Health Policy Research Program
Summary of Research Results

Title:	**Patient Safety Law: From Silos to Systems**
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Research Category:	**Synthesis**
Institution:	**Dalhousie University**
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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.

**The views expressed herein do not
necessarily represent the views of Health Canada**

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In addition to the above summary, the full report can be accessed in the following ways:

- A print version of the full report in the language of submission can be borrowed from the Departmental Library; requests may be sent to HCLibrary_BibliothequeSC@hc-sc.gc.ca.
- An electronic version of the full report in the language of submission is available upon request from Health Canada by e-mailing the Research Management and Dissemination Division.

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