Patient Safety Law: From Silos to Systems

Final Report

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EXECUTIVE SUMMARY

Background

Patient safety has become a significant and pressing policy issue. Around the world, governments, the health care sector and the public are increasingly cognizant of the need to improve the safety of care delivered by their health systems. Pressure for change has been created by highly publicized incidents in a number of countries involving unsafe acts that were significant both in scale and consequence and a number of empirical studies that revealed the high rates of unsafe acts and their consequences. The costs of unsafe health care – both personal and fiscal – to individuals, their families and their communities and to the state are massive.

In this research project we explored one particular avenue for change – that is, the use of legal instruments by governments to improve patient safety. We did this through a comparative review of the use of legal instruments or frameworks in other countries (specifically Australia, Denmark, New Zealand, the United Kingdom, and the United States) as well as two non-health care related sectors in Canada (transportation and occupational health and safety).

We began this research by reviewing the legal instruments and undertaking extensive literature reviews. Further information was gathered through in-person interviews with policy-makers and academics in the countries studied, and from policy-makers and academics expert in the health, occupational health and safety, and transportation sectors in Canada. Once descriptions of the various countries and sectors were drafted, we held small-group meetings with local experts on particular aspects of patient safety. We then hosted a national consultation meeting. We subsequently drafted this final report and the appendices, which fully describe the results of the background research. Finally, we prepared a summary version of the report as well as posters and papers to be published and delivered at conferences and meetings with relevant groups.

Key Contributions

1. Identification of general themes or trends in other countries (but not yet strongly in Canada)

- a growing unwillingness of governments to leave patient safety to their health care systems or to the institutions and providers who make up the health care system. The tendency is to turn, instead, to law.
- a shift to what is sometimes called meta-regulation. Much of the law that has recently been introduced in other countries creates legal frameworks of oversight, accountability, and/or supervision that either displace or supplement the legal frameworks that have traditionally conferred a significant degree of autonomy on providers, institutions, and community-level governing bodies.
- a shift from a preoccupation with regulating the specific source or setting of care to regulating through a broader system perspective.

- a heavy reliance on information and transparency as key enablers and drivers of patient safety.

2. Identification of a new area of law, i.e., patient safety law

Having taken a system governance perspective, we identified a body of law that can be described as patient safety law, in that it functions to protect the patient by reducing unsafe acts within the health care system. The different areas of law that affect patient safety (e.g., tort law, professional regulation, institutional regulation) are not usually conceived of as an integrated system of law. However, conceiving of patient safety law as an integrated entity has value since it allows the discussion to move away from thinking in terms of narrow siloed categories of law to thinking of the larger systemic objectives the legal framework should enable regarding the governance of patient safety.

3. Development of a patient safety law matrix

We developed a matrix as an analytical tool that brings together the areas of law that make up patient safety law. The matrix makes it apparent that these different areas of law are interrelated and interact in ways that can usefully be viewed through the lens of patient safety. The matrix is a tool for analyzing the state of patient safety law in a jurisdiction. Used as part of a process, the matrix is descriptive, diagnostic, and prescriptive in nature. It provides a structure for mapping out existing patient safety law, identifying gaps or deficiencies in the legal framework, and identifying the outcomes patient safety law should promote. In significant measure it does this by highlighting the actual and potential interaction between the different types of law that affect patient safety but that are commonly overlooked due to the traditional organization of legal analysis around bodies of law, rather than around the problems or issues to which the distinct bodies of law apply.

Key Recommendations

1. Address identified gaps and weaknesses

By applying the matrix to the current Canadian legal framework, we were able to identify significant gaps and weaknesses. For example, we unveiled the fact that there are sites of care delivery that are underregulated, that some health care professionals are unregulated, and that drugs and devices are underregulated. We also identified underreporting of adverse events as well as numerous barriers to sharing information across inquiry processes. We identified the need for a systemic response to be taken to unsafe acts. This approach should both drives improvements in the system and yet maintain individual accountability where appropriate.

2. Conduct further study

Further study is needed on the difference between Canada's approach to patient safety law and the approaches observable in other countries, in part because the difference is so significant. This further study should not be organized around and through an analytical

framework that only compares particular aspects or bodies of Canadian law to their counterparts in other countries; it should take a holistic approach.

More specifically, further research should be conducted into initiatives taken in other countries that might be transferable to Canada, including:

- adoption of national standards and certification for health care institutions and across health care settings (e.g., New Zealand national standards and certification)
- umbrella oversight of health care professionals (e.g., New Zealand Health and Disability Commissioner)
- oversight of clinical trial design quality (e.g., Danish Medicines Agency)
- mandatory adverse event reporting by health care providers (e.g., Danish system)
- harmonization of fatality inquiry legislation (e.g., Australia)
- accountability frameworks that apply across the spectrum of providers, institutions, and of actors who collectively are responsible for the delivery of safe care to individual patients (e.g., New Zealand legislation)

3. Apply the patient safety law matrix

On an ongoing basis, the patient safety law matrix should be used to reflect the current state of Canadian patient safety law, identify gaps and deficiencies, and identify the outcomes that patient safety law should promote.

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I. OVERVIEW

A. Context

Patient safety has become a significant and pressing policy issue. Around the world, governments, the health care sector and the public are increasingly cognizant of the need to improve the safety of care delivered by their health systems. Pressure for change has been created by highly publicized incidents in a number of countries involving unsafe acts that were significant both in scale and consequence[1] and a number of empirical studies that revealed the high rates of unsafe acts and their consequences.[2] The costs of unsafe health care – both personal and fiscal – to individuals, their families and their communities and to the state are massive.

Some of the pressure for change has been directed at issues relating to the governance of patient safety. This is in part because the trust accorded to health professionals and institutions in the past has eroded somewhat. This erosion is in turn due in part to perceived failures to self-regulate effectively, in part to a sense that professionalism has been and is eroding, particularly in medicine, and in part to the rise of the consumer movement.[3]

An additional reason for the focus on governance and patient safety is the fact that the nature of the state's role in governance is changing – many states are becoming so-called 'regulatory states,' which use a different kind of regulation and create different kinds of relationships between policy actors, including regulatory bodies. States are enacting new governance frameworks to regulate bodies in sectors that have been previously privatized or are traditionally self-regulating. In many of these frameworks, information is increasingly gathered and used to highlight the performance of sectors and to drive improvements. In many international jurisdictions, as in some sectors in Canada, the focus of regulation is moving towards adding another level of regulatory or quasi-regulatory activity – meta-regulation – to regulate the regulators or to govern multiple regulatory structures. Meta-regulation in its most common form involves an external regulator monitoring the activities of self-regulators to ensure self-regulation is externally acceptable and accountable.[4]

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[1] See Appendix 1.

[2] T.A. Brennan *et al.*, "Incidence of Adverse Events and Negligence in Hospitalized Patients. Results of the Harvard Medical Practice Study I" (1991) 324 N. Engl. J. Med. 370; R. Wilson *et al.*, "Quality in Australian Health Care Study (1996) 164 Med. J. Aust. 754; C. Vincent, G. Neale & M. Woloshynowych, "Adverse Events in British Hospitals: Preliminary Retrospective Record Review" (2001) 322 B.M.J. 517, erratum in: (2001) 322 B.M.J. 1395; T. Schioler *et al.*, Danish Adverse Event Study "[Incidence of Adverse Events in Hospitals. A Retrospective Study of Medical Records]" (2001) 163 Ugeskr Laeger 5370; P. Davis *et al.*, "Adverse Events in New Zealand Public Hospitals I: Occurrence and Impact" (2002) 115 N.Z. Med. J. U271; G. Baker *et al.*, "The Canadian Adverse Events Study: The Incidence of Adverse Events Among Hospital Patients in Canada" (2004) 170 C.M.A.J. 1678.

[3] See for example discussion in Michelle Mello, Carly Kelly & Troyen Brennan, "Fostering Rational Regulation of Patient Safety" (2005) 30 J. Health Pol. 375.

[4] John Braithwaite, Judith Healey & Kathryn Dwan, *The Governance of Health Safety and Quality* (Australia: Commonwealth of Australia, 2005) at 25-26, 58 [Braithwaite]. The paper identifies two regulated self-regulation strategies: enforced quality improvement and enforced self-regulation. The first stimulates a sector to improve performance by requiring self-regulators to choose an area of concern and develop continuous improvement strategies, whose impact is then measured. The second strategy, enforced self-regulation, gives self-regulators

This research project focuses on governance structures for patient safety in health systems. There is a complex array of public and private actors at the local, regional, national and international level that shape policy and practice in the health sector. These actors all play important roles and use a variety of tools to address patient safety issues. However, this research further focuses in on the role of only one actor, i.e., government, and primarily on the use of one instrument, i.e., law.

A function of government is to establish an "interlocking network of public powers that regulate and guide action in a relatively consistent way, providing minimum standards of conduct and relief from harm."[5] Government has somewhat asymmetrical relationships with other actors that shape policy and practice due to governmental monopolies over the process of establishing legislation.[6] Legal instruments are therefore one tool which government (unlike other actors) may use to achieve policy ends. Ideally, all parties involved collaborate to achieve the desired outcomes, choosing from a multiplicity of legal and non-legal solutions. Some possible solutions are the legitimate concern of law; in other contexts, law should only be used after other non-legal mechanisms have been unsuccessful. Scrutiny of why and how government uses its monopoly power over the creation of, or scope and coverage of, legal instruments with respect to patient safety is therefore important. It is important to note that governments' use of legal instruments is only a part of a broader government responsibility for governance of the health care system. However, it is this use of legal instruments that is the narrow subject of this report.

Governance choices about whether to use a legal tool and what tool to use are often constrained or influenced by the nature of the existing relationships between policy actors, as well as by constitutional structures. Health systems are shaped by the interdependent relationships between governments, government agencies, health care institutions, health professionals, professional and institutional associations, interest groups, insurers, and the public. The Canadian health system has been described as a system predominantly weighted toward medical professional and collegial mechanisms, a model which may favour governance choices that are collaborative (and accommodationist) in nature and thus utilize contracts, agreements and partnerships.[7] In Canada, as in other federalist states, governmental decisions in relation to the use of legal instruments occur at federal and provincial levels which often interact with each other in complex ways.[8] This has been noted as a significant challenge to the aims of consistency and continuity of outcomes.

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the freedom to create their own standards, which are then approved and monitored by an external regulator to ensure an externally acceptable minimum standard of performance is being met (*ibid.* at 27-28).

[5] P. Hirst & G. Thompson, "Globalization and the Future of the Nation State" (1995) 24 Economy & Society 408.

[6] R. Rhodes, *Understanding Governance: Policy Networks, Governance, Reflexivity and Accountability*, (Buckingham: Open University Press, 1997).

[7] Carolyn Hughes Tuohy, *Accidental Logics: The Dynamics of Change in the Health Care Arena in the United States, Britain and Canada* (New York: Oxford University Press, 1999).

[8] T. Jost, "Health Care Rationing in the Courts: A Comparative Study" (1997-1998) 21 Hastings Int'l & Comp. L. Rev. 639 at 640-644.

Historically, the relationship between government and providers of health services has been characterized by government's reliance on self-regulation, with government relying on the expertise, experience, and professionalism of health professionals and the institutions and organizations that provide health services to ensure that those services are provided safely and are of an appropriate quality. This has been supplemented by a consumerist approach of bottom-up enforcement by individual patients using tort law and or complaint processes to obtain compensation or other forms of redress and to deter future episodes of unsafe treatment. In this project, we examine these traditional legal means of governing patient safety as well as emerging legal instruments and reforms to traditional instruments.

Finally, in setting out the context for this report, we note that patient safety has traditionally taken a person-centered approach. Such an approach focuses on apportioning responsibility to the individuals who are seen to have caused the unsafe act.[9] Legal instruments used to address person-centered safety issues are aimed at individuals and generally fall within the compliance or control mode of regulation.[10] Person-centered legal instruments create clear frameworks for individual accountability, which is important as individuals should most often be held accountable for their actions or omissions. However, critics argue that a person-centered approach isolates unsafe acts from their context and does not always recognize the complexities of system failures. In addition, a focus on "naming, blaming and shaming" an individual is said to inhibit open discussions about episodes of unsafe care, resulting in an inability to learn from these episodes to facilitate the future provision of safe care.[11]

A systems-centered approach to patient safety is increasingly influential in policymaking in the health care sector.[12] The premise is that all humans are fallible, that systems should be developed to minimize opportunities for unsafe treatment, and that blame should be avoided in order to facilitate learning. Under the systems-centered approach, when an unsafe act occurs, the important issues are how and why the defences failed and what factors helped create the conditions in which the unsafe acts occurred. On the other hand, critics suggest that the systems-centered approach may limit or obscure legitimate individual or organizational accountabilities.

As both person-centered and systems-centered approaches are currently being used, the challenge of policy-making in this area appears to be to encourage the development of initiatives that will have a real and sustained impact upon the general level of patient safety, but at the same time to balance this with mechanisms that allow individuals and organizations to be held accountable when appropriate.

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[9] See discussion in Institute of Medicine, *To Err is Human: Building a Safer Health System* (Washington: National Academy Press, 2000) [Institute of Medicine].

[10] Christopher Newdick, "N.H.S. Governance after *Bristol*: Holding on, or Letting Go?" (2002) 10 Med. L. Rev. 111 at 117.

[11] See for example, U.K., The Bristol Royal Infirmary Inquiry, *The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol* (Norwich: The Stationary Office Limited, 2001); J. Bryan Sexton, Eric J Thomas & Robert L Helmreich, "Error, Stress, and Teamwork in Medicine and Aviation: Cross Sectional Surveys" (2000) 320 B.M.J. 745; Institute of Medicine, *supra* note 9.

[12] See discussion in Institute of Medicine, *ibid.*

B. Terminology

Please refer to the glossary at the end of this report for a discussion of key terms.

C. Objectives

A number of countries have undertaken patient safety-related law reforms. In this project, we sought to gain a comprehensive understanding of the legal instruments or frameworks being used in other countries to encourage safety in health care systems. We also sought to learn from the experiences of two non-health care related Canadian sectors and the legal frameworks they use to govern safety. Where evidence was available, our aim was to critically assess these legal frameworks and to explore whether there are reform possibilities for the Canadian legal framework surrounding patient safety to be drawn from the experiences of other countries and sectors.

D. Scope

In this project, we were concerned with how governments use law and legal instruments as tools for governing patient safety. In addition to Canada, we focused on the use of legal instruments in Australia, Denmark, New Zealand, the United Kingdom (the National Health Service in England/Wales) and the United States. These countries were selected because all had studies examining the incidence of unsafe acts in hospitals, and, in all, patient safety was identified as a policy priority within the management of health systems.

We also focused on how governments in Canada use law as an instrument to address safety issues in the transportation and occupational health and safety sectors. These sectors were selected because they place significant emphasis on the regulation of safety and have a long history of government involvement in regulation to ensure safety.

E. Methodology

We began this research by reviewing the legal instruments in place in each of the target countries and sectors. We also undertook extensive literature reviews, including an examination of grey literature such as policy documents. Further information was gathered through in-person interviews with policy-makers and academics in the countries studied, and from Canadian academics and policy-makers in the health, occupational health and safety, and transportation sectors in Canada. Once descriptions of the various countries and sectors were drafted, we held small-group meetings with local (Nova Scotia) experts on particular aspects of patient safety (e.g., professional regulation). We then held a national consultation meeting, bringing together experts from across Canada to ensure that our synthesis research was complete and accurate and to reflect on the lessons to be learned from this research. We then drafted this final report and the appendices in light of all of the research as well as the input from the external experts and the final reflections of the research team. Finally, to serve the goals of dissemination and knowledge translation, we prepared a summary version of the report as well as posters and papers to be published and delivered at conferences and meetings with relevant groups (e.g., provincial health care safety advisory committees).

It is important to stress that this research is comparative. We recognize that there are significant differences between Canada and the other countries studied. Each country has a unique model for managing the conglomeration of health services, professions, and organizations that constitute its health systems. Each health system is embedded in a broader system that manages social services and in turn is embedded in unique structures of government and a unique legal system. It follows that an initiative that is appropriate and works effectively in one country and system may not work so well in another. Transferability of law reform cannot be taken for granted. That said, comparison is nonetheless instructive as there are substantial similarities between the countries studied. Indeed, even reflecting on the experiences of other countries even in light of their differences from Canada can be illuminating.

Canada is a federal state with a particular cultural, constitutional, and political context. This makes Canadian health systems and the dynamics surrounding the use of legal instruments to create patient safety frameworks significantly different in many respects from the other countries studied in this report. Perhaps most similar are the U.S. and Australian contexts. These are somewhat constitutionally similar in that they too are federal models. It is, however, important to note that Australia has a relatively homogeneous population and lacks the regional tensions that occur in the Canadian system. The U.S. constitutional structure is also very different from the Canada. Although we can learn valuable lessons from the experiences of Denmark, England, and New Zealand, the unitary systems in these countries make them potential models for systems change primarily for individual provinces or for the federal government including in its role as regulator of drugs and devices. At the same time, the experience of countries with unitary systems may mean that they are not good models for a nationally driven patient safety governance framework.

It is also important to emphasize that this is largely synthesis research. We did not, for example, engage in any primary research on the effectiveness of particular reform initiatives in various countries. All assessments of the safety initiatives in the different countries and sectors are based on reports in the literature and anecdotal evidence gathered through interviews. The goal was to gather as much information as is available, to synthesize it, and where appropriate to use the results of the synthesis to point governments in the direction of further research and analysis aimed at specific law reform initiatives in the context of Canadian patient safety.

Where this report is normative, we have used the following criteria: effectiveness, accountability, transparency, equity and efficiency. We would argue that these criteria reflect principles of good governance and also of effective, or smart, regulation.[13] However, it is important to note that many patient safety legal initiatives described in this project are relatively new; those that are not so new, such as professional regulation, have often recently been substantially reformed. Given the nascent nature of some of these initiatives, there is often very little empirical data as to effectiveness or efficiency, although there may be much

[13] N. Gunningham & P. Grabosky, *Smart Regulation: Designing Environmental Policy* (Oxford: Claredon Press, 1998); Lester Salamon, ed., *The Tools of Government: A Guide to the New Governance* (Oxford: Oxford University Press, 2002).

anecdotal evidence. Even in the other non-health related sectors that were reviewed, there has often been little examination of macro level effectiveness or efficiency of the legal instruments used.

F. Other Materials Produced

In addition to this report, which discusses the key findings of our research, there are a number of appendices. Appendix One provides a detailed discussion of the key concepts of patient safety and governance. Appendix Two contains a series of country reports that describe the legal frameworks surrounding patient safety in the countries we studied, starting with Canada. The discussion in each country report is structured around the following uses of legal instruments:

- The regulation of health institutions
- The regulation of health professionals
- The regulation of health related products (drugs and devices)
- Inquiry processes
- Compensation systems
- Complaints mechanisms
- Adverse event reporting systems
- Other legislative instruments

Where evidence is available, legal frameworks in these countries are assessed in each country report using the criteria set out above. Appendix Three consists of reports that describe safety related legal frameworks in two Canadian non-health related sectors, transportation and occupational health and safety. A list of key Canadian and international informants who shared information with us through interviews or consultation meetings is presented in Appendix Four. Appendix Five summarizes both past and future dissemination activities.

II. RESULTS

A. General Themes

This study revealed a diversity and richness of approaches to the role of health system governance in addressing patient safety that defies easy summary or generalization. Subject to the obvious limitations imposed by our methodology and the scope of our study, we have done our best to capture at least the principal aspects of this diversity and richness in the appendices.

At the same time, however, certain general patterns have emerged with sufficient clarity and consistency as to suggest that the approach being taken in diverse countries strongly reflects certain common themes or trends. Perhaps the most obvious is simply that law is increasingly being used as an instrument for improving system-wide performance on patient safety. To put it differently, one of the themes that we have identified is growing unwillingness of governments to leave patient safety to their health care systems or to the institutions and

providers who make up the health care system. Not always, but frequently, these greater levels of governmental intervention take the form of new law that modifies the autonomy that has, in each of the jurisdictions studied, been entrusted to varying degrees to health care institutions and providers. If nothing else, this new law illustrates the extent to which patient safety has become a matter of general public policy that must be pursued at the national or sub-national level. It seems also to strongly indicate a declining level of trust and confidence in providers and in self-governance within the health care system, though this seems to be much more strongly the case in New Zealand or the United Kingdom (for example), than it is in the United States.

This leads to a second theme of general scope – that much of what we have seen in the countries studied is consistent with a shift to what is sometimes called meta-regulation. Much of the law that has recently been introduced in these countries creates legal frameworks of oversight, accountability, and/or supervision that either displace or supplement the legal frameworks that have traditionally confirmed a significant degree of autonomy on providers, institutions, and community-level governing bodies. Again, the impetus for this "regulation of the regulators" seems clearly to be a decline in trust and confidence in providers and health system governors and managers. But it also appears to be a response to the recognized need for broader frameworks of accountability and oversight that cut across the boundaries of legally defined autonomy that have traditionally separated providers into distinct self-governing professionals and the system into distinct vertically defined sectors such as primary, acute, and chronic care.

This shift from a preoccupation with the specific source or setting of care to a broader system perspective is the third theme we have seen across the countries we have studied. Part of this is simply a repetition of what was said above – much of the activity that we have seen taking place in these countries consists of the creation of law and (using law) institutions that are more system-wide than those they have either replaced, supplemented, or modified. But equally important is the uneven but nevertheless pronounced movement towards greater emphasis on prevention and avoidance either in place of or alongside of the traditional reliance on blaming and compensating. In significant degree, we have seen law being increasingly used to encourage, often through the creation and mandating of new advisory or oversight bodies, the development of a culture of safety. It is here that we have observed the greatest overlap between the use of law as an instrument of patient safety in the countries we have studied with the role that law has played in advancing safety in workplaces and in transportation in Canada.

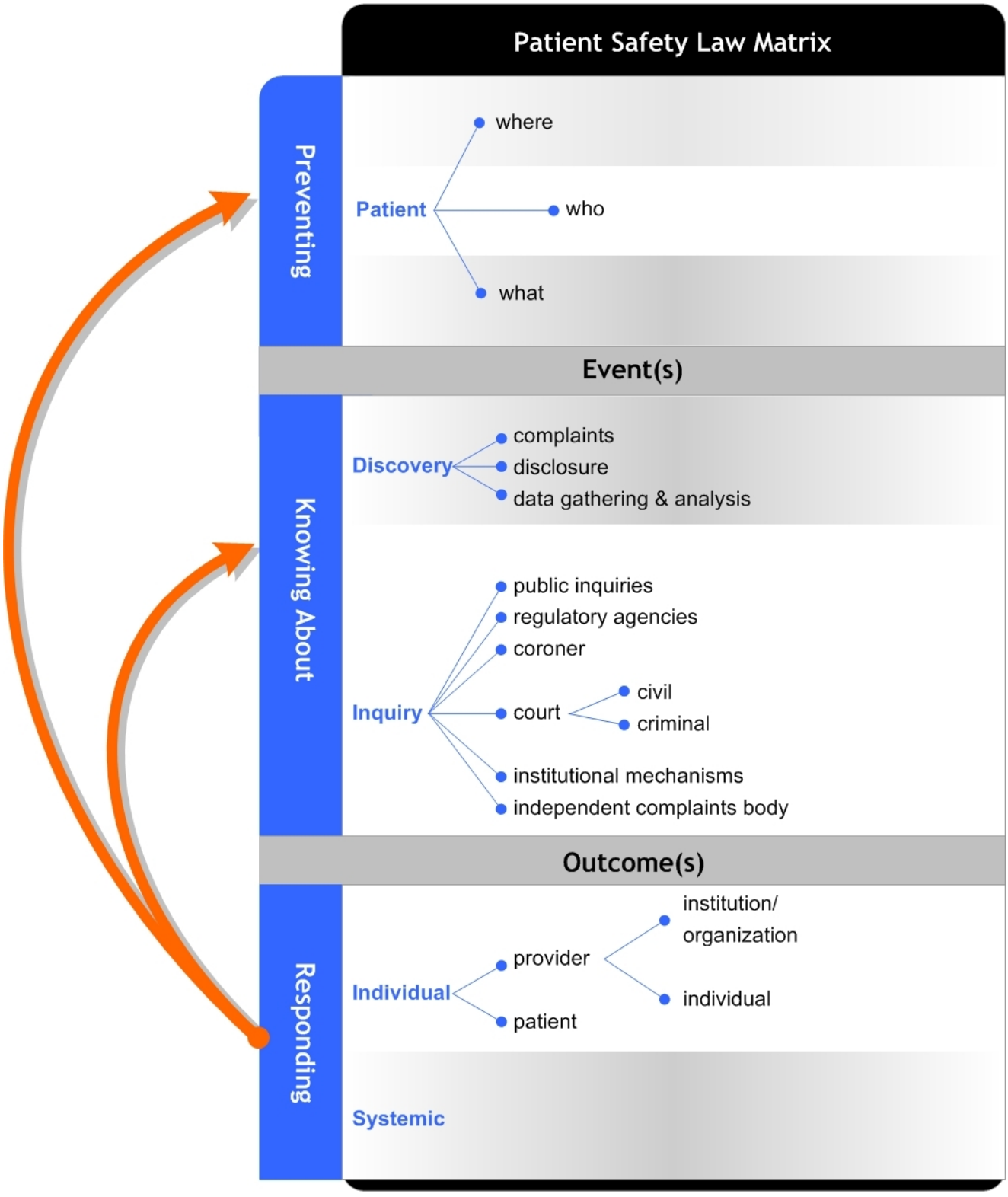
The fourth and final theme that we think worthy of mention here is the heavy reliance of the initiatives underway across the countries studied on information and transparency as key enablers and drivers of patient safety. In each of the countries, providers and institutions and systems of care are being required to track and disclose information on their performance in keeping patients safe. These obligations extend not only to events that cause injury but also to events that could have caused injury. As such, reliance on professional codes of practice as well as on the fear of possible liability or reprimand are being supplemented by increasingly detailed accountability not only to external regulatory oversight but also to the glare of publicity, with its implications either for reputational integrity or to market share or to both.

In our view, these themes capture something of the essence of what is happening outside Canada on governance and patient safety, at least to the extent that the countries we studied are representational. With the possible exception of Quebec and the example of some relatively isolated initiatives in other provinces, we are struck by the extent to which these themes do not appear to have made their presence felt in Canada. Here the legal framework around patient safety has been, in contrast to the situation in these other countries, remarkably stable. For the most part, this means a continuing reliance on a decentralized system of multiple self-regulators, a high degree of relative autonomy of providers from the state, and the continuing dominance of blame and shame as the foundation of the law. In our view, the very extent of the apparently growing divergence between Canada and such a varied group of comparator countries suggests the need for more detailed and thorough research into what is happening outside Canada with a view not only to assessing its transportability to Canada but also with a view to understanding the causes and implications of Canada's relative comfort with the legal *status quo* on patient safety.

B. Patient Safety Law Matrix

In significant measure, our principal recommendation is the one given above: further study is needed on the difference between Canada's approach to law and patient safety and the approaches observable in other countries, in part because the difference seems so significant. Beyond that, however, our more detailed recommendation is that this further study should not be organized around and through an analytical framework that only compares particular aspects or bodies of Canadian law to their counterparts in other countries. While these micro level studies undoubtedly have their importance, they are likely to be more interesting to lawyers who are interested in comparative questions of legal doctrine or technique than they are to policy-makers who are interested in understanding legal tools as instruments of system governance. From that perspective, an analytical framework that embraces the full range of instruments that are available either as alternatives to one another or as complementary instruments of governance, is critically important.

In our view, especially from a system governance perspective, there is a body of law that can be described as patient safety law, in that it functions to protect the patient by reducing unsafe acts within the health care system. The different areas of law that affect patient safety (e.g., tort law, professional regulation, institutional regulation) are not usually conceived of as an integrated system of law. However, conceiving of patient safety law as integrated has value in that it allows the discussion to move away from thinking in terms of narrow siloed categories of law to thinking of the larger systemic objectives the legal framework should enable in regard to the governance of patient safety. The matrix we have developed (see below) is an analytical tool that brings together these areas of law in a framework. Once highlighted in this fashion, it becomes apparent that these different areas of law are interrelated and interact in ways that can usefully be viewed through the lens of patient safety.


Patient Safety Law Matrix
Preventing
Patient
where
who
what
Event(s)
Knowing About
Discovery
complaints
disclosure
data gathering & analysis
Inquiry
public inquiries
regulatory agencies
coroner
court
civil
criminal
institutional mechanisms
independent complaints body
Outcome(s)
Responding
Individual
provider
institution/
organization
individual
patient
Systemic

The matrix is a tool for analyzing the state of patient safety law in a jurisdiction. Used as part of a process, the matrix is descriptive, diagnostic, and prescriptive in nature. It provides a structure for mapping out existing patient safety law, identifying gaps or deficiencies in the legal framework, and identifying the outcomes patient safety law should promote. In significant measure it does this by highlighting the actual and potential interaction between the different types of law that affect patient safety but that are commonly overlooked due to the traditional organization of legal analysis around bodies of law, rather than around the problems or issues to which the distinct bodies of law apply.

Obviously, a health care system's ability to prevent, identify, analyze, and respond to unsafe acts is influenced by the legal frameworks in place. Patient safety law functions within each of the three parts of the matrix: preventing, knowing about, and responding. Legal frameworks or instruments interact and may affect each other, either positively or negatively, both within and across the three parts. A particular legal instrument or framework, such as tort law, may figure in all three parts.

In the first part, legal instruments are used to help prevent and/or minimize the risk of unsafe acts in the health system. Some areas of law have traditionally tried to do this by deterring unsafe behaviour by assigning responsibility for such behaviour after it has caused injury or been the subject of a complaint. Examples are tort law and the disciplinary processes established by the laws governing self-regulating professions. Proactive legal frameworks recognize the risks in the system and establish processes, tools or responsibilities that try to create a preventative culture of safety. Examples include laws that establish accountability frameworks for patient safety, standards for health care delivery, continuing competency requirements for health care practitioners, and licensing processes for drugs and devices. Patient safety law seeks to prevent or minimize unsafe acts by regulating where health care is delivered, who delivers health care, and what services, tools, and products can or must be used in the provision of care.

A health care system's ability to identify unsafe acts and to learn from them is an important aspect of patient safety. In the second part of the matrix, legal instruments are used to create mechanisms or conditions that facilitate both the discovery and bringing forth of unsafe acts and the subsequent inquiry into or analysis of their causes.

The final part of the matrix addresses responses to unsafe acts occurring in the health care system. The response of the system depends on the outcomes it wishes to achieve. In turn, the ability of the system to achieve a desired outcome is influenced by the legal frameworks in place. Responses can be directed at either an individual or a systemic level, or both. At the level of the individual provider (individual or institution/organization), the outcome may serve accountability and/or restorative (rehabilitative or facilitative) functions. For the patient, the outcome may be restorative in nature (compensation/truth-telling/apology). On the systemic level, the desired outcome is system-wide learning and improvement that seeks to convert lessons learned into improved practices and processes across the system. By incorporating lessons learned, the system is ideally continuously improving its preventative and detective/investigative capacity at the first and second parts of the matrix.

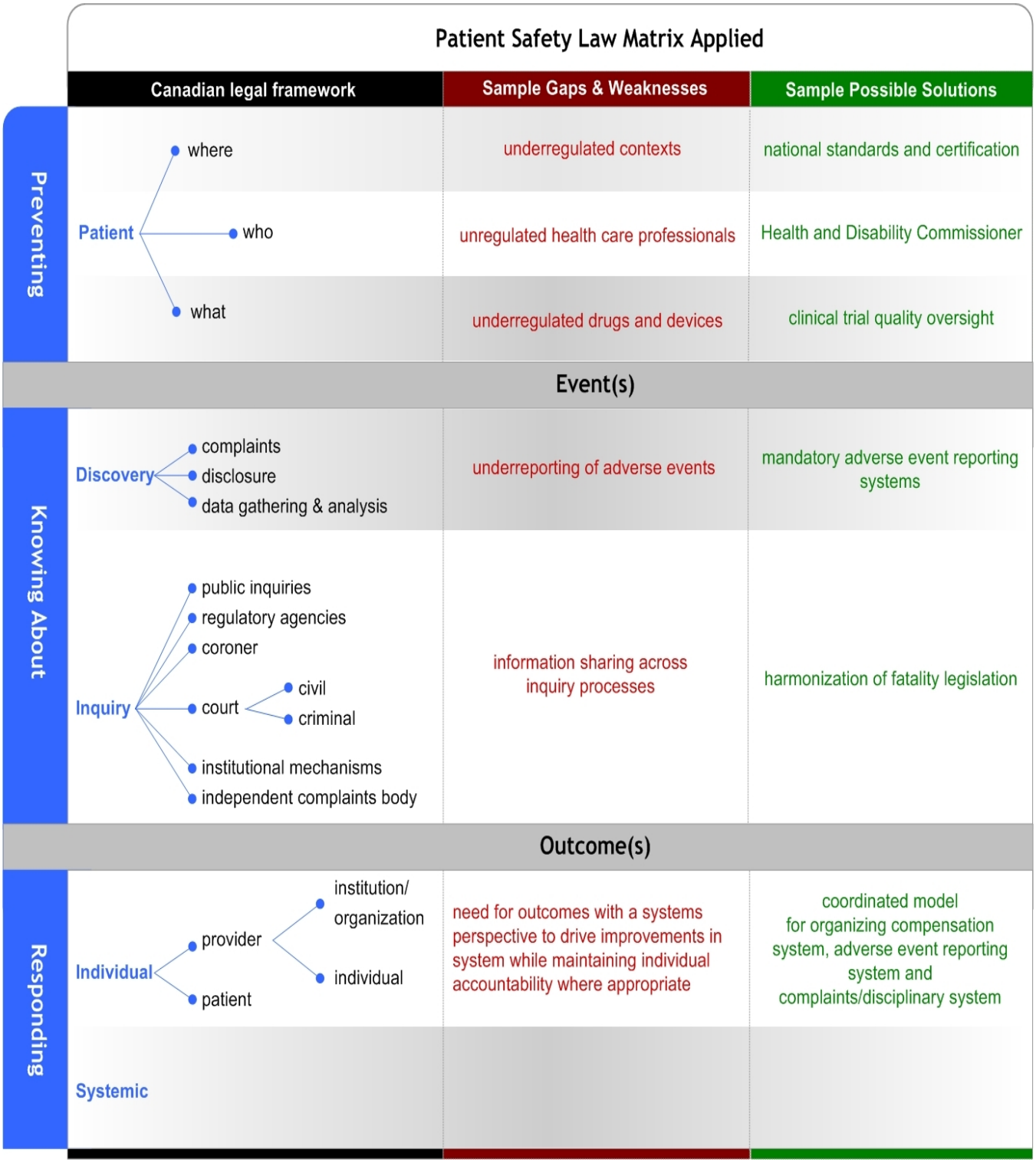
When using the matrix, the first step is to map out the existing legal instruments and frameworks at play in each part. In this report, we have included a matrix that represents the current state of patient safety law in Canada in black (see below). In order to assess the weaknesses or gaps of a health system's legal framework, evaluative criteria must be chosen. The criteria of effectiveness, efficiency, equity, transparency and accountability have been incorporated in this project where possible. Possible solutions need to be assessed using the criteria as well, with an eye to their direct and indirect effects on activities in other parts in order to avoid the 'push-down pop-up' phenomenon where addressing one issue creates another unexpected problem elsewhere in the system.

C. Recommendations

In addition to promoting the matrix as a tool for analyzing how legal frameworks and instruments affect patient safety in health systems, we recommend that certain key weaknesses and gaps in Canada's legal framework surrounding patient safety be addressed. Having identified these gaps and weaknesses by applying the matrix, we then highlight possible solutions that might, with further research and analysis, be adopted (with appropriate modification) from the patient safety experience of other countries or from the Canadian experience with transportation or general occupational health and safety. The discussion is framed around the matrix as a whole and its three parts: preventing, knowing about, and responding.

1. The Importance of a Global View

The matrix reflects an integrated system or framework for patient safety. While in the following sections we analyze the strengths and weaknesses of the Canadian patient safety legal framework at the national and provincial/territorial levels in regard to the individual or distinct parts of the matrix, we also think it important that the overall picture not be lost sight of. Many of the countries and other sectors that we have studied have in common an intention to move the analysis of safety related issues from a focus on individuals to a focus on systems, their failures, and what can be done by and through systems to improve safety: to prevent; to know; and to respond. In parallel to this shift is another shift from a focus on reform of specific fields of law (tort law, professional regulation, institutional regulation, etc.) to a general reform of all or at least multiple bodies of law that have in common their concern with patient safety. In these two shifts, law is being used as an instrument to create safer systems of care. To that end, these countries and sectors recognize that preventing or minimizing the risk of unsafe acts in a health system calls for leadership and coordination from all involved in the delivery of health services. Legal frameworks that take a systems approach clarify the responsibilities and thus accountabilities between the many actors in the health system around patient safety and require safety focused systems to be put in place. They thereby establish patient safety as a priority, reduce uncertainty, and create a foundation for the development of patient safety regulatory initiatives and programs. To do that, they need also to deal with and clarify or modify the interaction between distinct bodies of law, whether that is done to maximize cumulative impact through alignment or to minimize or eliminate the tendency of one to work at cross purposes with another.


Patient Safety Law Matrix Applied
Canadian legal framework
Sample Gaps & Weaknesses
Sample Possible Solutions
Preventing
Patient
where
who
what
underregulated contexts
national standards and certification
unregulated health care professionals
Health and Disability Commissioner
underregulated drugs and devices
clinical trial quality oversight
Event(s)
Knowing About
Discovery
complaints
disclosure
data gathering & analysis
underreporting of adverse events
mandatory adverse event reporting systems
Inquiry
public inquiries
regulatory agencies
coroner
court
civil
criminal
institutional mechanisms
independent complaints body
information sharing across inquiry processes
harmonization of fatality legislation
Outcome(s)
Responding
Individual
provider
institution/ organization
individual
patient
need for outcomes with a systems perspective to drive improvements in system while maintaining individual accountability where appropriate
coordinated model for organizing compensation system, adverse event reporting system and complaints/disciplinary system
Systemic

The Australian approach is a valuable model with respect to a systems approach for Canada particularly since (as was discussed earlier) Australia has a somewhat similar constitutional framework. Early on Australia recognized that patient safety and healthcare quality is a national priority and must be addressed consistently across the provinces and territories and at the federal level. Accordingly, they developed the Australian Conference to meet annually to try to achieve consistent approaches to health policy. Patient safety and healthcare quality is always on the agenda at these conferences and is always publicly reported. This provides leadership at the highest level for patient safety and quality initiatives. Through the development of a consensus, the Conference prioritizes patient safety and quality initiatives and endeavors to achieve consistency, at least at the level of the development of principles to guide policy making between governments. In addition, the Conference has created an Australian Health Ministers' Advisory Council comprised of representatives of the Regional Health Authorities in each state and territory to provide advice on matters of health policy. Lastly, the Australian Commission on Safety and Quality in Health Care reports directly to the Ministers' Conference and provides strategic advice. Canada could learn from this approach, which prioritizes safety and quality at the national level and tries to achieve consistency in application.

At the provincial level, few provinces have created clear system level accountability frameworks for patient safety and there have been few attempts to use law to put practices in place to change cultures and make patient safety a priority for all. In the other sectors studied, law is used to establish processes, tools and duties that attempt to create internal cultures of safety in the sector. Canadian occupational health and safety (OHS) law sets out the responsibilities of governments and workplace parties as well as a framework for the internal governance of workplaces in respect of occupational health and safety. Employers, employees and other workplace parties have a general legal duty to take every reasonable precaution to ensure workplace safety, as well as a number of other specific responsibilities. OHS law requires larger employers to establish joint health and safety committees, which act as a forum for encouraging cooperation between management and employees on occupational health and safety issues. Smaller employers are required to facilitate participation through alternative means, such as the appointment of an employee safety representative. Their legal functions may include investigating complaints, identifying hazards, auditing activities, and making safety recommendations. As part of a system of regulated self-regulation, government conducts external inspections and other enforcement activities.

In the Canadian railway and aviation sectors, rail and airline companies must have in place a safety management system (SMS). These systems for managing risk include a number of internal processes, such as processes for safety goal setting, hazard identification, maintaining properly trained and competent staff, internal incident or accident reporting, employee awareness of responsibilities, and internal auditing of the system. Transport Canada maintains a system of formal audits to assess compliance with safety regulations and the effectiveness of SMSs. In the Canadian aviation sector, companies are also required to appoint an accountable executive who is responsible for corporate decisions affecting safety. There is evidence to suggest that SMSs can be both effective and cost-efficient.[14] We therefore suggest that

[14] SMSs have been successfully implemented in the chemical industry in the United Kingdom. SMS systems have been voluntarily used for a number of years by Air Transat, who reports fewer reactive and more proactive

transportation (particularly in the aviation sector) and occupational health and safety show promise in this respect and are worth further study as possible role models for system level frameworks for patient safety.

New Zealand's patient safety framework also shows promise in this regard in that it not only establishes the accountabilities of actors within the system for safety, but also requires that certain practices be in place within institutions/organizations to endeavour to embed safety as a cultural norm. The Minister of Health provides health sector direction and is required by law to develop a quality improvement strategy for the health sector.[15] The Ministry of Health is responsible for monitoring the performance of District Health Boards (DHBs) and annual Crown Funding Agreements reached between the Ministry and the DHBs set out funding and performance expectations, including safety and quality expectations. DHBs are responsible for monitoring the performance of providers contracted with. The responsibilities of providers for safe outcomes are expressed in the *Code of Health and Disability Services Consumer Rights* and through national standards which require the development in each organisation of quality and risk management processes, adverse event reporting systems, and complaints processes.[16] Accountability to consumers is enhanced through the Health and Disability Commissioner, an independent complaints resolution body responsible for protecting and promoting the consumer rights in the *Code* as well as through a free national independent advocacy service that supports consumers in resolving concerns with providers.[17] We recommend that Canadian governments work towards the adoption of accountability frameworks and effective safety standards that are process-based and reinforced by internal and external audit processes. The specific content of such frameworks requires further research. However, based on the research conducted for this report, it is clear that accountability frameworks that profile and prioritize patient safety governance should be given careful consideration.

2. Part One – Preventing

Areas of law relating to prevention include institutional regulation, products regulation, professional regulation and tort law. As stated above, patient safety law that aims to prevent unsafe behaviour or injury from unsafe behaviour can generally be said to do so by

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reports received and also savings of approximately $2 million per month. From the experiences of Air Transat, Transport Canada argues that it appears that such systems can be effective and also cost-effective to implement (Transport Canada, "Safety Management Systems (SMS) – Frequently Asked Questions (FAQ)," online: Transport Canada <http://www.tc.gc.ca/civilaviation/SMS/FAQ/General/Q1.htm>; Michael Dilolo, "Safety Management Systems: A Way of Life," online: Transport Canada <http://www.tc.gc.ca/civilaviation/systemsafety/CASS/2004/PDF/Dilollo2.pdf>).

[15] *New Zealand Public Health and Disability Act 2000* (N.Z.), 2000/91, s. 9. Under the law, the strategy must involve the development of nationally consistent standards and quality assurance programmes for health services that address patient or consumer safety and nationally consistent performance monitoring. The Minister is required to consult with appropriate organizations before developing the strategy and must report publicly each year on the progress made in implementing the strategy.

[16] *Health and Disability Sector Standards* (N.Z.), S2001/8134 [*Health Standards*]; *Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996* (N.Z.), 1996/78, Sch. I.

[17] Both the Commissioner and the independent advocacy service were established under the *Health and Disability Commissioner Act 1994* (N.Z.), 1994/88.

controlling or influencing one of three variables: where care is delivered, who delivers care, and what is delivered.

a. Where

Canada uses a traditional licensing model to regulate institutions such as hospitals and long-term/residential facilities. The model focuses on inputs, such as the size of rooms, the number of bathrooms, etc., rather than outputs or the safety and quality of outcomes for patients. The model is a static rather than a dynamic one that equates safety with environmental conditions, ignoring the agency of human actions or the functioning of care delivery processes. In other countries and sectors, a more rigorous systems approach that is focused on outcomes and continuous improvement is taken, coupled with enhanced monitoring and enforcement mechanisms.

Possible examples from other countries exist on a spectrum with respect to levels of government involvement in the setting of standards and/or the monitoring of compliance with standards. Some jurisdictions make use of legal frameworks in which outcome-based standards are set by government based on input from the health sector and then compliance is independently audited (New Zealand, United Kingdom, Australia's aged care sector). Other jurisdictions make greater use of legal frameworks that require or recognize accreditation by a private accreditation body (United States, Victoria, Australia, and Quebec). We recommend further study of New Zealand's legislative framework concerning standards and certification found in the *Health and Disability Services (Safety) Act 2001*.[18] The *Health and Disability Sector Standards*[19] developed under this framework are wide-ranging, outcome-driven and process-based. Criteria on how to achieve these outcomes are provided in the standards, which are intended to foster continuous improvement. Independent audit agencies assess providers for compliance with the standards. The costs of implementing such a framework would need to be assessed in terms of the funds required to help institutions achieve the desired outcomes, as well as administration and enforcement costs, measured against the potential benefits, both fiscal and otherwise, of safer outcomes. Statutory authority for Health Ministers to develop health care delivery standards currently exists in a number of provinces.[20] The exercise of political will is now needed.

Improving the safety of care delivered by the Canadian health system involves recognizing that the settings in which health care is delivered are shifting beyond traditionally regulated institutions. Home and community care, primary care and private care in Canada are unregulated or under-regulated in terms of patient safety. In the jurisdictions examined, the general trend has been to expand the use of legal frameworks to regulate quality and safety across the legal boundaries that have usually defined and separated different places of care. For example, in the United Kingdom, core standards apply to NHS care providers across care settings, including primary care, and compliance is assessed by the Health Care Commission,

[18] *Health and Disability Services (Safety) Act 2001* (N.Z.), 2001/93.
[19] *Health Standards*, *supra* note 16.
[20] *Health Authorities Act*, R.S.B.C. 1996, c. 180, s.3; *Regional Health Authorities Act*, C.C.S.M. c. R34, s. 3(2); *Hospitals Act*, R.S.A. 2000, c. H-12, s. 28(b); *Hospital Act*, R.S.B.C. 1996, c. 200, s. 56(g); *Hospitals Act*, R.S.N.L. 1990, c. H-9, s. 37(a).

a statutory agency. Similarly, the private health care sector is regulated under the *Care Standards Act 2000,* and providers in this sector seeking to operate certain facilities or offer specific services must register with the Health Care Commission. The Commission inspects private health care establishments to ensure compliance with sector specific regulations and national minimum standards.[21] Legal frameworks for addressing the governance of patient safety in these settings should be the subject of future research and subsequent action in Canada.

b. Who

The types of professions and occupations that deliver health care are expanding. New providers, such as home care workers and personal care workers, are largely untouched by state regulation. Some jurisdictions, such as New Zealand and the State of Victoria, Australia, have developed patient complaint mechanisms that include these actors and therefore the complaints commissioner in these jurisdictions can investigate the quality of care they provide as well as complaints against those against the members of the traditionally regulated professions. The New Zealand Health and Disability Commissioner can also refer cases involving unregulated health professionals to New Zealand's Human Rights Tribunal. The deterrence factor of complaints investigations may contribute to prevention. Ontario's Health Professions Regulatory Advisory Council (HPRAC) is currently considering whether personal support workers should be regulated through traditional professional self-regulation under Ontario's *Regulated Health Professions Act, 1991*.[22] The appropriate role of law in ensuring the safe delivery of care by these occupations in order to protect the public from harm is a gap in knowledge that requires future study.

Quality assurance and continuing competency programs for health professionals are proactive mechanisms aimed at maintaining the competency and safe practice of health professionals throughout their career. There is a lack of literature and "little evidence of implementation and few evaluations" [23] of such programs in Canada. We are struck by the greater emphasis, backed by law, on ongoing competency and continuous improvement in most of the countries we studied. Alberta and Ontario are progressive in this area. Their legislation requires colleges to develop continuing competency or quality assurance programs and makes participation in these programs mandatory. Under Alberta's legislation, a health professional has to complete a continuing competence program in order to receive a practice permit, which is usually issued annually by colleges. Alberta's legislation also enables approved colleges to use practice visits or on-site assessment activities as a mechanism to ensure their continuing competence program requirements are being met. Member commitment and understanding is important for the successful implementation of these programs. Care should be taken so that the objectives of mechanisms, in particular practice assessments or visits, are clear and reflect

[21] *Care Standards Act 2000* (U.K.), 2000, c. 14; *Private and Voluntary Healthcare (England) Regulations 2001* (U.K.), S.I. 2001/3968; Department of Health, *Independent Health Care National Minimum Standards Regulations* (London: The Stationary Office, 2002).
[22] *Regulated Health Professions Act, 1991,* S.O. 1991, c.18, s. 11(1)(a) [*Regulated Health Professions Act*]; Health Professions Regulatory Advisory Council, online: < http://www.hprac.org/english/new.asp>. One of HPRAC's statutory duties is to advise the minister on "whether unregulated professions should be regulated."
[23] Health Professions Regulatory Advisory Council, *Executive Summary* (Sept 2005), online: HPRAC <http://www.hprac.org/downloads/sep05/ExecutiveSummary-Sept26.pdf>.

a broader continued competency and continuous improvement approach.[24] Programs should be evaluated based on their ability to improve patient outcomes through the use of methods that can produce measurable changes in professional practice, and colleges should be accountable to the government and the public for the effectiveness of their programs.[25]

The number of hours worked by health professionals is an issue that has important implications for patient safety. Research indicates that excessive working hours contribute to an increased risk of unsafe care. Other sectors, such as transportation, have regulated the number of hours worked in the sector to protect public safety. The regulation of working hours in the health sector is also a major issue in the United States. Of course, the regulation of working hours in the health care sector has complex human resource planning and funding implications. One might query the transferability across sectors here. However, it should be emphasized that legislation has been used in some states in the United States and the European Union to regulate working hours for health professionals, while collective agreements are used in New Zealand. It was the strongly expressed view of some of the patient safety experts that we consulted for this project that some structured reduction of working hours for at least some health care professionals is required in Canada. The European Union and New Zealand, using different legal instruments, have had some success in achieving structured reductions in working hours. We recommend that these options be explored further and steps be taken to establish controls on working hours.

c. What

Regulation of drugs and devices plays a necessary and valuable role in ensuring that drugs and devices are safe for patients to use.[26] It is an important mechanism to set standards for drugs and devices and their design, manufacture, trials and use, and to monitor and react to signals that the risks associated with a particular drug or device are too high and the drug or device should be withdrawn from the market. However, the Auditor General of Canada has identified numerous weaknesses in the regulation of devices[27] and, with respect to drugs,

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[24] See Health Professions Regulatory Advisory Council, *Report to the Minister of Health and Long-term Care: Effectiveness of Colleges' Quality Assurance Programs* (Toronto: HPRAC, 2000) at 7,8, 17, online: HPRAC <http://www.hprac.org/downloads//qualityassurance/QaHPRAC.pdf>, where in a review of the effectiveness of College Quality Assurance programs, Ontario's HPRAC concluded that practice assessment activities were the most rigorous and objective method to evaluate practitioner performance and the translation of continuing education lessons into practice. It noted that some colleges experienced significant member resistance to practice assessments due to its invasiveness and that some colleges viewed practice assessments as punishment for substandard practice. It recommended that the Minister develop detailed guidelines regarding practice assessments.

[25] Under Ontario's *Regulated Health Professions Act*, *supra* note 22 at ss. 6(2)(a), 11(1)(d), HPRAC has a general duty to advise the Minister on matters concerning QA programs and was required to report on their effectiveness five years after the provision came into force. HPRAC recommended in its report that one of its statutory duties should be the ongoing monitoring and evaluation of QA programs. Alberta's Act requires each college to submit an annual report, including information about the College's continuing competency program, to the Minister, which must then be presented to Legislative Assembly. See also *ibid.* at ii and *Health Professions Act*, R.S.A. 2000, c. H-7, s. 4.

[26] *Food and Drugs Act*, R.S.C. 1985, c. F-27; *Medical Devices Regulations*, S.O.R./1998-282; *Food and Drug Regulations*, C.R.C., c. 870.

[27] Auditor General of Canada, *Report of the Auditor General of Canada to the House of Commons* (Ottawa: Office of the Auditor General of Canada, 2004) c. 2 at 4.

there is a burgeoning literature identifying and analyzing the deficiencies in the regulatory system.[28] Concerns focus on inadequacies in the systems of oversight in advance of licensing and inadequate monitoring, analysis, and communication of adverse events post-licensing. Lack of transparency, conflicts of interest, and lack of resources and capacity in the system have all been identified as causes of these problems. It must be noted that similar problems are being faced in many countries. A number of possible solutions are being proposed and tried. For example, the Danish Medicines Agency (an independent agency) is empowered under Danish law to implement and enforce the legislation relating to medical devices and medicinal products. The Agency evaluates the quality of proposed clinical trials and, post-approval, physicians as well as the pharmaceutical industry are required to report adverse drug reactions to the Agency which, together with the Council for Adverse Drug Reactions, monitors and evaluates the reports and communicates the results of the evaluations.[29]

There is an immediate need for the federal and provincial governments to acknowledge the need for law reform and to commit to it. Then, governments must explore the various possible ways to address the problems. Drawing on the academic literature and the experiences in other countries, we can conclude that these include: mandatory participation in clinical trials registries; the creation of a truly independent research ethics oversight system; greater transparency in the drug approval process; and mandatory reporting, analysis, and communication of reports of adverse events related to drugs and devices.

3. Part Two – Knowing About

In this part of the matrix, law can be seen to work to inhibit or support the discovery and open discussion of unsafe acts in a health system. A number of fears keep health care providers from acknowledging unsafe acts, including damage to one's reputation and exposure to professional discipline or litigation. A number of legal instruments seek to address these concerns by creating protected environments for providers to use. These instruments include qualified privilege legislation that grant evidentiary protections for peer review as well as quality assurance activities and statutory adverse event reporting systems with similar protections. On the other hand, disclosure and public accountability are also important interests and legal instruments are being used to increase disclosure to patients, the gathering of patient complaints, and the public availability of safety information in order to drive improvements to patient safety.

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[28] For a compilation of stories reporting concerns about the monitoring of adverse reactions to approved drugs refer to Health Coalition, online: <http://www.healthcoalition.ca/drugs-media.pdf>; Janice Graham, "Smart Regulation: Will the Government's Strategy Work?" (2005) 173 C.M.A.J. 1469; Joel Lexchin & Barbara Mintzes, "Transparency in Drug Regulation: Myth or Oasis?" (2004) 171 C.M.A.J. 1503; Science Advisory Board Committee on the Drug Review Process, *Report to Health Canada* (Ottawa: Science Advisory Board Committee on the Drug Review Process, 2000).

[29] See Danish Medicines Agency, online: <http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=7696>, where it is stated that on 6 December 2005, the Danish Parliament passed the *Medicines Act* (DK), 2005/1180, online (in Danish online): www.retsinfo.dk. The Act was affirmed by the Queen on 12 December 2005 and entered into force on 17 December 2005.

a. Discovery

One important mechanism by which unsafe acts are acknowledged and discussed is through their disclosure by providers to patients, peers, the public, or other data gathering processes. In the case of patients, ethical obligations exist for providers to inform patients of unsafe care. These obligations may find expression in voluntary codes of conduct (sometimes referred to as "soft law") developed by professional bodies. Canadian common law cases exist that establish a positive legal duty for providers to disclose errors to patients.[30] However, tort law and professional sanctions have been seen to be significant legal disincentives to disclosure. Possible legal responses to overcoming these disincentives to disclosure to patients used in other jurisdictions with tort-based systems include the passage of apology laws in some states in the United States and Australia, in which apologies do not constitute admissions of civil liability and also in some states do not constitute admissions of unsatisfactory professional performance for the purposes of professional regulation.[31] A number of U.S. states and two provinces in Canada have also passed laws which require disclosure of unsafe acts but not admissions of liability. In Manitoba, health care organizations will soon have a positive duty to ensure that a patient is fully informed about the facts of a critical incident,[32] its consequences for the patient, and past and future actions for addressing the consequences. In Quebec, users have the right to be informed by public institutions as soon as possible of any accident[33] that has actual or potential consequences for their health and the measures to be taken to address any consequence they suffered, as well as steps to prevent such an accident from recurring.[34] Law reform, such as in Quebec or Manitoba, that requires the disclosure of unsafe acts and the development of policies and processes that support both parties in having such a discussion should be considered.

There are also a number of data gathering and analysis processes used around the world. These include quality assurance processes, mortality and morbidity review processes,[35] and

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[30] Tracey M. Bailey and Nola M. Ries, "Legal Issues in Patient Safety: The example of Nosocomial Infection" (2005) 8 Health Care Q. 142; Philip C. Hebert, Alex V. Levin & Gerald Robertson, "Bioethics for Clinicians: 23. Disclosure of Medical Error," (2001) 146 C.M.A.J. 509.

[31] See *e.g. Wrongs and Other Acts (Public Liability Insurance Reform) Act 2002*, (Vic.), amending *Wrongs Act 1958*, (Vic.).

[32] See *The Regional Health Authorities Amendment and Manitoba Evidence Amendment Act*, S.M. 2005, c. 24, ss. 53.1, 53.2(2) where a critical incident is defined as "an unintended event that occurs when health services are provided to an individual and results in a consequence to him or her that (a) is serious and undesired, such as death, disability, injury or harm, unplanned admission to hospital or unusual extension of a hospital stay, and (b) does not result from the individual's underlying health condition or from a risk inherent in providing the health services." This Act had not been proclaimed in force as of December 30, 2005.

[33] See *An Act Respecting Health Services and Social Services*, R.S.Q. c. S-4.2, s. 8 [*Health Services and Social Services Act*], where an accident is defined as "an action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user, a personnel member, a professional involved or a third person." Respect for user rights under the legislation is monitored via Quebec's statutory patient complaints scheme.

[34] *Ibid.* The wording of this right in Quebec's legislation places a clearer emphasis on learning and future prevention than Manitoba's legislated duty.

[35] In New Zealand, there are statutory national mortality review committees for child, youth, perinatal and maternal deaths. In the state of Victoria, Australia, the Government has established a number of statutory consultative councils which analyze mortality and morbidity data in the areas of surgery, anaesthesia, obstetrics and paediatrics. England has a system of confidential inquiries for Maternal and Child Health; Patient Outcome

adverse event reporting systems. A relatively new innovation in health systems, adverse event reporting systems are a feature of safety regulation in other sectors and have contributed to measurable improvements in safety in those sectors.[36] Reporting systems can potentially detect trends or patterns in adverse events that point to system failures and enable corrective strategies to be developed and implemented to prevent future events, as well as provide greater information to stakeholders on the overall performance of the system. Legal instruments have been used in a number of the jurisdictions studied to establish adverse event reporting systems for their health systems. These reporting systems can operate at the national, provincial/state or institutional level.

In Canada, to maximize effectiveness, such a reporting system could involve all provinces and territories establishing harmonized statutory reporting systems that can collect standardized data which is then integrated into a national database, so that data can be pooled, patient safety trends identified, and lessons learned shared across jurisdictions. The alternative is thirteen siloed provincial and territorial reporting systems, where information is not shared and events have a greater chance of appearing to be isolated one-off occurrences. To date, three provinces currently have legal frameworks establishing provincial adverse event reporting systems, although only one province's legislation is fully in force. For input in designing a statutory adverse event reporting system to improve patient safety, we recommend further study of Denmark. Its mandatory learning system is non-punitive, confidential, and allows for anonymous reporting. Near-miss[37] data is collected as well as adverse events and information is used locally, in addition to being recorded in a de-identified form in a national register. A national body tracks events and reports on identified safety risks.

Another means of discovering unsafe acts is through patient complaint mechanisms, as both patients and providers are sources of knowledge in terms of the safety and quality of health care delivery. Complaints can be a valuable patient safety learning tool when handled appropriately. In order to enhance learning from patient experiences, accessible mechanisms need to be in place, members of the public need to be aware of them, and patients and providers must be encouraged and supported in bringing forward safety and quality concerns.

In Canada, patient complaints are either not gathered or their collection is not coordinated across the continuum of care. Concerns exist among experts about the independence of the statutory complaints mechanisms administered by professional colleges and the largely voluntary internal complaints mechanisms maintained in a variety of health institutions and regions, which may be perceived by the public as being weighted towards provider interests rather than the public interest.[38] A number of the jurisdictions studied, including the United

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and Death; and Suicide and Homicide by People Using Mental Health Services. These reviews have a preventative purpose and can lead to strategies or standards to improve practice.

[36] See *e.g.* the discussion in Paul Barach & Stephan Small, "Reporting and Preventing Medical Mishaps: Lessons from Non-Medical Near Miss Reporting Systems" (2000) 320 B.M.J. 759.

[37] A near-miss is an event that could have resulted in harm but did not, either by chance or intervention.

[38] See IBM Business Consulting Services, *Health Insider*: *Survey No. 8*, Fall/Winter 2002 (Toronto: IBM Consulting Services, 2002), as cited in C. Flood and T. Epps, "Waiting for Health Care: What Role for a Patients' Bill of Rights?" (2004) 49 McGill L.J. 515 at 519., where it is reported that in a national survey conducted in 2002, nine out of ten Canadians indicated their support for an independent commissioner or

Kingdom, New Zealand, Australia (Commonwealth aged care regulation)[39] use legal instruments to require internal complaints systems in places of care to enhance local learning and action, coupled with an external independent complaints system. In Canada, the same is done most extensively in Quebec. These frameworks recognize the effectiveness of good internal complaints systems and an independent external body in increasing systems improvements and accountability. As part of the legal framework in the above jurisdictions, independent advocacy services are also available to provide patients with support in bringing forward concerns.

The experience of the Canadian occupational health and safety sector illustrates the potential role of patient advocates and third party reinforcement in these complaint processes. In terms of worker safety, we encountered a view strongly held among experts that occupational health and safety law often works best where workers are strongly positioned to act as their own advocates, as when they are represented by a union. In comparison, patients are in a position of relative dependency in the health care system and are therefore not in a good position to insist on their rights and interests. This vulnerability is perhaps increased by the shifting of care to home and community settings. We recommend looking further at both the Quebec and New Zealand models for input in designing a complaints system.

Quebec's legislative framework for complaints mechanisms enhances consistency at the local level in that it requires a complaints procedure with mandatory elements to be in place in all public institutions and regional agencies.[40] Compliance is monitored by an independent body, the Health Services Ombudsman. Local or regional quality commissioners, whose independence is protected by boards of directors, are responsible for investigating complaints and enforcing user rights, including the right to receive health services "with continuity and in a personalized and safe manner."[41] Complainants who disagree with the conclusions reached at the local level or the response taken to local recommendations can apply to the Health Services Ombudsman for further examination. Institutions and regional authorities are required to respond to the Ombudsman's recommendations in writing. Evidentiary protections are included in the legislation to enhance provider co-operation and retaliation against complainants is prohibited. Learning is shared throughout the system in that local institutions send reports containing complaint summaries and significant recommendations to regional agencies, who then submit an annual report to the Minister, which is tabled in the National Assembly. The Ombudsman reports a high voluntary uptake of recommendations. Weaknesses of the Quebec system include that it is limited to public institutions and the Ombudsman is accountable to the Minister, rather than the National Assembly.

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ombudsperson with the power to hear complaints about health care providers and services and make recommendations.

[39] In addition, all Australian states/territories are required to have in place independent complaints bodies to resolve complaints involving the provision of public hospital services as part of Australian Health Care Agreements between the Commonwealth and state or territorial governments. These agreements also set out Commonwealth funding levels.

[40] *An Act respecting the Health and Social Services Ombudsman*, R.S.Q. c.P-31.1 [*Health and Social Services Ombudsman*]; *Health Services and Social Services Act, supra* note 33

[41] This right is not freestanding and is limited by "the human, material, and financial resources" of institutions (*Health Services and Social Services Act, ibid.*).

In New Zealand's legal framework, the *Code of Health and Disability Services Consumers' Rights 1996* sets out ten "consumer rights" which providers must comply with. The *Code* includes a right to services of an appropriate standard, which includes "the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer" and "the right to co-operation among providers to ensure quality and continuity of services."[42] The *Code* also contains a right to complain and requires that providers have a complaints procedure in place that meets specified requirements.[43] An independent third party, the Health and Disability Commissioner (HDC), can receive complaints concerning breaches of the *Code* by any individual or organization that provides health or disability services, making the system broader in scope than that of Quebec. The Commissioner can investigate all parties to an event and can address both individual and systems issues affecting the quality of care.[44] The Commissioner sends important findings to key agencies and professional bodies and there is evidence that providers are increasingly using reports to educate themselves and to implement changes.[45] Recent legislative changes to the scheme designed to improve the complaints process in New Zealand make the HDC the initial "one window" recipient of complaints concerning health services providers and give the Commissioner more flexible options for resolving complaints.[46]

b. Inquiry

Many of the traditional legal inquiry mechanisms developed when the focus was primarily on individual responsibility and few are currently equipped to address systems issues. Inquiry processes also tend to be siloed provincially and recommendations are not readily shared across provincial boundaries. An example is the recommendations of the Sinclair report, which only saw substantial uptake in Manitoba, despite broad distribution.[47] More needs to be done to collate and share lessons learned from these processes nationally.

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[42] *Health and Disability Commissioner Regulations (Code of Health and Disability Services Consumers' Rights) Regulations 1996* (N.Z.), 1996/78, as am. by 2004/116. It should be noted that these rights are not absolute. If a provider can show they have taken reasonable steps to give effect to the rights given all the relevant circumstances, including the clinical circumstances of the consumer and the resource constraints of the provider, the provider will not have breached the Code.

[43] *Ibid.* at ss. 10(6)-(7). Also, additional complaints management requirements, such as linking the complaints process to quality and risk management systems in order to enhance learning, are included in the *Health and Disability Sector Standards NZS 8134:2001* for providers who require certification.

[44] The Commissioner's findings are publicly available, usually in the form of an anonymised report. See See The Health and Disability Commissioner, Case 03HDC10460 and Case 03HDC03134, online: HDC <http://www.hdc.org.nz/casenotes.php?year=2003>, for examples of the Commissioner's reports that address quality of care issues at both levels.

[45] The Health and Disability Commissioner, "A Review of the *Health and Disability Commissioner Act 1994* and the *Code of Health Disability Services Consumers' Rights*: A Resource for Public Consultation" (2004), online: HDC < http://www.hdc.org.nz/theact.php?content=19> at 11. This evidence is anecdotal in nature (correspondence from Nicola Sladden, HDC Legal Manager (August 2005)).

[46] Previously, the Commissioner had to investigate all complaints unless he or she referred it to an advocate or decided to take no action. Under the new Act, the Commissioner conducts preliminary assessments and can choose from low level resolution mechanisms such as mediation in addition to investigation. It should be noted that if the Commissioner decides to conduct an investigation, at its conclusion, he or she can choose to refer the case to the Director of Proceedings, a statutorily independent prosecutor who decides whether to take the case to the independent Health Practitioners Disciplinary Tribunal or before the Human Rights Review Tribunal.

[47] Jan Davies, "Painful Inquiry: Lessons from Winnipeg" (2001) 165 C.M.A.J. 1503.

In Australia, coronial inquest results are shared via a national information system. The first of its kind in the world, the National Coroners Information System (NCIS), is a database that contains information such as the medical cause of death and the circumstances surrounding a death from all Australian coroners cases since 2000. Information from the system has been used in the context of patient safety in areas such as deaths associated with pregnancy, the insertion of naso-gastric tubes, and the administration of medication in nursing homes.[48] In Canada, variability in the statutory criteria for coronial review, variability in the scope, extent, and quality of individual investigations, variability in the extent of examination and the quality of the evidence produced, and variations in the types of deaths investigated would cause difficulty in establishing such a database. We recommend further study be undertaken to explore the utility of harmonizing Canadian fatality legislation as a means of improving patient safety.

Across the jurisdictions we studied, we observed changes in law that reflected a number of concerns with the legislative framework for professional regulatory inquiries. These concerns included: a lack of standardization; a lack of a systems perspective; a lack of alternative processes that minimize the punitive nature of the process while still addressing patient safety concerns; and a lack of public trust and transparency. New Zealand's independent HDC is one possible model in that the Commissioner is able to look at the multiple professionals and institutions involved in an incident and to look at both individual actors and systems factors. The HDC is also able to use low level resolution mechanisms, such as mediation, to resolve concerns. Alternate dispute resolution is also a statutory mechanism available to colleges in Alberta.[49] In Canada, consideration should be given to wider standardization of professional regulatory processes through the use of umbrella legislation to create greater consistency for the public. In addition, the move towards interdisciplinary practice exposes a weakness in current disciplinary systems in that these systems are not equipped to address broad systemic issues nor the complexities of multidisciplinary practice. Currently, multiple professions and bodies may potentially investigate a single incident. This creates inefficiencies, both fiscal and in terms of effectiveness of investigation of the incident. A single collaborative review mechanism capable of identifying individual and/or system factors at work may be useful.[50]

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[48] Victorian Institute of Forensic Medicine, "The National Coroners Information System" (November 2004) 2:4 Coronial Communiqué 2, online: VIFM <http://www.vifm.org/attachments/o352.pdf>. See also Australian Council for Safety and Quality in Health Care, "Safety in Numbers", Attachment to Safety in Practice-Making Health Care Safer, Second Report to the Australian Health Ministers Conference, (1 August 2001) at 17.

[49] Under Alberta's *HPA*, a college's complaints director may refer the complainant and the member, with their consent, to an alternative complaint resolution process any time before a hearing is held. The college will be required to participate in the process and any proposed settlements are subject to ratification by a complaint review committee.

[50] National Steering Committee, National Steering Committee on Patient Safety, *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care* (2002), online: RCPSC <http://rcpsc.medical.org/publications/building_a_safer_system_e.pdf> at 15. In Health Professions Regulatory Advisory Council, *Adjusting the Balance: A Review of the Regulated Health Professions Act - A Report to the Minister of Health and Long-Term Care* (Toronto: Health Professions Regulatory Advisory Council 2001) at 15, online: HPRAC <http://www.hprac.org/downloads//fyr/RHPAReport.pdf>, Ontario's Health Professions Regulatory Advisory Council (HPRAC) indicates that some support was expressed for empowering colleges to identify and report practice setting or systemic issues. HPRAC did not recommend using *RHPA* as a mechanism

The decline in public confidence concerning the inquiry processes administered by professional colleges, in that they are perceived to be weighted towards protecting members of the profession rather than the public, seems to explain a good deal of the legislative and regulatory change we observed in the jurisdictions that we studied. Possible solutions include meta-regulation or regulating the self-regulatory professions, as is the case in the United Kingdom. The U.K.'s Council for the Regulation of Health Professionals is an agency that monitors the performance of each regulatory body and may refer to court the decision of a regulatory body in relation to professional discipline that it considers unduly lenient or which in its view should not have been made.[51] Other jurisdictions, such as New Zealand and Victoria, Australia, have removed one or more of these processes to an independent body. In Victoria, serious disciplinary matters are now heard by an administrative tribunal, while in New Zealand, investigatory and disciplinary functions have been transferred from professional registration bodies to the HDC and a separate disciplinary body. While we are not in a position to say if a comparable decline in public confidence has occurred in Canada or to the validity of it if it has occurred, we can say that these examples demonstrate that other countries have moved to increase the accountability and independence of disciplinary processes and to create frameworks that promise more consistency in how complaints are addressed across professions. They have also moved to facilitate the ability of patients to make what amount to "system complaints" instead of a series of complaints to different regulatory bodies. These trends appear responsive to many of the concerns about the traditionally structured system of professional self-regulation that have often been raised and that seem inherent in a system of decentralized self-regulation that must operate within a system of health care in which the delivery of care is increasingly integrated. It therefore seems that there is good reason to carefully consider the relevance of these patterns of change in other jurisdictions to Canada.

4. Part Three – Responding

When an unsafe act occurs in the health care system, the traditional legal response has focused on assigning fault to the actions of individual providers and compensating victims. This focus can create a tendency towards blaming and penalizing individuals, which in turn can inhibit disclosure and learning from unsafe acts. In the sectors and jurisdictions studied, there has been a general shift to a systems perspective in legal frameworks, so that when an unsafe act occurs, the response involves identifying system deficiencies that contributed to the unsafe act and creating improved practices and processes in the system in order to prevent future occurrences. Individual accountability remains important, but there is an increased focus on learning and prevention through systems improvements. In Denmark, for example, a statutory mandatory adverse event monitoring system was created to focus exclusively on shared learning from unsafe acts and near miss-incidents and its success is measured in part on its ability to create changes in practice in hospital wards.[52] Denmark's compensation

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for addressing broader quality of care issues in the health system, but rather setting up a taskforce on system errors.

[51] *National Health Service Reform and Health Care Professions Act 2002* (U.K.), 2002, c. 17, s. 29.

[52] *Act on Patient Safety in the Danish Health Care System*, No. 429 of 10 June 2003. Reporters to the learning system, as it is called in Denmark, cannot be subject to criminal sanctions by courts or disciplinary investigations

scheme does not require that fault be proven. Individual accountability is maintained through a separate disciplinary process. In order to improve patient safety, the Canadian legal framework needs to work towards generating outcomes that reflect a systems perspective to unsafe acts and their causes, while maintaining individual accountability where appropriate.

At a systemic level, outcomes from different processes are not being shared at the provincial or national level and their cumulative effects are not felt across the system. Effective feedback mechanisms are needed and lessons learned must not only be shared across the system, but translated into action. Law can be used to facilitate these goals. In Quebec, the legal framework for the patient complaints scheme requires that lessons learned move from the local level through the regional level to the provincial level via reporting to the Minister. This allows information to reach those who can make changes to the system. By requiring institutions or regional agencies to send a written report to the Health Services Ombudsman and to the complainant detailing what actions have been taken in response to the recommendations or the reasons why no actions have been taken, the legal framework increases accountability and may contribute to greater action.[53] Information about the safety performance of the system also needs to reach the public for accountability and transparency purposes. For example, in Pennsylvania, the state's Patient Safety Authority is required by law to make available on its website an annual report that contains the number of reported serious events and incidents on a geographical or regional level, as well as recognized patient safety trends identified from the data.

When a patient receives unsafe care, legal attention must be paid to both accountability and restoration. That is, to holding those who are responsible for the act and the harm accountable and to restoring the person who has been harmed. This is a difficult and complex task. For example, sometimes the choice of legal instrument results in high accountability returns with low restoration (e.g., a criminal or professional disciplinary case) or vice versa (e.g., a settled civil action). Sometimes the choice of legal instrument results in some individuals being held accountable but fails to attach accountability to institutions or systems (e.g, a lawsuit against a physician). Sometimes the choice of legal instrument makes possible some kinds of restoration (e.g., financial) but not others (e.g., emotional).

For example, in some jurisdictions studied, the effectiveness and/or efficiency of tort law as a means of achieving restoration or accountability, as well as the broader goal of systems improvement is being questioned.[54] Although a strength of the traditional tort-based system

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or measures by employers or the health professions regulatory body (National Board of Health) based on their reports. Except for county councils who are responsible for analyzing reports and using them to improve patient safety, identifiable information is not shared with any other body. These elements were seen as critical to obtaining the support of health professionals.

[53] *Health and Social Services Ombudsman*, *supra* note 40 at s. 15.

[54] Two significant claims made for the fault-based model are that it is an effective deterrence mechanism for the health provider being sued and other health providers and is an important educative tool. The evidence to support these claims is decidedly mixed. See P.H. Osbourne, "Compensation for Medical Injuries: An Uncertain Future" in Barney Sneiderman, John C. Irvine & Philip H. Osborne, eds., *Canadian Medical Law*, 3rd ed. (Toronto: Carswell, 2003); M. Mello & T. Brennan, "Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform" (2002) 80 Texas L. Rev. 1595; L. Dubay, R. Kaestner & T. Waidman, "The Impact of Malpractice Fears on Caesarian Section Rates" (1999) 18 J. Health Econ. 491; A. Localio *et al.*, "Relationships

is that it may fully compensate patients for loss when fault is proven, a related weakness of the system is the difficulty and expense of proving fault, with the result that many legitimate claimants are not compensated at all. Further equity issues are raised by the numbers of potential plaintiffs who do not make a claim and those who are not aware that they could make a claim because it was not disclosed to them that the treatment or care provided was possibly negligent. Arguably as significant is the inequitable treatment of those who suffered an adverse event that was not due to negligence but who have no avenues to seek redress. In terms of emotional restoration, tort law forces both patient and provider into adversarial positions that can be emotionally damaging.

Possible solutions include moving to a non-negligence-based system of compensation, as is the case in Denmark and New Zealand. In terms of compensation, it is suggested by some that these systems are more efficient in that the model generally involves one agency with defined procedures and thus there are significant efficiency savings, even though the numbers of persons receiving coverage substantially increase. This results in costs that are similar to or less than the current tort system.[55] Others argue the opposite.[56] A broader compensation system can allow for more supportive and open relationships between health professionals and patients after an unsafe act occurs in that the professional assists the patient in receiving compensation. In Quebec, a public institution's quality and risk management committee is required by law to ensure victims and their families are provided support services after an accident or an incident.[57] Restorative justice models for addressing unsafe acts in health systems have potential for achieving better outcomes for individuals and systems, in that they can restore relationships and may lead to plans of action for future systems improvements. Restorative justice models may be one means of maximizing accountability and restoration and for situating accountability at the level of the individual but also institutional and systemic and for providing financial, emotional, and/or relational restoration. Further research should be conducted to explore restorative justice's potential benefits.[58]

In order to improve patient safety, Canadian patient safety legal frameworks need to work towards developing sophisticated accountability mechanisms and restorative mechanisms for dealing with unsafe acts in the health care system. Denmark's patient safety legal framework is worthy of further study in this regard. Under Denmark's legal framework, the country's compensation scheme is separate from its patient complaints and disciplinary process. Providers and patients can participate in a restorative process through their compensation scheme, which allows them to work as partners rather than adversaries and also facilitates

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between Malpractice Claims and Caesarian Delivery" (1993) 269 J.A.M.A. 366; D. Kessler & M. McClellan, "Do Doctors Practice Defensive Medicine?" (1996) 111 Q. J. Econ. 353.

[55] See *e.g.* David Studdert & Troyen Brennan, "No-Fault Compensation for Medical Injuries: The Prospect of Error Prevention" (2001) 286 J.A.M.A 217.

[56] See *e.g.* Canadian Medical Protective Association, *Medical Liability Practices in Canada: Towards the Right Balance* (Ottawa: CMPA, 2005). The company commissioned by the CMPA to undertake this analysis suggests that in Canada the adoption of a no-fault plan would see costs rise from $225 million to approximately $40 billion. Even the application of "filters" requiring injuries to be "unintended and avoidable" could see annual system costs rise to $2.6 billion.

[57] *Health Services and Social Services Act*, *supra* note 33 at s. 183.2.

[58] Braithwaite, *supra* note 4 at 29-31.

open dialogue. This partnership may make it less likely that patients will seek to access the more punitive accountability mechanism of professional discipline, although this accountability option remains open to them. No identifiable information from the compensation process is shared with the complaints body. Denmark's statutory mandatory adverse event reporting system is for the purposes of shared learning and patient safety improvement, and while providers are required to report, they are permitted to do so anonymously and further, disciplinary or criminal sanctions are not permitted as a result of information reported. Thus, there is a clear demarcation between on the one hand information gathered for purposes of complaints, investigations, and compensation, and information gathered under the national adverse event monitoring system. This element is seen as critical to gaining the initial and ongoing support of the health care professionals themselves, and does not appear to have resulted in discontent within the Danish public.

III. GLOSSARY

Accountability
A principle that individuals, organizations, and government are to be held responsible for their actions and omissions.

Data-gathering and analysis
The act or process of gathering information and analyzing it to identify trends or patterns. In the context of patient safety, these processes include but are not limited to: quality assurance, adverse event reporting, and confidential inquiries.

Disclosure
The act or process of revealing information to a patient, the patient's family, peers, the public, and to data-gathering or inquiry processes.

Effectiveness
Success in achieving a given goal.

Efficiency
The production of the desired effects or results with minimum waste of time, effort, money, or skill.

Equity
Dealing fairly, equally and justly with all.

Governance
"The sum of the many ways individuals and institutions, public and private, manage their common affairs."[59]

Health Services
Personal health care services (e.g., mental health services, drugs and devices, primary care services, long-term care facilities, and acute hospital care) and public health care services (e.g., the provision of blood products, and measures relating to communicable and infectious diseases).

Health Systems
All of the organizations, institutions, and resources that culminate in the delivery of health services.[60]

[59] Kernaghan Webb, "Sustainable Governance in the 21st Century: Moving Beyond Instrument Choice" in Pearl Eliadas, Margaret Hill & Michael Howlett, *Designing Government: From Instruments to Governance* (Montreal: McGill-Queens University Press, 2005).
[60] Marie Lassey, William Lassey & Martin Jinks, *Health Care Systems Around the World: Characteristics, Issues and Reforms*, (New Jersey: Prentice Hall, 1997).

Law
A process of social order – more specifically it is the top down projection of state authority expressed through the use of instruments and institutions (i.e., statutes, regulations, central agencies, administrative boards, regulatory tribunals).[61]

Legal Instruments
Legislation and statutory instruments, contracts, and torts.

Patient Safety
"The reduction and mitigation of unsafe acts within the health care system."[62] 'Unsafe acts' include "error, violation and sabotage."[63] "Error should be defined as the failure to complete a planned action as it was intended, or when an incorrect plan is used in an attempt to achieve a given aim. Violation should be defined as representing a deliberate deviation from standards, rules or safe operating procedures. Sabotage should be defined as an activity in which both the acts and the harm or damage are intended."[64] Unsafe acts, if unchecked, may result in physical, emotional, psychological and/or spiritual harm.

Quality
A degree of excellence that encompasses measures to ensure patient safety, practice that is consistent with socially defined values and norms, practice that is consistent with current medical knowledge, and customization (the ability to meet customer specific values and expectations).

Restoration
As much as it is possible, to return a person, or people, to their former position. This may include truth-telling, apology, reconciliation, and provision of compensation.

Transparency
The free, public, and timely availability of reliable and relevant information.

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[61] This theory, that law is a product of the political state and its institutions, is grounded in the theory of legal positivism. Only the state and its agents create law and its paradigmatic form is legislation. Law is seen as a top down projection of state authority and there is a clear distinction between what is and is not law. A broader view suggests that non-state normative orders are part of the legal system and the enterprise of law is a joint project of the law subject and the law maker. So, law or regulation can be understood to include tacit and implicit processes of social ordering such as custom, practice, and culture. We acknowledge the truth of the latter – that custom, practice and culture developed by actors at all levels in the health system (including government) plays a significant role in shaping and establishing social order in the health system. However, for the purposes of this project we focus on the former. See discussion in Roderick MacDonald, "The Swiss Army Knife of Governance" in Pearl Eliadas, Margaret Hill & Michael Howlett, *Designing Government: From Instruments to Governance*, (Montreal: McGill-Queens University Press, 2005).
[62] J. Davies *et al.*, *Canadian Patient Safety Dictionary* (Ottawa: College of Physicians and Surgeons of Canada, 2003).
[63] *Ibid.*
[64] *Ibid.* at 57.