# *Health Policy Research Program*
# *Summary of Research Results*

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| **Title:** | **Governance for patient safety: Lessons from non-health risk-critical high-reliability industries** |
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## *Summary*

The challenge of enhancing patient safety is now well established as a public policy issue. Despite the Hippocratic Oath to “do no harm”, the annals of medicine are filled with examples where harm was and is being done. From Semmelwiez in 1854 noting that child bed fever was directly related to the behaviour of physicians and preventable, to the events in Sweden that led to the Lex Maria (a law that established the first adverse event reporting system) in 1936, to various papers pointing out the hazards of modern hospital care in the 1950’s, Thalidomide in the 1960’s, to the studies of negligence leading to the Institute of Medicine (IOM) report in 1999 and subsequent national studies in the UK, Australia, Denmark and Canada, the facts and magnitude of patient harm and need for approaches to enhance patient safety are many and patent.

Health care is a high-risk, safety-critical industry, as are aviation, nuclear power, and railways. However health care did not, in general, think seriously about patient safety until the collective magnitude of the problem became clear and could no longer be ignored. Unlike health care, these other high-risk industries focused on safety almost since their establishment, in part because of the recognition that error led to catastrophe and in part (with the exception of the early history of railways) because they were global industries that required global control to set and enforce regulations and standards of operation.

The International Civil Aviation Organization (ICAO) established in 1944 and the International Atomic Energy Agency (IAEA) in 1957 were mandated by the international

community to create governance structures and tools to enhance safety to which governments of all member states agreed to adhere. National governments, in turn, established governance structures to implement the ICAO regulations and standards regarding airline operation, air navigation systems, professional training and certification, aerodrome operations, maintenance processes, nuclear reactor design and control functions, disposal of spent fuel and a myriad of other safety-critical activities and issues.

Moreover, research and reflection since the 1980's have led to the recognition in high-risk industries that human error (an early and easy target of public concern and thus regulation) was in fact embedded in a wide array of system failures and frailties. The system perspective led to a consideration of safety culture, and human factors research, which in turn led to important insights regarding problems of communication, clumsy technology, the need for vigilance and anticipating problems before they occur, the thorough investigation of accidents after they occur, as well as the need for an accounting process to understand the magnitude and trends of adverse events. A key observation was the need to establish Safety Management Systems to undertake these tasks and the need to establish bodies (e.g. independent Agencies or components of traditional Ministries) whose sole function is a focus on safety within said industries unhindered by political consideration or the imperative to promote the industries' economic health.

Health care generally has only begun to take seriously the insights described above, although some clinical specialties, such as anesthesia and pharmacology have learned from this body of work with an important impact on adverse events. The rate of adverse events, in these specialties is not zero, nor is this the objective of safety initiatives; harm in health care and other high-risk industries will always occur since they happen in the context of "normal people, doing normal work, in normal organizations". The objective is therefore fourfold: 1) reduce to a degree that is reasonably practicable the rate of adverse events by learning to anticipate and manage them, to reduce the likelihood and severity of their occurrence; 2) study adverse events in detail and understand how they arise; 3) feed this knowledge into the design of machines, professional practice and systems; and 4) redesign systems to make organizations more resilient to the inherent risks, hazards and harms of "doing business".

The key attributes of safe systems are an obsession with and vigilance in detecting possible sources of error and hazard scenarios, and understanding the complex causal pathways leading to harm, and the application of this knowledge in real time. A concept of critical importance is the sharp end-blunt end dichotomy: the sharp end is where action is undertaken (cockpits, air traffic control centres, nuclear power control rooms, emergency departments (EDs), operating theatres (ORs), intensive care units (ICUs), etc.; the blunt end is where decisions are taken affecting, directly or indirectly, sharp end practice (e.g. management offices, boardrooms, Ministry offices, etc.). Both the sharp and blunt ends must have these attributes to create, or successfully work within, governance structures these attributes dictate.

Traditionally governance structures have been hierarchical and processes have been based on command and control. The regulatory framework and standards in high-risk,

high-reliability, safety-critical industries conform to this model. Recently however, alternative models of governance have been proposed and in some cases put into place (e.g. “smart regulation”). The “new governance” at both federal and provincial levels in Canada, as elsewhere, seeks to divest provision of services to other bodies (e.g. health authorities, not-for-profit corporations such as NAV CANADA) while retaining policy responsibility centrally. The concept is for ministries at the federal and provincial level to “steer more and row less”, reducing, it is said, bureaucratic red tape and internal agendas, the cost of government, while increasing efficiency, enhancing service, greater stakeholder involvement, etc. In some cases it is thought that the Principal-Agent Theory of liberal economic markets is the appropriate framework, but whether market or non-market structures are developed the overarching theme is the reinvention of government through deregulation, decentralization, performance-based regulation, contracting out, privatization, and generally the creation of “third parties” to do the work that was traditionally done primarily by government or its directly controlled structures and personnel.

The zeal with which the transition from bureaucratic to market mechanisms occurs is dependent on the ideological bent of government, though it must be said that across the ideological spectrum adherents to either extreme find the “new governance” attractive. A considerable body of theoretical (if not empirical) literature exists to justify the need for some reconfiguration of governance and although there is considerable energy behind the transition, most government activity remains more or less a mixture of governance models. However, it should be noted that there is empirical evidence that health care generally (and even information technology (IT) specifically in health care) is inappropriately considered in a market context. Thus, between the traditional bureaucracy and the market there exists what is called the “Third Way” involving partnerships and networks of organizations working with government bodies, though the objective of “steer more and row less” is also central to this arrangement.

The “new governance” process (whatever the structure) entails the development of performance based targets and measures (i.e. outcomes) to ensure accountability in meeting policy objectives. This in turn requires that the objectives are clear and measurable, that actual mechanisms for measuring outcomes exist and are valid, reliable and relevant. The degree to which these attributes have been successfully implemented has been challenging and thus variable. Moreover, to some extent there has been a trade-off of problems: third party stakeholders tend to have the same degree of self-interest and delight in power as do bureaucracies; networks create new and increasingly confusing sets of, and greater contention about, objectives; public problem solving is conflated with private interest, or worse, public objectives are made subservient to private interest.

Health care has generally been an odd amalgam of public and private governance. In Canada the predominant mode of payment has been public but service provision has been mixed, from direct government services, to partnerships with not-for-profit independent hospitals (and more recently health authorities), to essentially private physician and pharmacy firms (largely governed by self-regulating bodies) with which government negotiates but only loosely controls. Federal and provincial roles and responsibilities

have also been mixed, with health service provision being primarily a provincial domain (with exceptions, e.g. First Nations, prisons, the armed forces), while public funds gathered through taxation at both levels provide the funds. The federal government also assesses and regulates pharmaceuticals and medical devices, and now coordinates public health services through the new Canadian Public Health Agency.

Given the developmental history of high-reliability industries (which are in many ways still highly prescriptive) and the fact that health care has yet to achieve high-reliability status, the evolution toward the "new governance" models as it has been proposed for health care is problematic. Simply put, safety in health care is not at a stage of development where deregulation, privatization, decentralization, etc., will create high-reliability. In fact the opposite may be true. In aviation for example, deregulation has placed increased financial pressures on industry, and increases risk to safety as well as making approaches to safety more complex. Moreover, a recent analysis of "smart regulation" by Graham has raised a number of serious concerns that deserve serious attention prior to its wider implementation. While Graham's critique relates primarily to Health Canada's drug and device approval processes, it is equally applicable to a safety regulatory framework and her critique has very clear echoes in the history of regulation in aviation in Canada and elsewhere.

We therefore, believe, based on the evidence available in the literature and triangulated in our discussions with those in high-reliability industries and health care, that effective governance must be based on regulations and standards developed through a process of engagement with the health care system and the expertise therein, and promulgated by Health Canada through the legislation and structures (particularly safety management systems) that we propose.

**The views expressed herein do not**
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- 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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