantification of issues, and persistent reactionary leadership, all present barriers to effective management of risk. Brazeau (2008) also indicate that these traits are magnified by: fragmented decisions, competing interests, and the labour intensive nature of the health care system. Balding (2008) goes as far as concluding that it is difficult (if not impossible) to implement a systems approach to strategic risk management within a highly individualized health professional environment (encompassing countless sub-cultures, each with its own priorities, traditions, territories, rules and languages), without expressly acknowledging and engaging these groups on their terms. This is especially difficult given local / federal funding strategies, a bureaucratic system that can sometimes appear to be more about politics than patients, a bottomless demand fed by growing populations and rising community expectations fanned by public inquiries into sub-standard care, often justifying, if not explaining, inaction on key risks/challenges facing healthcare (Balding, 2008).

When asked, all of the survey respondents strongly agree or agree that health care leaders are often limited by time / workload (system) constraints, and that system / financial impediments were the most commonly reported barrier to effective / successful risk management (Appendix 2). Other specific systematic barriers that were commonly identified by respondents include: competing priorities on management / health leader time; lack of resources, expertise and time to be proactive on risk management; uncertainty on strategic direction, importance, roles, responsibilities and accountability for strategy and risk management; and the lack of a system-wide approach to risk management that is based on the overall strategy of the organization. These findings suggest that systemic challenges, in multiple forms within the management process, present a considerable barrier to effective organizational risk management. The survey highlights that almost half of senior health leaders felt that clear accountability for risk management was lacking in their organization, with over half of respondents expressing that they have identified risks that have not been acted upon. A further 53% expressed that it is very common or common for identified risks to be ignored or not addressed in a timely fashion. The survey also confirms that many barriers described in the literature (including inadequate education on risk management and strategic planning, inadequate/untimely information to make an informed decision, unclear or no set avenue or structure for risk decision-making, poor communication of risks between silos, and uncertainty of individual roles within the risk process), are evident in the study health care system.

The above findings are principally indicative of the published literature on systematic barriers to effective risk and health care management. As captured succinctly by Fraser (2008), the literature in general is largely silent on that one firm direction (i.e. a magic bullet) on how to deal with the myriad of cultural, logistical, historical challenges that exist in the health system beyond exploring and addressing each of these issues head-on within the local organization. In fact, research has shown that direct involvement and coordination of as many stakeholders (internal / external) as possible to key organizational processes (such as risk management) has been shown as a way to address broader obstacles that arise in an organization (Smiechewicz, 2009; Neilson, Martin, & Powers, 2008; Robertson, 2006; Pagach & Warr, 2007).

b) Local Organization Strategic Planning / Risk Management Barriers

Main evidence findings:

1. The current health planning process appears ineffective and has resulted in some health leaders pursuing subsequent parallel processes (i.e. breaking the planning function into capital plans, health service plans, operational plans, etc.).
2. Strategic planning is not as effective with only a top down approach.
3. Risk management needs to be broadly approached and not siloed.
4. Health leaders see value in working towards an integrated risk planning framework.

The strategic planning process within the Study Organization is based on a rolling three year planning exercise that culminates with a yearly Health Plan that is submitted to government. The purpose of the Health Plan is to describe the structure, processes, intended strategy, and accountability between the Health Minister and the Study Organization (Corporate Operations Division Alberta Health & Wellness, 2007). The Health Plan is a legislated document that must meet the requirements set by government (including the prescribed form and structure), and serves as a conduit between government and the established lines of authority within public health delivery (Corporate Operations Division, Alberta Health & Wellness, 2006).

The main identified challenge within the health planning process is that it appears to be a largely contrived exercise that has more to do with fulfilling legislative requirements than actual planning. For example, the budgeting process is separate from the health planning process, which presents a considerable barrier as health leaders are expected to develop strategies without knowing if they will be funded. Secondly, Health Plans are based primarily on provincial versus local priorities (Alberta Health & Wellness, 2006). This serves to foster objectives and initiatives that are higher level in nature, without an extensive ability to explore local health service delivery priorities. Thirdly, the document is publically available, which causes health care leaders at both the ministry and Study Organization level to be cautious in terms of what specific information and strategies are included in the plan (i.e. broad strategy statements without much on the operational ‘how to’). This has caused Health Plans to become very generic in nature, and for the most part, removed much of the functional utility of the plan as a strategic document.

Lastly, the health planning process arguably fosters gaps in planning and issue mitigation as it is a top down approach that does not emphasize communication or the identification of local or unique problems (or risks) for fear of perceived weakness of management. Within the Study Organization, these challenges led to multiple parallel processes evolving to fill the void in coherent strategic planning. For example, service plans, capital development plans, and operational plans all emerged as distinctly separate approaches health leaders use to plan service delivery.

Similarly, risk management processes are equally varied. A primary observation is that risk management has long been considered a function that is housed in different silos depending on distinct service lines, rather than as a broad organizational objective. For example, within the Study Organization, risk management was traditionally viewed in the clinical care context, and was a longstanding part of the quality function. Other risk components were, until recently, distributed across various portfolios, such as quality improvement, patient safety, legislative compliance, internal audit, insurance, and maintenance. This led to a divergence of process, masking the overall risk profile of the organization.

Recognizing the value of a broad organizational approach to planning and risk management, the Study Organization determined that a combined framework was needed. The issue is how to properly do this. In surveying senior health leaders, the following findings highlight the barriers to strategic planning and risk management, as well as offer insight into potential improvements.

- The strategic planning function should play an important role in risk management as a mechanism to ensure calculated mitigation of risks (100% strongly agree or agree).
- Risk management should focus on the risks to the entire organization (83% strongly agree or agree).
- Risks tended to be longstanding and known about locally but not necessarily acted upon (42% very common or common).
- Accountability for risk management was clear in the organization (47% very common or common).
- I have identified risks that have not been acted upon (43% very common or common).

- Communication of risk issues is frequent, effective, and allows risks to be acted upon in a timely manner (76% strongly disagree or disagree).
- Risk processes are a key component of strategy and planning processes (90% strongly agree or agree).

c) Barriers within the Decision Making Process

Main evidence messages:

1. The pressure/demand to make quick decisions fosters fragmented/ineffective decision-making.
2. Health care leaders desire strategic mechanisms that coordinate risk management / decision-making.
3. The availability, assessment and application of information greatly influences the decision-making process.
4. Decision making (in general and within the risk management context) is best approached as a coordinated process rather than a series of independent events.

Clancy (2003) and Eisenhardt (2008) capture succinctly the reality that executives/decision-makers face tremendous pressure to be decisive and take action quickly. Further, rushed or forced decisions often lead to additional long term challenges as outcomes often take years to be fully felt (Clancy, 2003). These findings emphasize the importance of the decision-making process on effective risk management, as it is the decision-making process that plays a fundamental role in determining how to manage risks and set strategy through to successful conclusion. However, the literature, as well as local perceptions, suggests considerable challenges are inherent in decision-making, which pose significant barriers to the risk management process (and broader decision-making in general) if not strategically addressed.

Gavetti and Rivkin (2005) explain that faced with an unfamiliar problem or opportunity, senior managers often think back to some similar situation they have seen or heard about, draw lessons from it, and apply those lessons to the current situation. This has the potential to ignore (or not

seek out) available evidence, and leads to poor decisions (Gavetti & Rivkin, 2005). Taking this further, Garvin and Roberto (2001) suggest that:

Most leaders get decision-making wrong. The reason: most [leaders] treat decision-making as an event – a discrete choice that takes place at a single point in time, whether they're sitting at a desk, moderating a meeting or staring at a spreadsheet. The fact is, decision-making is not an event. It's a process, one that unfolds over weeks, months, or even years; one that's fraught with power plays and politics and is replete with personal nuances and institutional history; one that rife with discussion and debate; and one that requires support at all levels of the organization when it comes time for execution (p. 113).

The process of decision-making, as described by Garvin and Roberto (2001), appears to be central to good outcomes (i.e. effective decisions), however, other researchers as well as the survey respondents have emphasized further challenges. AbouZahr (2007) found that decision-making is fragmented and decisions are sometimes difficult to make because of several players and interests, with high-level policy likely to support established power structures, core values and objectives of powerful elites. Survey respondents indicated (84% strongly agree or agree) that health care leaders are required to make quick decisions with limited evidence or supporting rationale. Clancy (2003) also observed that there is a great tendency in decision-making to bypass a thorough analysis of the problem and move quickly into solutions.

As important as sound decision-making is, many executives neglect to utilize any formal decision-making process (Clancy, 2003). Frei (2008) reports a basic yet fundamental challenge in that decision-makers do not have the time, inclination, or technical skills to analyze formally alternative options. Jewell and Bero (2008) further explain this phenomenon by indicating that administrators are not taught to continuously use research to inform their decisions or to inform practice, citing two key factors: research quantity (too few relevant studies) and research quality (poor quality, limited applicability, or difficult for decision-makers to evaluate). Teng, Mitton and Mackenzie (2007) found that decision priorities were described by decision-makers as being set in an ad hoc manner, if made at all, with health resources generally allocated along historical lines reflecting organizational cultures where norms and incentives have implicitly supported historically based resource allocation processes. Hammond (1998) explored the origins of poor

decisions and found that in many cases, bad decisions can be traced back to the way decisions were made: the alternatives were not clearly defined; the right information was not collected; the costs, benefits, and risks were not accurately weighed; or biases overtook the decision such as a strong tendency toward alternatives that perpetuate the status quo (e.g. seeking out information that supports existing instinct or point of view while avoiding information that contradicts it). This is reinforced by a considerable portion of survey respondents (42%) who felt health care leaders are not taught to use research to inform their decisions, and by the small portion (16%) who felt that health leaders have adequate education on strategic planning / risk management decision-making.

What information and process is required to strategically manage identified risks?

How should the awareness of risk be translated into the strategic planning process?

d) Use of Information/Evidence

Main evidence messages:

1. Health care leaders face challenges in accessing and/or linking evidence into the decision-making process.
2. The transfer of research evidence into risk management practice requires a coordinated and strategic process.
3. Mechanisms need to be established to link information, expertise and assessment with decision-makers.
4. Clear accountability for implementation and evaluation is required to determine if expected results have occurred.
5. Knowledge translation/transfer is an essential component of risk management.

Despite the considerable resources devoted to health sciences research, a consistent finding from the literature is that the transfer of evidence into practice is often a slow and haphazard process (Graham et al., 2006). Lavis (2006) has commented extensively on this and remarks that:

Public policymakers must contend with a particular set of institutional arrangements that govern what can be done to address any given issue, pressure from a variety of interest groups about what they would like to see done to address any given issue, and a range of

ideas (including research evidence) about how best to address any given issue. Rarely do processes exist that can get optimally packaged high-quality and high-relevance research evidence into the hands of public policymakers when they most need it, which is often in hours and days, not months and years (p. 39).

This is further described by Jewell and Bero (2008) who focused on four facets of information / evidence flow: a) research quantity – there are few relevant studies for many important health policy / risk issues, much less systematic reviews of evidence; b) research quality – sometimes existing research is of poor quality or limited applicability; c) accessibility – even when available, policy makers may have difficulty obtaining it or the fact that a large amount of data is never published, and d) usability – the most commonly cited reason attributed to limited usability of existing data was that policymakers’ needs do not drive research. In looking at the information or evidence requirements of decision-makers (within the risk management process and in general), survey respondents indicated that:

- There are very few relevant research studies for many important health policy issues or identified risks (62% strongly agree or agree).
- Data integrity was identified as a significant barrier to effective / successful risk management (57% of respondents).
- 53% of respondents strongly disagreed or disagreed that health care leaders often have the necessary information to make an informed strategic decision.
- 94% of respondents strongly agreed or agreed that risk management should be a process that takes into account all available data in the evaluation and review of risk management decisions.

The above findings emphasize that the use of information / evidence by decision-makers in processes such as (traditional) risk management is very fragmented and serves as a key barrier to successful outcomes. Whereas there is a genuine (if not rhetorical) desire to make evidence-informed decisions, the process and linkage of evidence to the decision process is complex and requires a formal mechanism to link together internal and external stakeholders to allow / facilitate information flow and/or effective communication. While it is not expected that rigorous evidence will exist on every issue or risk that is presented, it is nonetheless important to ensure that information that is available is in no way impeded from decision-makers (Clancy, 2003).

e) Elements of Successful Risk Management and Strategic planning

Main evidence messages:

1. Enterprise Risk Management is a broad term that represents an organizational view of the risk process.
2. An enterprise or organizational approach to risk management can be implemented in a customized way within a health organization.
3. Key components that should be a part of a comprehensive risk management framework include: 1. Problem formulation, 2. Stakeholder involvement, 3. Communication, 4. Quantitative assessment, 5. Iteration and evaluation, 6. Informed decision-making, and 7. Flexibility.
4. Risk management and strategic planning are interrelated processes that form part of the overall organizational decision-making process.
5. Successful and strategic risk management relies on an understandable framework that is supported by senior leaders and implemented across the organization in a principled / ethical way.

As a core component of the project, critical review and appraisal of risk and planning models took place. What was observed is an increasing number of organizations (initially non health related, but now more so) that appear to be addressing ineffective strategic planning and risk management by way of one of many enterprise risk strategies intended to ensure corporate governance accountability (Kaluzny, 2007; Hexter, 2008). ERM stems from many of the quality assurance and risk identification strategies previously in place in business, with the added viewpoint of uniformly assessing risk across all parts of an organization so that leaders can make effective decisions, thus expanding (or overcoming) the traditional siloed approach to risk management (Balding, 2008). Investigation of ERM has highlighted that there seems to be multiple approaches to risk management and strategic planning, warranting a due process of assessment prior to contemplating an organizational approach.

The systematic research of Jardine et al. (2003) highlights the differences, commonalities, strengths, and weaknesses among various common risk management approaches, and identifies

core elements that should be included in an effective, current, and comprehensive approach to risk management. Based on the extensive review of more than 80 frameworks, Jardine et al. (2003) reported seven key elements that make up a successful and comprehensive risk management framework, specifically: 1. Problem formulation, 2. Stakeholder involvement, 3. Communication, 4. Quantitative assessment, 5. Iteration and evaluation, 6. Informed decision-making, and 7. Flexibility. When explored for how a particular framework approaches risk, these seven elements then become an informed basis for reviewing the strength of a particular risk management framework. In addition to these seven key principles, Jardine et al. (2003) demonstrate that comprehensive and sound principles are critical to providing structure and integrity to risk management frameworks. Guiding principles are intended to provide an ethical grounding for considering the many factors involved in risk management decision-making, and Jardine et al. (2003) propose ten principles to guide strategic risk management decision-making. As risk management is inherently a process in search of balance among competing interests and concerns, each risk management decision will be a balancing act of competing priorities, and trade-offs may sometimes have to be made between seemingly conflicting principles. The 10 decision-making principles (with corresponding ethical principles in italics) are:

1. Do more good than harm (*beneficence, nonmalifcence*).
2. Fair process of decision-making (*fairness, natural justice*).
3. Ensure an equitable distribution of risk (*equity*).
4. Seek optimal use of limited risk management resources (*utility*).
5. Promise no more risk management than can be delivered (*honesty*).
6. Impose no more risk than you would tolerate yourself (*the Golden Rule*).
7. Be cautious in the face of uncertainty (*“better safe than sorry”*).
8. Foster informed risk decision-making for all stakeholders (*autonomy*).
9. Risk management processes must be flexible and evolutionary to be open to new knowledge and understanding (*evolution, evaluation, iterative process*).
10. The complete elimination of risk is not possible (*life is not risk free*).

Combined with the seven key framework elements, what is achieved is a comprehensive review mechanism for potential frameworks from the strategic planning and risk management context (this key finding is discussed further below).

Other research has confirmed the findings of Jardine et al (2003). For example, Eisenhardt (2008) identifies that managers need tools and a clear risk management framework in order to make decisions inclusive of: real time operating information from which to compare multiple alternatives, quick conflict resolution, advice and integration of decisions and tactics to build confidence to make decisions. Jeffs et al. (2006) take this further and suggest that what is required is a system that includes a combination of internal stakeholders throughout the strategic planning process, balanced with external review and consultation. Jeffs et al. (2006) also expand on the concept of informed decision-making and propose that a process for transformational change and knowledge transfer is essential in order for evidence to be effectively used. Brook (2008) also touches on the importance of knowledge and evidence use within the risk management approach and postulates that key requirements include: obtaining data necessary to understand the issue, presenting options in an unbiased manner so that they inform debate, and involving the public in understanding the issues and developing responses. Kaplan and Norton (2005) look at risk management from the context of a key component of corporate execution of strategy and specify that a successful framework requires: clear communication of intended organizational values and strategy; processes to ensure enterprise level plans are translated into the plans of the various units and departments; alignment of employee competencies, skill sets, goals and incentives; and a clear understanding of the overall objectives of the framework – from the senior board level through to the front line. Overall, Kaplan and Norton (2000) emphasize the key to executing a strategy or framework is to have people in your organization understand it – including the crucial but perplexing processes by which intangible assets will be converted into tangible outcomes.

Information stemming from the survey also highlights key elements that should be a part of a comprehensive risk management framework from the Study Organization context. Risk management should focus on the risks to the entire organization (83% strongly agree or agree). Effective risk management considers both the internal and external organizational environment (100% strongly agree or agree). An effective risk management framework provides key principles and concepts, a common language and clear direction and guidance to an organization (100% strongly agree or agree). Risk processes are a key component of strategy and planning

processes (90% strongly agree or agree). Risk management should be a process that takes into account all available data in the evaluation and review of risk management decisions (94% strongly agree or agree). Other essential components of a risk management program include (open ended):

- Ongoing executive and Board support
- Focused and ongoing communication (both up and down).
- Data collection/management system dedicated resources to support program and organizational risk assessment.
- A clearly defined framework that supports: identification of risk, full understanding of risk issues, prioritization of risk, research of best practice, tools for evaluating and acting on incidents, and communication/education of identified action plans to address risk as it applies across the organization.

Health Care Risk Management – Evidence for Change

As suggested cumulatively by the above presented findings, what is observed in both the literature and experiences within the Study Organization is a clear willingness by health leaders to do a better job at managing risks (AbouZahr, 2007). This willingness is confounded by the complexity of the health care system, its multiple players and interests, and the absence of a clear mechanism or common approach to risk management. Commonly reported by health leaders from the Study Organization were situations where risks were known, but no clear avenue to have the risks addressed was apparent. Similarly, risks would be reported, but no apparent action taken by senior leaders would be observed, leading to questions and uncertainty of whether or not the risks were addressed or even taken seriously.

This highlights the need for a defined organizational risk management approach. A commonly reported observation is that the function of risk management is housed in different silos depending on operational structure. For example, within the Study Organization, risk management was traditionally viewed in the clinical care context. Other risk components were distributed across various portfolios – leading to a divergence of processes and masking the overall understanding of risks to the organization. Recent reports done by Minsky (2007) on the

state of risk management and in particular ERM suggest that broadly coordinating an organizational risk program reduces uncertainty and, over time, improves the prospects of success in terms of addressing financial and insurable hazards, as well as guiding strategy, operations and technology, reputation, and regulatory compliance within the organization. Jeffs et al. (2006) take this further and suggest that what is required is a system that includes a combination of internal stakeholders throughout the strategic planning process, balanced with external review and consultation. Kaplan and Norton (2005; 2000) describe such a system in terms of a risk management framework that is an embedded component of corporate execution of strategy, with a successful framework requiring: clear communication of intended organizational values and strategy; processes to ensure enterprise level plans are translated into the plans of the various units and departments; alignment of employee competencies, skill sets, goals and incentives; and a clear understanding of the overall objectives of the framework – from the senior board level through to the front line.

From these findings, what is concluded is that an organizational risk management model that links current and new risk practices from across the organization into a defined and supported risk framework is required. Further, the ERM framework needs to be customized to the organization itself, dependent directly on the organizational structure, resources, local context and overarching goals and objectives. The risk framework needs to interface strategically with the planning and decision-making function in order to action and/or strategically address risks in a timely fashion. The entire organizational risk management strategy requires dedicated support and clear communications between stakeholders (internal / external) in order to link together information, methodology, and skills, and overcome critical barriers.

Relationship of Quality, Safety and Enterprise Risk Management

In the majority of health organizations, there are multiple operational areas whose function could be defined as being risk related. Examples of this include the many quality improvement and patient safety programs that seek to advance organizational effectiveness and the patient experience. Taken from the perspective that both quality and safety are operational processes that have (in certain aspects) considerable exposure to organizational risks, it is this risk exposure

that ERM is trying to systematically capture from each part of the organization. The distinction between these concepts is that ERM considers the whole spectrum of issues that could and can go wrong to the organization, which not only includes safety involving staff, patients and the public, administrative errors that impact on patient care, and clinical incidents that have a direct effect on the quality of patient care, but also the management of the business risks associated with running the health organization (including financial, ethical, information technology, and strategy risks) (Haynes & Thomas, 2005). Through ERM, an intentional focus is placed on how these interrelated activities impact the decisions and actions of the organization so that overall business improvement can be made in terms of cohesively addressing risk (Balding, 2008). However, it is not suggested that ERM take over or otherwise replace these other programs, but rather build off of and capture the risk information from these key quality and safety activities. In other words, the goal behind taking a decentralized organizational approach to managing risks is to tap into (i.e. leverage) these and other key operations in order to fully capture and cohesively address risk across the organization.

Pursuing Enterprise Risk Management: A Local Roadmap for Canadian Health Care

Leaders

Throughout this project, emphasis has been placed on the key notion that strategic development and alignment of organizational risk management is most successful when driven from within the organization. Taking this concept and the accumulated findings together, the following model is presented as a road map for ERM to be pursued by senior health leaders (see Figure 2).

The *Model for Organizational Risk Management* (termed ‘the Model’) is based on the identification of 5 key components that make up a comprehensive organizational risk management strategy. The five components consist of:

1. An Organizational Risk Network
2. The ERM Framework
3. The Strategic Planning / Decision Process
4. Implementation
5. Evaluation

Functional support of the Model for Organizational Risk Management is accomplished by way of emphasis on a decentralized organizational approach maintained by an ERM support department. The components of the Model are now discussed.

Components and Key Elements of the Model

Model Component 1. Organizational Risk Network

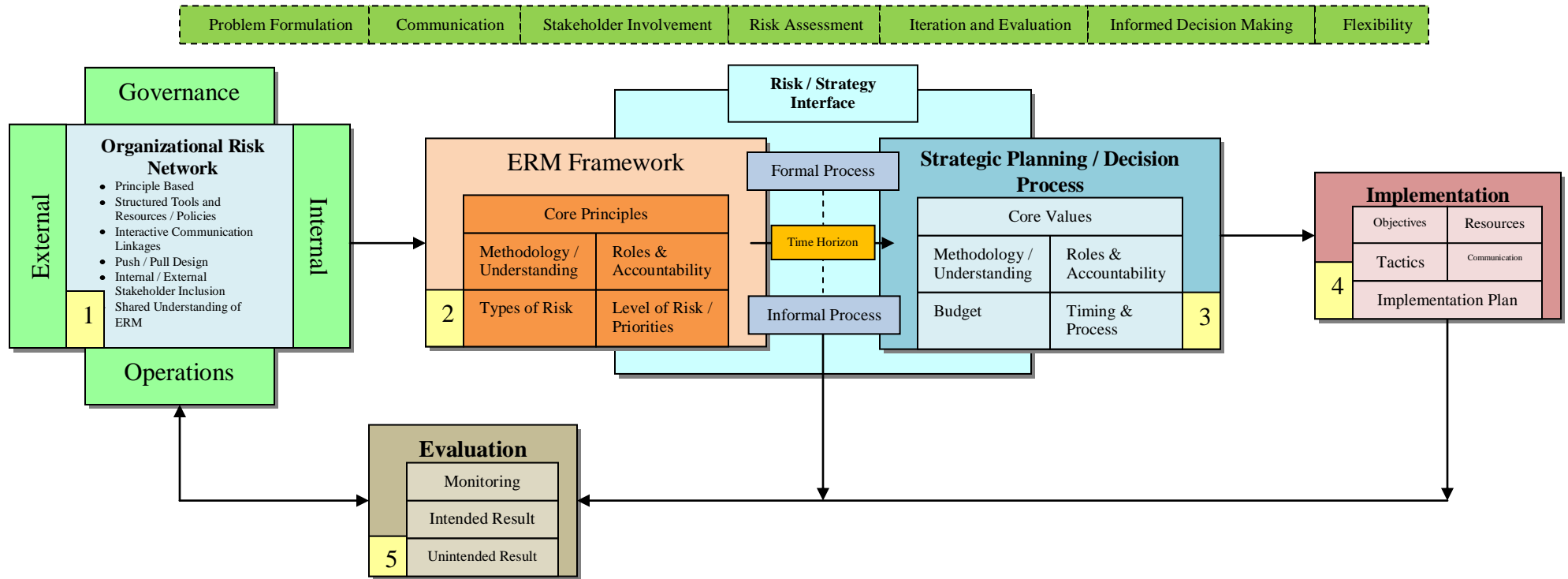
Of fundamental importance to the whole system of organizational risk management is how to build buy-in and incorporate key risk management tools so as to be able to successfully identify and manage enterprise risks. What is needed is a comprehensive mechanism to link the organization and stakeholders into the risk management framework. The Organizational Risk Network (or Risk Network) is designed to link operational leaders (from across the organization) and other stakeholders into a shared organizational risk management program in order to directly overcome accountability and information flow barriers that have been identified in health organizations. By establishing a clear communications conduit (the Risk Network) that is rooted in a organizational risk program (i.e. the ERM Framework - discussed further), staff and stakeholders have a clear forum to exchange information based on a shared approach to identifying and addressing organizational risks across the many aspects and levels of the organization.

The Risk Network can be thought of as a virtual working group having many of the same characteristics as a committee structure (i.e. operating principles, structured tools and resources, internal / external membership, defined reporting / communication obligations), but also having characteristics of a network (in the technological sense), as it is constructed to go beyond a traditional committee in terms of its reach (or connection) with stakeholders to link information, expertise and resources. The Risk Network works by providing continuous support to the risk management program based on champion building and the application of timely tools and resources. Such an approach is required to identify risks from both internal and external participants as well as administrative and operational personnel. When brought together in this fashion, information can be generated (pulled) as well as disseminated (pushed) throughout the

organization, as well as externally. It is from the Risk Network that ERM Framework is operationalized. Linkage into the Risk Network is accomplished by a variety of means, depending on the resource capacity of the organization, and includes primarily electronic methods (such as email, web resources or dedicated risk alert applications) as well as interpersonal approaches as required (such as periodic meetings, focus groups, or resource centres). Interactive communication is the fundamental premise behind the Risk Network, as the flow of information needs to exist within a clearly developed mechanism in order to support and link the organizational risk program with the business. By premising the Risk Network as a virtual working group, the size and integration of Network has the flexibility to mature and expand in lockstep with the needs of the membership based on a progressively accumulating skill set. This allows the Network to continually expand in size, without necessarily being limited by the constraints of a traditional committee, which often can become limited by the time and resources required for in person meetings. For example, once champion building and technological capabilities have been fine tuned (i.e. the Risk Network established), the emerging virtual processes become the accepted/familiar go forward approach, allowing subsequent emphasis to be placed on: ensuring elements of the risk program are understood and applied consistently, refining electronic tools to match the evolving communication and information needs of the Network, and rationalizing the most resource intensive activities (i.e. in person meetings) on specific risk issues where warranted.

Put into practice, the Risk Network could be approached as follows. First, health leaders would structure and endorse a defined terms of reference for the Risk Network (establishing size, scope, and function). Second, representatives from each operational area of the organization and key stakeholders could be selected as Risk Network members. Rather than focusing on a particular level or seniority, membership would ideally be based on selection of individuals with roles that afford a broad exposure to the scope of operations within a particular area of the organization. Third, the Risk Network members would be educated on the organizational risk program and in particular the ERM Framework (expertise / champion building). Fourth, the Risk Network members would identify / evaluate tools and resources required to identify risks within their sphere of operations. Fifth, the Risk Network would be a conduit through

Figure 2: Model for Organizational Risk Management



Key Elements:

- 1 Organizational Risk Network Interface**
- Commitment and vision from the top of the organization to establish cultural norms. Everyone is a risk manager.
 - Use multi-disciplinary teams to share risk attitudes and horizontal issues.
 - Set up dedicated department to act as the process support resource for the organization.
 - Make risk management a part of the normal management process.
 - Emphasize risk communication
 - Recognize the multiple levels of risk management.
 - Ensure stakeholder acceptance.

- 2 ERM Framework**
- Ethics based core principles
 - Shared understanding, terminology and roles / accountability
 - Complexity is not necessarily better
 - Emphasize the importance of correctly defining the actual problem
 - Risks are considered in a comprehensive context, considering other objectives
 - Explicit treatment of uncertainty and prioritized risks
 - The process is flexible and iterative
 - Focus on clear evaluation and reporting of risk information
 - Use all available evidence to understand risk.
 - Analyze trending information.

- 3 Strategic Planning / Decision Process**
- The decision process is documented, open and understood.
 - Actions and resources directed where they will be most effective
 - Recognize the multiple levels of risk management decision-making
 - The process balances the costs of managing the risks, the benefits to be gained, and the level of risk management that is reasonable to apply.
 - Risk assessments should not be the sole tool used to determine risk decisions.
 - Flexible approach based on short, medium or long time horizon.

- 4 Implementation**
- Detailed implementation plan / operational tactics targeted to the appropriate level of the organization.
 - Clear procurement & commissioning strategy (education & training)
 - Open stakeholder dialogue / communication.
 - Monitor implementation amongst organizational levels
 - Adequate assessment of time horizon and goal setting.
 - Resources clearly defined deployed.
 - Objectives easily understood.
 - Consideration for measurement of strategies.
 - Ensure approach address the risk.

- 5 Evaluation**
- Emphasize performance measuring.
 - Evaluate the organization's performance against stated objectives / identified risk.
 - Continuous environmental analysis can identify possible future changes in the legislative framework, the exposure, the hazard, risk acceptability, stakeholders, or technology.
 - Analyze and openly discuss successes and failures
 - Monitor for intended and unintended outcomes.

which risks as well as associated risk information could be brought forward and addressed (in accordance with the ERM Framework). Sixth, the Risk Network becomes a key mechanism for organizational risks to be linked into the senior decision-making process in the form of structured reporting, issue elevation, and priority setting. Lastly, the Risk Network becomes the communications dissemination channel of outcomes, issues awareness, mitigation activities or trending information. Overall, the Organizational Risk Network is a decentralized approach to capturing, assessing and prioritizing risk activities of the organization.

Central to the Organizational Risk Network concept is the need to establish operational champions who would be the local resource (expert) to and for their area of accountability and would maintain current knowledge of ERM strategies as the liaison to and from the Risk Network. In this way, the operational champions would be equipped with the skills and tools needed to employ the ERM program in terms of capturing, assessing, prioritizing and reporting risks. Operational champions would be identified throughout the organization in order to encompass all areas. The same approach could also be applied to external stakeholders.

Summary of Key Organizational Risk Network Components:

- Core Shared Principles
- Structured Tools and Resources
- Interactive Communication
- User Driven Push / Pull Conceptual Design
- Internal / External Stakeholder Inclusion
- Shared Understanding of ERM

Linkages

Model Component 2. ERM Framework

The ERM Framework is an essential component of the overall key requirements of successful organizational risk management. The ERM Framework outlines the overarching premise or the shared organizational how to in the treatment of risk. As discussed earlier in this document, many ERM frameworks and modalities exist, which presents an opportunity for health organizations to determine the most practical framework to adopt / implement. As part of the research methodology undertaken in this study, an additional key outcome has been the development of an *ERM Framework Evaluation Tool*. This tool is intended to equip health care

leaders with a research supported mechanism to assess and compare different ERM frameworks in order to select the most appropriate framework (or combination thereof) for the local context.

The ERM Framework Evaluation Tool is based on three key benchmark categories of assessment (Jardine et al., 2003).

1. The fundamental elements of successful risk management
2. The key elements of strategic risk decision-making, and
3. The underlying local organizational vision, mission, and values.

Each of the three categories is broken down into a series of expected elements or key requirements in an ERM framework. This benchmark then serves as a basis for potential ERM frameworks to be assessed by the individual health organization. Comparison (i.e. strength of a particular ERM Framework) is based on scoring by local health leaders of each element, with emphasis placed on predetermined weightings of importance to the organization (see Figure 3 and Appendix 1). After scoring potential ERM frameworks with the tool, the resulting scores can be compared. Based on the unique needs and characteristics of the organization, an ERM framework can be selected with the full knowledge of its strengths and weaknesses (which then can be customized to the organization).

Figure 3: Sample Section from the ERM Framework Evaluation Tool

Key Overarching Elements to be Included in a Comprehensive Risk Management Framework (Ceniceros, 2008; Jardine et al., 2003; Leadbetter, Kovacs, & Harries, 2008)	Method Addressed in Potential Framework?	Weighting / Score (Set Weightings based on Organization Priority)
1. Problem formulation stage.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	Overall [?]/15
• Framework combines context with clear techniques to define problem.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/4
• The dynamic nature of risk is acknowledged.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/3
• Correct definition of the problem is fostered.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Problems are identified, formulated, and characterized within the local context.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Risk management goals, authority, responsibility and resources are understood.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Recognizes the need for collaboration and communication with stakeholders in defining problem.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2

It is within the ERM Framework where the mechanics of risk management come into play. Most, if not all, ERM frameworks share the following characteristics, which then become the basis for

how an organization defines and treats risk. It is the approach to each of these characteristics that in many cases differentiates ERM frameworks and allows customization depending on organizational need.

Common features of ERM Frameworks include:

<p>Preliminary analysis (identification):</p> <ul style="list-style-type: none"> • Hazard identification • Risk context (the dimensions of risk) 	<p>Risk treatment options:</p> <ul style="list-style-type: none"> • Generate options • Risk analysis of options • Optimization of strategies and options
<p>Risk analysis:</p> <ul style="list-style-type: none"> • Risk estimation • Benefit-cost analysis • Socioeconomic analysis 	<p>Risk mitigation:</p> <ul style="list-style-type: none"> • Assessment of resources and priorities • Selection of course of action

The above common features of ERM frameworks lead up to the next Model component.

Model Component 3. Strategic Planning / Decision Process

One of the main barriers to effective organizational risk management is the interface between the risk program and the *Strategic Planning / Decision Process* of the organization. Challenges emerge as traditionally these processes have been seen as distinct, which presented natural barriers to identified risks being advanced (or actioned) through the strategic process (Eisenhardt, 2008). With the development of ERM, which intentionally combines risk management with strategy and planning, emphasis now is placed on appropriately channeling (or reporting) sequential risk information into the strategy / decision process. In other words, ERM by definition is the bridge between risk management and decision-making, as identified risks are treated through the ERM Framework to produce information that is used to make strategic decisions. In this Model (see Figure 2), the interrelationship between the ERM framework and the Strategic Planning / Decision Process is depicted as the Risk / Strategy Interface.

Recalling the ERM Framework Evaluation Tool described earlier, key elements of decision-making are assessed in order to ensure the selected ERM framework will align with the strategic planning / decision process of the local health organization. This is done by evaluating the ERM Framework against current planning / decision processes as well as organizational values and

mission. Rigorous assessment up front of potential ERM frameworks, ensures that the information generated from the risk process is useful in the strategic decision-making process.

Risk information stemming from the ERM Framework will consist of a range of issues depending on their complexity and their origin from within the organization. Each will have an inherent time horizon, or urgency to them, requiring a flexible strategic decision process. This variable nature is depicted in the Model at the center of the Risk Strategy Interface. Building on the fact that health organizations (as will all businesses) have multiple levels of decision-making, a similarly flexible interface of risk information with the organization planning / decision-making process is required. As such, a key strength of the ERM Framework needs to be its ability to categorize and distill issues in order to foster strategic decisions at the most appropriate organizational level(s) by knowledgeable personnel. Depending on the nature of the risk, multiple areas of the organization may be involved in the strategic decision process. This is fostered by the linkages created in the Risk Network, which serves as a means to bring risk and stakeholders together.

Overall, the complexity of the assessed risk needs to have an equally robust corresponding interface with the Strategic Planning / Decision Process. Two avenues of strategic decision-making are represented in the Model, a *Formal Process*, and an *Informal Process*, which are distinguished (for illustrative purposes) based on the time horizon of the issue and the nature of the risk. Briefly described:

1. Strategic risks— tend to have a longer-term time horizon and warrant a formal strategic decision by senior leadership, who make decisions on programs, departmental structure, etc. For example, the decision to commit resources to a new health service initiative or program.
2. Tactical risks— tend to have a medium time horizon and can warrant either a formal or an informal strategic decision at the senior or department level based on policy analysis. For example, the decision to make changes in methods for implementing a new service initiative or program.
3. Operational risks— tend to have a short-term time horizon and warrant an informal strategic decision at the operational level on day to day, control of risks in operations

through supervision, correction, retraining of staff, and other quality control methods. For example, the decision to make corrections to an identified challenge within a new service initiative or program.

The Risk / Strategy Interface can be further illustrated by the following simplified example that pulls together the components of the Model described so far. Say that during a routine risk assessment there is a noticeable difference identified between the success rate of a procedure at a local health facility compared to external benchmarks. This risk is then reported to the Risk Network and analyzed utilizing the processes of the ERM Framework, which identify the problem as consisting of staffing misalignment, technology cycle breakdown and responsibility/accountability uncertainty. Related members of the Risk Network (i.e. human resources, information technology, clinical and medical services, and a member of the senior leadership team) form a focused sub-group to assess potential risk treatment options based on a mixture of shorter (Operational / Informal) and longer term (Tactical / Formal) solutions. A course of action is developed (considering organizational core values, resources and context) and communicated widely to the Risk Network. The senior leadership, where required, provide endorsement (see further examples in Figure 4).

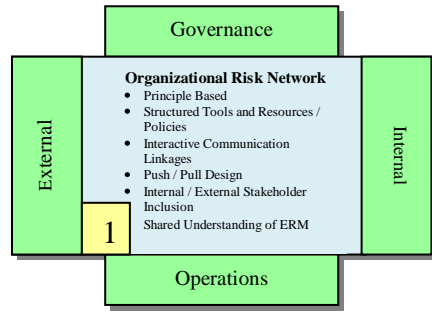
The above example is intended to emphasize the need for flexibility between the ERM Framework and the Strategic Planning / Decision process of the local health organization depending on the nature of the risk. However, it cannot be understated that regardless of the process employed, information identified through the ERM Framework (i.e. each and every issue) must be dealt with and not ignored. Tracking and shepherding risks is a shared process throughout the Model and is supported by a combination of the Organizational Risk Network, reporting features of the ERM Framework, and the ERM Support Department (discussed below).

Figure 4: Examples of Use of the Model Components

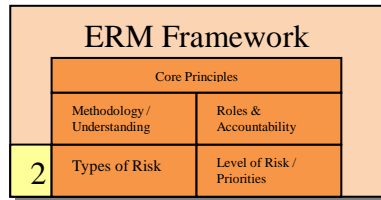
Risk Program Element

Model Component

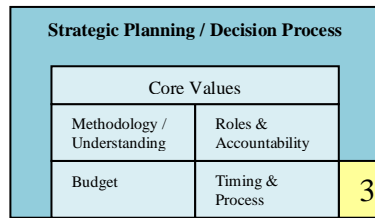
- Assessment / Screening Tools
- Issue Identification
- Communication
- Internal / External Considerations
- Initial Risk Perception
- Background Information Gathering
- Identification of Related Stakeholders
- Initial Impact Analysis
- Issue Prioritization



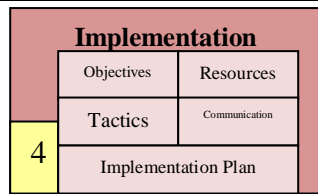
- Risk Assessment Methodology
- Clear Problem Definition
- Impact Analysis (Who?)
- Risk Classification / Prioritization
- Resource Scan
- Time Horizon
- Initial Risk Response Options
- Formal / Informal Process



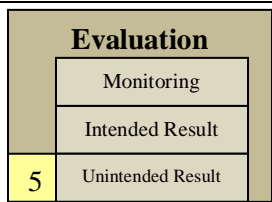
- Defined Decision Level
- Decision / Planning Methodology (Core Values)
- Refined Preferred Options
- Resource Implications / Opportunity Costs
- Stakeholder Impact Assessment
- Time / Impacts on Strategy
- Assigned Accountability



- Defined Accountability
- Clear Goals / Objectives
- Documented Implementation Strategy (Plan)
- Approved Resources
- Iterative Stakeholder Interaction
- Performance Measurement



- Determine if Risk Eliminated (Mitigation)
- Assess Intended and Unintended Outcomes
- Consider New Opportunities
- Environmental Context Scan
- Stakeholder Perceptions
- Follow-up Reporting



Example: Strategic Risk

A neighboring Region experiences an unexpected patient death at a contracted health provider organization which we also contract with for similar service.

- Initial Stakeholders Identified: Senior Management, Contracted Provider, Neighboring Region, Medical and Allied Professional Staff, and Communication Staff
- Background / Initial Analysis: Regulatory / Liability Risk
- Possible Contributing Factors: Staffing Vacancy, Accountability Uncertainty, Provider Suitability / Appropriateness, Patient Acuity Level

- Assessment: High Priority, High Potential for Local Occurrence. Reputation, Regulation & Political Components. Risk Prevention
- Defined Problem: Provider Inexperience, Compliance to Standards Failure, Inadequate Monitoring / Role Confusion, Inadequate Contract Specification
- Formal Process Required

- Stakeholder Perceptions Considered
- Senior Management Decision
- Selected Option: End Existing Contract, Redefine Roles, Bring Partial Services Back In House, Seek Alternate Provider, Commit Resources to Shared Education / Training/ Performance Measurement
- Implementation Plan Pursued and Assigned to Executive Member

- Formal Implementation Plan Generated
 - Set Goals / Objectives
 - Redefine Care Pathway / Define Partnerships
 - Education Expectations
 - Performance Evaluation
- Supported Plan Rollout

- Defined Quarterly Interval of Reporting
- Comparison of Performance Against Defined Goals
- Patient / Staff Surveys
- Continued External Monitoring for Related Issues
- Review of Unexpected Outcomes

Example: Tactical Risk

Current electronic health record software provider bought out by unknown multinational corporation.

- Initial Stakeholders Identified: Senior Management, External Software Provider, Information Systems Department, Privacy Commissioner, Privacy & Security Office, Finance Department, Health Records Department
- Background / Initial Analysis: Regulatory / Liability Risk , Service Interruption
- Possible Complicating Factors: Dispute Over Data Ownership, Withdrawal of Service Support

- Assessment: High Priority, Medium Immediate Impact. Possible Health Service Delivery, Reputation & Regulation Components
- Defined Problem: Questionable Ownership of Data. Possible. Withdrawal of Tech Support to Software and Privacy Implications
- Formal Process Required

- Senior Management/ Operational Level Decision
- Selected Option: Seek Clear Commitment / Understanding from Software Company. If Required, Seek Intervention from Privacy Commissioner. Explore Alternate Software Providers
- Implementation Plan Pursued by Executive / Departments

- Formal Implementation Plan Generated
 - Set Goals / Objectives
 - Foster Relationships / Prepare Back ups
 - Performance Evaluation Criteria
- Supported Plan Rollout

- Comparison of Outcome Against Initial Challenge
- External Monitoring for Related Issues
- Sharing of Implications for Future Software Agreements.
- Performance Measure Reporting
- Review of Unexpected Outcomes

Example: Operational Risk

An increase in the number of fetal hypoxic events as compared to external benchmark.

- Initial Stakeholders Identified: Maternity / ICU Departments, Medical and Allied Professional Staff, Finance Department, Information Systems Department, ER Staff
- Background / Initial Analysis: Standards of Care, Medical Malpractice, Patient Injury
- Possible Contributing Factors: Staff Training, Policy Uncertainty, Proper Use of Technology / Equipment, Communication Gap

- Assessment: High Priority, High Immediate Impact. Essential Health Care Component. High Potential for Severe Adverse Patient Outcome
- Defined Problem: Failure to recognize fetal distress and/or interpret fetal monitoring. Inability to perform emergency c-section.
- Informal Process Required

- Operational Level Decision
- Stakeholder Perceptions Considered
- Selected Option: Establish Bi-annual Fetal Monitor Training, Identify / Purchase New Technology, Float Obstetricians, Host 'Mother to Be' Event, Update Policy Controls / Care Standards
- Implementation Plan Pursued and Assigned to Maternity Department

- Formal Implementation Plan Generated
 - Set Goals / Objectives
 - Foster Relationships Between Departments and Professional Staff
 - Performance Evaluation Criteria
- Supported Plan Rollout

- Defined Annual Interval of Reporting
- Comparison of Performance Against Defined Goals
- Staff Surveys
- External Monitoring for Technological Enhancements
- Performance Measure Reporting
- Review of Unexpected Outcomes

Model Component 4. Implementation

In this stage of the Model, once a strategic decision has been made, the decision needs to be pursued or implemented (see Figure 2). This most often involves the mobilization of capital, personnel, detailed plans (tactics) with clear objectives, and continual communication. It also needs to involve clear techniques for managing the change process in direct proportion to the magnitude or size of the implemented decision. A key feature of the Implementation component of the Model is its direct relationship with the strategic planning process, which is the driver for implementation. In other words, issues or risks do not exist in isolation, and strategic decisions to pursue a course of action need to be made within the context of the overall direction of the organization (at all levels).

In practical terms, the Implementation stage of the Model needs to be characterized by a well thought-out implementation plan, as it is the implementation plan that is the basis for carrying out the selected decision. The plan should document the specific tasks and timeframes for completion; the roles, responsibilities, and accountabilities of participants; tactics for communication and engagement of interested and affected parties; and the criteria to be used for monitoring and evaluation. The plan should include show stopping criteria that will stop the implementation and return the issue to the planning / decision process to prevent deviation from expectations (e.g. unintended risks emerge, implementation has adverse consequences on other organizational programs, or that anticipated budget or resource requirements are exceeded) (Adams, 2005). Consideration of staff training, and the availability of regular performance information that can assist in identifying improvements resulting from the action taken, also need to be made. Of key importance, the implementation plan also must consider the common barriers to change within an organization and intentionally address them. Some effective change strategies that should be consciously considered include (Brockner & Wiesenfeld, 1996):

- Identifying potential sources of resistance to the intended change
- Creating a sense of urgency for the change
- Providing a vision of the future state
- Clearly outlining the process to move from status quo to future state
- Developing a strong leader role – role modeling, rewarding / emphasizing small wins

- Lining up political sponsorship (stakeholders) and leverage support
- Communicating, involving people, and being honest
- Reducing the personal cost of change:
 - Address the basis of individual resistance
 - Ensure a fair process Illustrate the cost-effectiveness of change
- Removing barriers:
 - Lack of knowledge
 - Lack of understanding of positive effects
 - Lack of motivation
 - Threats to power

Throughout the implementation process, the Organizational Risk Network can be of considerable use as an information conduit for the implementation plan, in the identification of internal and external stakeholders and expertise, as well as a resource on approaches and methodology for making strategic improvement.

Model Component 5. Evaluation

The last component of the Model involves evaluation and monitoring of implemented decisions in terms of intended and unintended consequences (see Figure 2). Evaluation in this sense includes assessing the organization's performance in meeting its objectives, including the implementation of strategic programs and activities and their risks and benefits. Evaluation and review activities provide important information to determine whether the risk decisions are efficient, cost-effective, and reflect the strategic and operational context of the organization and whether the overall decision-making process is adequate. Monitoring is an essential and integral step in the process for managing risks in order to identify emerging risks and facilitate continuous improvement in the decision process.

Evaluation, although represented as a distinct component in the Model, has been included in each portion of the Model. For example, the Organizational Risk Network includes tools to pull together trending information from both internal and external sources (such as the regulatory environment, stakeholder views, and new technology or care advances). Similarly, the Risk /

Strategy Interface needs to evaluate costs and benefits and discussions with stakeholders to determine the effectiveness of risk management actions. Ongoing evaluation of the resulting implementation plan to ensure that risks are mitigated is also essential. Since the organizational risk management process is a circular process, both evaluation and monitoring can occur at any point in the loop.

Effective risk-management programs are those that deliver cost-effective risk outcomes and reflect the strategic and operational context of the organization. The context includes the financial, operational, competitive, political (public perceptions/image), social, cultural and legal aspects of the organization's functions. It is necessary to understand the objectives and mandate of the organization and its capabilities when making decisions about risk. This helps to define the criteria by which risks are evaluated and from which better or more effective health care decisions and outcomes can evolve.

Barriers to Risk Management – Revisited

With the development of Model for Organizational Risk Management, it is important to revisit key barriers to effective risk management that were raised by the literature and Study Organization. In particular, the apparent widespread accountability uncertainty for managing risks and information gaps in planning and decision making.

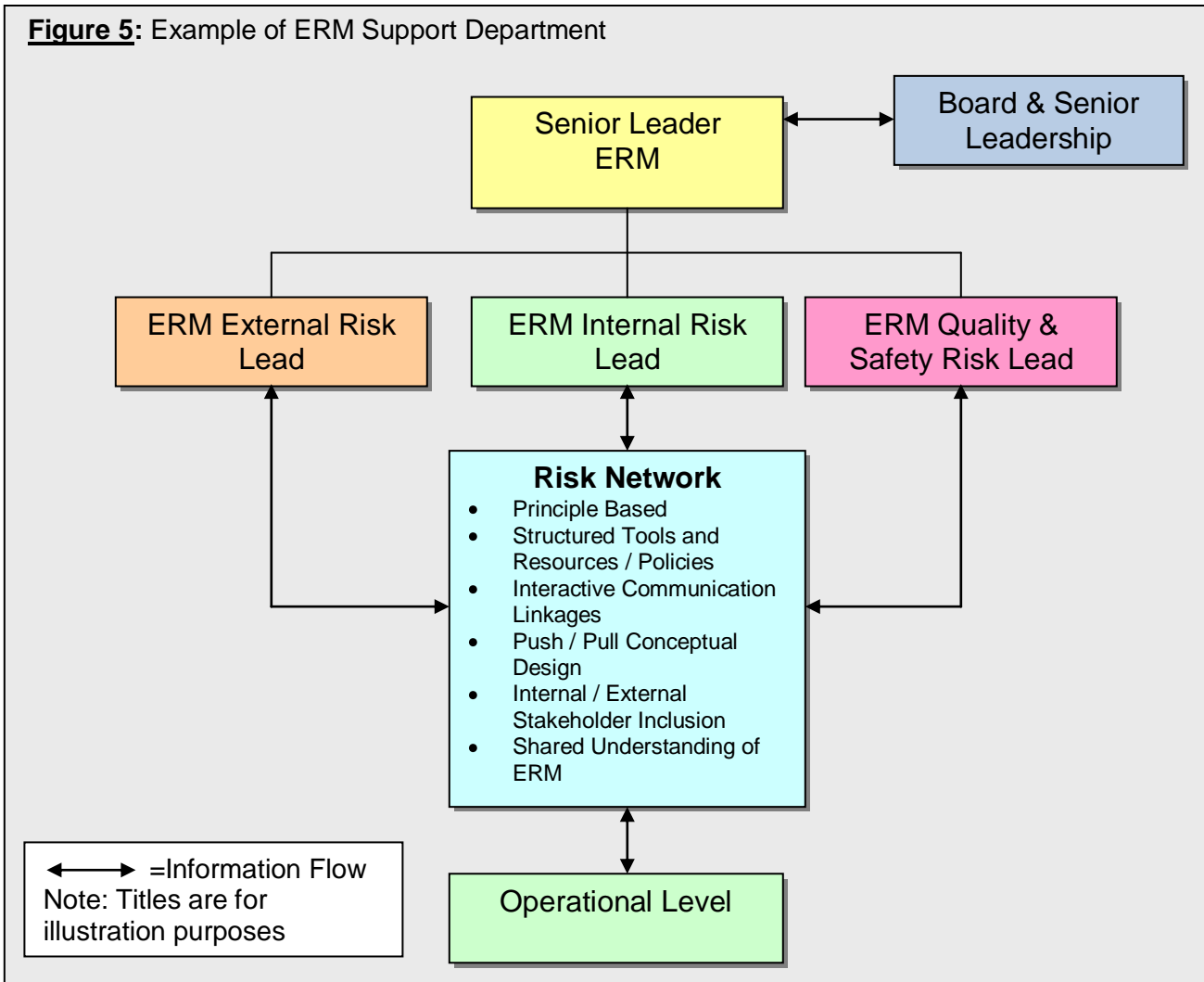
The Model directly addresses these issues by first defining an explicit approach to risk management through the ERM Framework, second by establishing a Risk Network that links information with existing accountability structures, third by emphasizing the importance of utilizing risk information to reach strategic decisions, and fourth by explicitly addressing how risk mitigation will be actioned. Taken together, the ERM Framework sets out the rules for how risk is understood, how it is treated, and by whom; the Risk Network fosters unified information exchange between staff and stakeholders by providing a defined destination for local observations, questions, or perceptions of risk – ensuring that information is communicated broadly and leveraging organizational expertise; the Strategic Planning / Decision Process brings to the forefront the necessity of looking at risk organizationally by promoting strategic decisions

that address risk at the appropriate organizational accountability level based on the nature of the risk; and the Implementation Process ensures that decisions are supported by clear tactics that will result in the desired outcomes being realized. Taking the Model as a whole, questions around accountability and information gaps are addressed and an approach that fosters broad engagement and genuine participation across the organization is achieved. While it is difficult to anticipate every potential barrier, application of this Model intentionally removes much of the prevalent uncertainty around risk management, and positions a health organization to be able to focus on managing organizational challenges.

Functional Support for the Organizational Risk Management Model

In order to administer the concepts presented in this Model, a formal support structure or ERM Resource (endorsed by senior leadership to develop and maintain the risk management program) is needed (see Figure 5 example). The risk management program is then delivered (or operationalized) by each of the areas of the organization. In this way, the organization is blanketed by the risk management program, supported by the ERM Resource, with accountability directly retained by the operational levels to identify and manage risks for their area. This decentralized approach leverages the expertise and functional knowledge that exists within the diverse programs that make up the organization. The ERM Resource is essential in establishing and maintaining the mechanisms used to tap into this knowledge, so as to apply and benefit organizationally from the ERM framework. Recalling the fundamental premise of ERM to be enterprise wide, caution is needed to ensure that the ERM Resource is structured as a support department and not as the functional risk manager. In other words, the organizational risk program cannot be done by a single area, but instead, needs to be a component of operations throughout the organization. This is fostered by the explicit recognition that ERM be delivered via a decentralized approach.

Figure 5: Example of ERM Support Department



When viewed as a support department, key functions of the ERM Resource include:

- Designing the structure, administration, and education of the risk management program
- Developing and maintaining supporting policies and risk management program mechanisms (technological / interpersonal)
- Synthesizing and presenting risk information / organizational risk profiles
- Working with and supporting the Risk Network and participants
- Fostering linkages both internally and externally as part of the Risk Network
- Developing and implementing ERM tools and resources (i.e. Risk Audit Teams)
- Facilitating communication of identified risks and mitigation strategies throughout the organization (push / pull)

- Linking the risk management program closely with existing core risk processes
- Stewarding issues throughout the Risk / Strategy Interface to action
- Fostering robust and timely implementation plans and follow up evaluations

Depending on the breadth of the health organization, the size of the ERM Resource is scalable in terms of the number of dedicated resources required to implement an effective organizational risk management program. When determining the size of the ERM Resource, emphasis needs to be placed on ensuring knowledgeable staff (in terms of ERM and health care in general), are in place who can work closely with existing personnel and programs to foster a common understanding and approach to risk management. Relationship building, technological skills, and the ability to communicate are a crucial component of the ERM Resource. The strength of the presented Model and in particular the reliance on a decentralized approach, is not in developing an extensive ERM Resource, but rather leveraging the existing talents and resources within a unified organizational risk management approach.

Practical Development of a Sustainable Health Care Organizational Risk Management Program

The Model for Organizational Risk Management has been designed to be approached in a stepwise fashion within the context of a local health organization. As described, the Model lays out five core components that need to be explored and customized to the local setting based on the unique characteristics of the organization. In this manner, adoption of the Model represents a commitment to assess current processes, and in a systematic way, incorporate ERM into the risk management program. While the exact approach employed may differ between organizations, the following is an example of a procedure that could be undertaken to implement this Model.

Sample Stepwise Implementation

Adoption of this Model suggests that a local process be undertaken to:

1. Understand the current existing organizational processes (including risk management functions and decision-making processes). This may involve process mapping in order to

fully understand how it works now. Compare against Key Elements described in the lower portion of Figure 2.

2. Confirm the need for changes in practice (what has worked well, what has not worked well, what could be improved). Do barriers that have been identified in the literature apply to this organization? What are the local perceptions of current practice?
3. Work with the senior health care leaders to assess (using the ERM Evaluation Tool) the most viable ERM framework for the organization (based on interrelationship of current practices, organizational capacity and desired outcomes). Set initial key priorities, measure and confirm commitment of resources.
4. Develop implementation plan.
 - a. Establish the ERM Resource (or equivalent) tasked with implementing the organizational risk management program. Focus on a decentralized approach supported by knowledgeable expertise.
 - b. Establish an Organizational Risk Network. Based on senior health leader input and endorsement, development of: a network with representation from each functional area and a defined terms of reference; a common understanding of ERM (including language); interactive communication tools; educational resources; as well as clear reporting mechanisms.
 - c. Identify and develop a core group of champions from which to further develop local expertise. What are the natural areas that will have an interest in ERM? Who are the individuals who have been involved in 'risk management' to date? What skills and resources already exist? Clearly articulate the benefits of looking at a unified risk management approach.
 - d. Understand and define the ERM process as it relates to strategic decision-making and planned outcomes. Clarify roles and accountabilities. Develop risk prioritization tools, tracking mechanisms and reporting instruments.
5. Implement the Organizational Risk Management Model. Promote early wins, adapt based on stakeholder feedback.
6. Link in external stakeholders and refine processes of reporting and communication.
7. Evaluate progress. Ensure the risk process is working, beneficial, and addressing core organizational needs. Assess / adjust as required to unexpected barriers / resistance.

Following the above steps (or variations thereof) should position the health organization with the means to implement a viable ERM framework as part of the overall organizational risk management program.

Successes, Challenges, and Future Avenues of Study

The Model for Organizational Risk Management is designed as a roadmap that health care leaders can use to pursue ERM in a local health setting. Development of this Model appears to have been well-timed as interest in risk management has generated opportunities to introduce these concepts throughout jurisdictions in Canada (Haney, 2010). Resulting feedback has been very supportive of the Model, and in particular, the concept of a Risk Network. Being able to link a risk strategy throughout the organization in an integrated and cost effective manner appeals considerably to health leaders, particularly in the current fiscal and political environment. Health leaders have also been very receptive to the background analysis and clarification of what ERM is and how it relates to healthcare, which appears to have been a poorly understood concept.

The opportunity to share this work broadly has also generated common areas where questions about the Model have been raised, these have tended to include: 1) how best to identify potential ERM frameworks (as there appear to be many, and the ERM Framework Evaluation Tool only works to assess ERM frameworks that have already been identified), 2) how to determine the appropriate size and scope of the risk network, and 3) how to balance formal support (or control) of the organizational risk management strategy and still allow staff and stakeholders opportunity to take beneficial ownership of the process. These potential challenges are key lessons on the level of detail that health leaders may require in order to successfully adopt an organizational risk management program, and are an excellent indication of where future avenues of study should focus. As a key next step, this Model is currently being adopted by a major health organization which will allow direct study of the successes and failures associated with Model component. These results are intended to be the subject of further reports on this subject.

Conclusion

The findings from this project present a comprehensive methodology for approaching organizational risk management within a health care setting. Based on a wide assessment of published literature and comparative analysis within the Study Organization, the *Model for Organizational Risk Management* has been developed as a basis for linking the components of an ERM Framework into the existing processes of a health organization in order to overcome the barriers that commonly disrupt strategic risk management within health care. The approach taken looks beyond simple adoption of an ERM framework, but instead looks at how best an ERM framework can fit within an existing multifaceted health organization by building off of and/or enhancing existing processes and resources in order to ensure familiarity, acceptance, and ultimately sustainability of the risk management program. By approaching the Model in a stepwise fashion based on local organizational context, health care leaders are provided with a road map from which to initiate or advance their own organizational risk management program.

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Appendix 1: ERM Framework Evaluation Tool

Key Overarching Elements to be Included in a Comprehensive Risk Management Framework (Ceniceros, 2008; Jardine et al., 2003; Leadbetter et al., 2008)	Method Addressed in Potential Framework?	Weighting / Score (Set Weightings based on Organization Priority)
1. Problem formulation stage.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	Overall [?]/15
• Framework combines context with clear techniques to define problem.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/4
• The dynamic nature of risk is acknowledged.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/3
• Correct definition of the problem is fostered.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Problems are identified, formulated, and characterized within the local context.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Risk management goals, authority, responsibility and resources are understood.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Recognizes the need for collaboration and communication with stakeholders in defining problem.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
2. Stakeholder involvement.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	Overall [?]/15
• Framework is clear and widely applicable.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/5
• Fosters strong and defined involvement of stakeholders.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/3
• Elicits views of those affected by the risk and considers multiple perspectives.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Promotes mechanism(s) for listening, considering, and respecting opinions, ideas and contributions.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Sustains stakeholder involvement throughout the Framework.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/3
3. Communication.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	Overall [?]/15
• Framework is simple and easy to understand.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/5
• Utilizes a defined communications approach.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/3
• A clear set of terminology is defined and used.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Linkage with stakeholders (internal and external) is explicit.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Recognizes the value of a reciprocal two-way process to exchange information, knowledge and experience.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/3
4. Quantitative risk assessment components.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	Overall [?]/15
• Framework provides specific detail on conducting scientifically based risk assessment.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/3
• Includes approaches for: 1. Risk Identification	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• 2. Risk Assessment	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• 3. Risk Classification	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• 4. Risk Scoring (or Prioritizing)	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• 5. Evidence Evaluation	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• 6. Option Generation.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
5. Iteration and evaluation.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	Overall [?]/10
• Framework is able to accommodate new information.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Recognition that risk management cannot be a sequential process.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Evaluation occurs throughout the process and ensures that changing information or perspectives are recognized and linked back into the process.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Purposeful effort is made to determine the effectiveness of solutions or decisions made.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Learnings from one circumstance can be brought forward into future practice.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
6. Informed decision making.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	Overall [?]/15
• Framework is broad based and comprehensive to help all types of risk managers make good risk management decisions.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/5

• Decisions are principle based and consider scientific, social, cultural, ethical, political, and legal aspects.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Fosters clear decisions and policies.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/4
• Elicits the views of those affected by the decision.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Employs a deliberate method of analysis based on available information / evidence.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
7. Flexibility.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	Overall [?]/10
• Framework is able to address many types of risks, as well as adapt to the power structure of the organization.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Different levels of risk urgency (and associated timelines for mitigation) can be addressed simultaneously.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Acknowledgement that risk management is complex and cannot be 'one size fits all'.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Intentionally ensures that risk management process encompasses the considerations of each unique situation.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Ability to change a decision if/when new information becomes available.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
Key Elements of Decision Making to be included in a comprehensive Risk Management Framework	Method Addressed in Potential Framework?	Weighting / Score
1. Do more good than harm (<i>beneficence, nonmalficence</i>).	Yes <input type="checkbox"/> or No <input type="checkbox"/>	Overall [?]/12
• Generated decisions prevent or minimize risk, or to “do good” as much as possible.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Framework acknowledges that zero risk is unattainable, but that prevention or minimization of risk is beneficial.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Emphasis on improving human health is explicit.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Consideration is made for the broad nature of risk.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Actions are promoted that will achieve the greatest risk reduction.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Priority is given to preventing risks, vs. controlling, managing or reacting to risk.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
2. Fair process of decision making (<i>fairness, natural justice</i>).	Yes <input type="checkbox"/> or No <input type="checkbox"/>	Overall [?]/10
• Decisions are equitable, impartial, unbiased, dispassionate, and objective as far as possible given the circumstances of each situation.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/3
• Proposed strategies balance conflicting needs, rights, demands, and evidence.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/5
• The approach to risk decision making is clearly documented so that stakeholders can contribute.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
3. Ensure an equitable distribution of risk (<i>equity</i>).	Yes <input type="checkbox"/> or No <input type="checkbox"/>	Overall [?]/10
• Risks are distributed equally in terms of benefits and burdens.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/3
• There is a process to balance who benefits with who is harmed (or the cost) by any risk.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Decisions have a high probability of fostering fair outcomes and equal treatment of all concerned.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/3
• Risk is not able to be transferred or off-loaded onto another group or organization.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
4. Seek optimal use of limited risk management resources (<i>utility</i>).	Yes <input type="checkbox"/> or No <input type="checkbox"/>	Overall [?]/10
• Use of limited resources is emphasized where they will achieve the most risk reduction or overall benefit.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/5
• There is an explicit realization that resources are limited.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• Decisions emphasise what is important to the organization.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/3
5. Promise no more risk management than can be delivered (<i>honesty</i>).	Yes <input type="checkbox"/> or No <input type="checkbox"/>	Overall [?]/10
• Unrealistic expectations of risk management are avoided explicitly.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/5
• Processes are present to communicate what is known and not known.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
• There is a clear understanding of what can be done and not done with the risk framework. (i.e. knowing limitations).	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/3
6. Impose no more risk than you would tolerate yourself (<i>the Golden Rule</i>).	Yes <input type="checkbox"/> or No <input type="checkbox"/>	Overall [?]/10
• Decision makers are not detached from decisions and are held accountable to those affected.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/5
• Decision process clearly identifies those who will bear the risk.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/5
7. Be cautious in the face of uncertainty (<i>“better safe than sorry”</i>).	Yes <input type="checkbox"/> or No <input type="checkbox"/>	Overall [?]/10
• Decisions must be approached cautiously when faced with a potentially serious risk	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/5
• Evidence, or what is required in order to make the best decision, is understood.		[?]/5
8. Foster informed risk decision making for all stakeholders (<i>autonomy</i>).	Yes <input type="checkbox"/> or No <input type="checkbox"/>	Overall [?]/10
• Stakeholders have the opportunity to participate with all of the information required / available.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/5
• Communities or groups affected by the problem are included in the process.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2

<ul style="list-style-type: none"> The 'right level' of participation by stakeholders is fostered. 	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/3
9. The risk decision processes must be flexible and evolutionary to be open to new knowledge and understanding (<i>evolution, evaluation, iterative process</i>).	Yes <input type="checkbox"/> or No <input type="checkbox"/>	Overall [?]/10
<ul style="list-style-type: none"> New evidence can be introduced into the decision process at any time. 		[?]/5
<ul style="list-style-type: none"> Evaluation of the strength of evidence is explicit and ongoing (iterative). 	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/5
10. The complete elimination of risk is not possible (<i>life is not risk free</i>).	Yes <input type="checkbox"/> or No <input type="checkbox"/>	Overall [?]/10
<ul style="list-style-type: none"> The framework acknowledges that risk is pervasive in our society, and cannot be totally eliminated. 	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
<ul style="list-style-type: none"> A cautious approach is pervasive when faced with complex risks. 	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/2
<ul style="list-style-type: none"> Prudent action / decisions must be possible without having to wait for scientific certainty. 	Yes <input type="checkbox"/> or No <input type="checkbox"/>	[?]/4
Underlying Organizational Principles for Risk Management Decision Making (Customized to Local Organization Values and Principles)	Method Addressed in Potential Framework?	Weighting / Score
Example: Maintaining and improving health is the primary objective.	Yes <input type="checkbox"/> or No <input type="checkbox"/>	Overall [?]/12

Appendix 2: Selected Study Organization Survey Questions

Primary Research Questions:

1. *What causes identified risks to be ignored in health care?*
2. *How is perceived inaction 'justified'?*
3. *What information and processes are required to strategically manage identified risks?*
4. *How should the awareness of risk be translated into the strategic planning process?*

Related Research Question	Q#	Survey Question (Author)	Survey Question Type	Survey Findings		
1	Q1	Health care leaders are often limited by time / workload constraints (Jewell & Bero, 2008)	Degree of Agreement	Strongly Agree & Agree 100.0%	Neither Agree nor Disagree 0.0%	Disagree & Strongly Disagree 0.0%
1	Q2	Health care leaders are often required to make quick decisions with limited evidence or supporting rationale (Graham et al., 2006; Lavis et al., 2004)	Degree of Agreement	Strongly Agree or Agree 84.2%	Neither Agree nor Disagree 10.5%	Disagree or Strongly Disagree 5.3%
1	Q3	Health care leaders are not taught to use research to inform their decisions (Jewell & Bero, 2008)	Degree of Agreement	Strongly Agree or Agree 42.1%	Neither Agree nor Disagree 21.1%	Disagree or Strongly Disagree 36.8%
1	Q4	There are very few relevant research studies for many important health policy issues or identified risks (Jewell & Bero, 2008; Jardine et al., 2003)	Degree of Agreement	Strongly Agree or Agree 61.9%	Neither Agree nor Disagree 28.6%	Disagree or Strongly Disagree 9.5%
1	Q6	Risks tended to be longstanding and known about locally but not necessarily acted upon (Balding, 2008)	Degree of Prevalence	Very Common or Common 42.9%	Neither Common or Uncommon 19.0%	Uncommon or Very Uncommon 38.1%
2	Q9	Accountability for risk management was clear in the organization (Minsky, 2007)	Degree of Prevalence	Very Common or Common 47.6%	Neither Common or Uncommon 14.3%	Uncommon or Very Uncommon 38.1%
2	Q11	I have identified risks that have not been acted upon	Degree of Prevalence	Very Common or Common 42.9%	Neither Common or Uncommon 14.3%	Uncommon or Very Uncommon 42.9%
2	Q15	In your experience, how common is it for identified risks to be ignored (or not addressed in a timely fashion) in health care? (Minsky, 2007)	Degree of Prevalence	Very Common & Common 52.4%	Neither Common or Uncommon 28.6%	Uncommon & Very Uncommon 19.0%

Related Research Question	Q#	Survey Question (Author)	Survey Question Type	Survey Findings		
2	Q17	Health care leaders have adequate education on risk management and strategic planning (Jeffs et al., 2006)	Degree of Agreement	Strongly Agree or Agree 16.7%	Neither Agree nor Disagree 50.0%	Disagree or Strongly Disagree 33.3%
2	Q18	Identified risks are often ignored in health care (Minsky, 2007)	Degree of Agreement	Strongly Agree or Agree 55.6%	Neither Agree nor Disagree 11.1%	Disagree or Strongly Disagree 33.3%
2	Q19	Health care leaders often have the necessary information to make an informed strategic decision (Minsky, 2007)	Degree of Agreement	Strongly Agree or Agree 31.6%	Neither Agree nor Disagree 15.8%	Disagree or Strongly Disagree 52.6%
2	Q22	Risk management should focus on the risks to the entire organization (Minsky, 2007)	Degree of Agreement	Strongly Agree or Agree 83.3%	Neither Agree nor Disagree 5.6%	Disagree or Strongly Disagree 11.1%
2	Q23	Communication of risk issues is frequent, effective, and allows risks to be acted upon in a timely manner (Minsky, 2007)	Degree of Agreement	Strongly Agree or Agree 0.0%	Neither Agree nor Disagree 23.8%	Disagree or Strongly Disagree 76.2%
3	Q28	Risk management decisions should be transparent (Jardine et al., 2003)	Degree of Agreement	Strongly Agree or Agree 100.0%	Neither Agree nor Disagree 0.0%	Disagree or Strongly Disagree 0.0%
3	Q31	Information flows freely across organizational boundaries (Minsky, 2007)	Degree of Agreement	Strongly Agree or Agree 5.6%	Neither Agree nor Disagree 5.6%	Disagree or Strongly Disagree 88.9%
3	Q32	Risk processes are a key component of strategy and planning processes (Brazeau, 2008)	Degree of Agreement	Strongly Agree or Agree 90.0%	Neither Agree nor Disagree 10.0%	Disagree or Strongly Disagree 0.0%
4	Q39	The strategic planning function should play an important function in risk management as a mechanism to ensure calculated mitigation of risks (Neilson, Martin & Powers, 2008; Jeffs et al., 2006)	Degree of Agreement	Strongly Agree or Agree 100.0%	Neither Agree nor Disagree 0.0%	Disagree or Strongly Disagree 0.0%

Appendix 3: Key Findings from Evidence Review

Theme 1) General Management / System Barriers to Organizational Risk Management	Theme 2) Local Organization Strategic Planning / Risk Management Barriers	Theme 3) Barriers Risk Management within the Decision Making Process	Theme 4) The Beneficial Use of Information/ Evidence	Theme 5) Elements of Successful Strategic Organizational Risk Management
<p>Main evidence messages:</p> <ol style="list-style-type: none"> 1. Complexity of the health system fosters considerable opportunity for gaps in risk management processes to occur. 2. It is not intentional management inadequacy that causes risks to be ignored, but rather the combined effect of multiple system barriers that result in failed strategic risk management execution. 3. Translation of strategy into operations is an essential component of effective risk management. 4. Data, role uncertainty, reactionary leadership, political interference, competing interests on health leader time, and financial constraints/uncertainty, explain in general what leads to inaction/ineffectiveness of health leaders on identified risks. 5. Clarity within a defined framework, dedicated resources, targeted education and focused organizational strategy, should be the underlying premise of a risk management program. 	<p>Main evidence messages:</p> <ol style="list-style-type: none"> 6. The current health planning / decision-making process is ineffective and has caused health leaders to pursue subsequent independent parallel processes (i.e. breaking the planning function into capital plans, health service plans, operational plans, etc.). 7. Strategic planning is not effective with only a top down approach. 8. Risk management needs to be broadly approached and not siloed. 9. Health leaders see value in working towards an integrated risk planning framework. 	<p>Main evidence messages:</p> <ol style="list-style-type: none"> 10. The pressure/ demand to make quick reactionary decisions fosters fragmented/ineffective decision-making. 11. Health care leaders desire strategic mechanisms that coordinate risk management / decision-making. 12. The availability, assessment and application of information greatly influences the decision-making process. 13. Decision making (in general and within the risk management context) is best approached as a coordinated process rather than a series of independent events. 	<p>Main evidence messages:</p> <ol style="list-style-type: none"> 14. Health care leaders face challenges in accessing and/or linking evidence into the decision-making process. 15. The transfer of research evidence into risk management practice requires a coordinated and strategic process. 16. Mechanisms need to be established to link information, expertise and assessment with decision-makers. 17. Clear accountability for implementation and evaluation is required to determine if expected results have occurred. 18. Knowledge translation/transfer is an essential component of risk management. 	<p>Main evidence messages:</p> <ol style="list-style-type: none"> 19. 'Enterprise Risk Management' is a broad term that represents an organizational view of the risk process. 20. An enterprise or organizational approach to risk management should be implemented in a customized way within a health organization. 21. Key components that should be a part of a comprehensive risk management framework include: <ul style="list-style-type: none"> • Problem formulation, • Stakeholder involvement, • Communication, • Quantitative assessment, • Iteration and evaluation, • Informed decision-making, and Flexibility. 22. Risk management and strategic planning are interrelated processes that form part of the overall organizational decision-making process. 23. Successful and strategic risk management relies on an understandable framework that is supported by senior leaders and implemented across the organization in a principled / ethical way. Key considerations are: <ul style="list-style-type: none"> • Do more good than harm • Fair process of decision-making • Ensure an equitable distribution of risk • Seek optimal use of limited risk management resources • Promise no more risk management than can be delivered • Impose no more risk than you would tolerate yourself • Be cautious in the face of uncertainty • Foster informed risk decision-making for all stakeholders • Risk management processes must be flexible and evolutionary to be open to new knowledge and understanding • The complete elimination of risk is not possible

Appendix 4: Study Organization

Situated in central Alberta, the Study Organization was the third largest provincial health region by population, serving nearly 300,000 residents and employing over 9,000 staff and physicians. Operating 45 health facilities with an annual budget of over \$600 million, the Study Organization was governed by a board of directors appointed by and responsible to the Government of Alberta, and administered by a senior executive team accountable for the comprehensive service delivery for this geographic area. The Study Organization was chosen because of its reputation for sustained and strong leadership, the ongoing availability and willingness of senior health leaders to actively participate in research initiatives, and the common expressed interest in studying and adopting a strategic organizational risk management approach (by supporting this project through the Executive Training for Research Application (EXTRA) Fellowship Program of the Canadian Health Services Research Foundation).

Appendix 5: Academic Mentorship

The author wishes to extend a sincere thanks to Dr. John Church, Associate Professor, University of Alberta, Dr. Gian Jhangri, Associate Professor, University of Alberta, and Dr. Sam Sheps, Professor, University of British Columbia, for their ongoing mentorship and input into the methodology and review of this project as part of the Executive Training for Research Application (EXTRA) Fellowship program of the Canadian Health Services Research Foundation.