

**From Good Intentions to Successful Implementation:  
The Case of Patient Safety in Canada**

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## **I. Introduction**

This paper applies implementation theory from the public policy and public management literature to the practical issues involved with the development and advancement of the leading ideas driving the patient safety movement within the Canadian health care system. Concern about patient safety has always been a feature of the health care system, but it has achieved much greater prominence over the past five years. There is widespread recognition that preventable errors are causing unforeseen and unwanted harm to patients, adding to the costs of the health care system in a variety of ways and contributing to the further erosion of public trust and confidence in the system. Most of the research and public debate has focused on mistakes and adverse events in the hospital sector, but there is a recognition that problems can arise in all parts of a complicated, sprawling and dispersed health care system.

If problem recognition is the first step towards improvement, the second step is agreeing on solutions. There is substantial consensus among care providers, health administrators, policy-makers and health researchers that the solutions to safety problems already exist. Of course, not everyone agrees. Forster, Shojania and Walraven (2005) have argued recently that our knowledge of the causes of adverse events is incomplete and that acting on recommendations without solid evidence may not produce improvements and may damage the credibility of all patient safety efforts. Most people working in the field, however, take the view that we cannot wait for more and certainly not for perfect research knowledge before we act on patient safety concerns. There are, in fact, many initiatives already underway throughout the world. Action plans have been developed in a number of countries at the national, provincial/state, regional and health institution levels. New safety and quality councils have been created to promote research, to stimulate action and to coordinate activities. Educational and regulatory bodies for the various health professions have become involved. Progress is being made but the scope and pace of change does not satisfy the leading researchers and practitioners in the field who point to frightening reports about the magnitude and seriousness of system breakdowns leading to serious harm to patients. Despite the availability of good ideas and good intentions, implementation is proving to be more complicated, difficult, and slower than patient safety advocates consider acceptable.

This paper undertakes the relatively rare task of applying implementation theory to the world of practice (O’Toole, 2004). The more conventional approach is to study implementation processes and practices to develop theoretical models and propositions about implementation. A review of the voluminous implementation literature reveals a number of theoretical perspectives and ongoing debates. Adopting a contingency approach, this paper seeks to determine which theoretical strands have the most relevance and offer the most insights into the practical challenges involved with implementation of the patient safety agenda. The analysis is based in large part on a review of the literature, including recent research and government reports on the topic of patient safety, as well as on the author’s experience as the first Chair of the Board of Directors of the Manitoba Institute for Patient Safety created in June, 2004.

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The paper proceeds as follows. The second section describes the context in which the patient safety issue has arisen by providing a brief overview of the Canadian health care system, which is more accurately described as thirteen provincial and territorial systems each with its own distinctive features but all involving a decentralized and indirect approach to the governance and delivery of services. A third section uses the concept of “agenda setting” in the policy process to analyze the emergence and content of patient safety agenda. The issues are seen to be multi-dimensional and the solutions must also be multi-faceted. Implementing reforms to prevent harm to patients and to promote learning from adverse events will involve numerous initiatives ranging across the boundaries of multiple policy systems and organizations. Drawing selectively upon the central propositions from the implementation literature, the paper analyzes the obstacles to the successful implementation of the policy ideas for enhanced patient safety. Finally, the paper also suggests possible ways to deal with those obstacles.

## **II The Context of the Canadian Health Care System(s)**

Context matters to how policy issues emerge are accepted and are handled on the various policy agendas of government. Health care presents a distinctive policy context. Canada has not one integrated health care system, but rather thirteen provincial and territorial systems, each of which is influenced by legislation and finances controlled by the national government. Federal-provincial negotiations represent a highly visible and crucial feature of the health policy process.

The thirteen provincial and territorial health care systems are arguably expensive, with total expenditures expected to reach \$130 billion in 2004, five percent higher than the previous year and estimated to be about ten percent of the GDP (Canadian Institute for Health Information, December 9, 2004, p. 1). Four broad sets of factors are driving changes within the health policy field: demographic shifts, particularly aging populations; technological innovations; economic conditions and the strained financial circumstances of governments; and political factors, such as a loss of public confidence in the long-term viability of their provincial health systems and growing debates over increased use of private sector institutions to provide services (Thomas, 2006).

Reflecting the pressures on the systems, there have recently been numerous royal commissions and task forces at the national and the provincial level setting forth blueprints for the future. Surveys tell us that health care has become the number one public policy concern of Canadians and nearly three-quarters believe their provincial health systems had declined over the preceding five years (Angus Reid, 2004). Also, Canadians are insisting on greater involvement in policy formulation, the delivery of health services and in their own use of those services. All of these trends have made the health policy field highly political and a focal point for continuous media attention.

The governance structures for health care are complicated and confusing. Provincial governments through ministries of health have primary control over health policy making, but they rely heavily on an indirect form of governance in the field. All provinces but Ontario have created regional health authorities (RHAs) to consolidate fragmented governing structures, to promote the integration of services, to increase responsiveness to local communities, to allow for less partisan decision-making and to strengthen accountability (Thomas, 2006). For service delivery, RHAs in most provinces rely upon a mix of organizations, especially hospitals, fee-for-service physicians (who are not employees of hospitals), non-profits, religious organizations and commercial firms.

Historically, physicians have been very influential in health policy formulation and have been the dominant decision-makers in most fields of health care delivery. Deference to their expertise led governments to delegate extensive authority to colleges of physicians and surgeons who were trusted to ensure safe, quality health care and to put the interests of patients first (O'Reilly, 2000). This thinking has not disappeared, but it has been increasingly challenged over recent decades as politicians, reflecting shifts in public opinion, no longer assumed that a highly autonomous medical profession would always act in "the public interest". The dominance of the medical profession has also been challenged by greater assertiveness of the other established health professions, by the emergence of new occupational groupings in the health field, and by the growing emphasis placed on multi-disciplinary teamwork in the delivery of integrated services. Reflecting the financial stresses within the health system, management has emerged as a new specialty and the result has been growing tensions between clinical and managerial perspectives on health issues, especially within hospitals.

There are numerous other institutions and actors who are part of the governance environment of the health care system – drug and technology companies, medical, nursing, pharmacy and other educational institutions, research foundations, "think tanks", advocacy groups, unions, the media and a fledgling patients' rights movement. Gradually courts are becoming more involved through the Charter of Rights and Freedoms in reviewing the allocation of scarce health resources. There are also bi-lateral and international health law issues which have impacts on Canada. Globalization in the form of liberalized trade agreements, multinational firms providing health care technology and products, new threats of disease transmission across national borders, the intersection of public health concerns with the terrorism threat and the impacts of rising health costs on the competitiveness of domestic firms, all add to the confusing swirl of forces which operate in and around the health policy system.

### **III Agenda Setting and Patient Safety**

At any point in time, there are hundreds of issues competing for active and serious attention from health policy-makers and health care providers. The concept of agenda setting has been developed to investigate how governments recognize, select from among and respond to the numerous issues facing them at any point in time. Different theoretical models of the agenda setting process have been identified over time which range from the investigation of broad economic and social determinants of agenda items to the impact of institutional and procedural arrangements on the outputs of different policy systems (Howlett and Ramesh, 2003, Chapter 5).

Related to the topic of agenda setting, there have been discussions of "policy styles" in different countries. In the health policy field, Carolyn Tuohy's comparative analysis of six countries (Australia, Canada, Netherlands, New Zealand, the U.K. and the U.S.A.) found that the health care reform strategies varied depending upon the power of different actors within the context of complex policy systems facing intense pressures for change (Tuohy, 1999). Canada's health care system(s) followed predominantly an *incremental* approach of gradual, marginal change compared to the "big bang" approach (comprehensive and fundamental changes forced through in a short-time frame) or the "blueprint" approach of a "game plan" to be implemented in stages. The overall characterization of Canada's health policy pattern as evolutionary and incremental hides the fact that when contextual factors (economic/financial, social, political,

technological) align in fortuitous ways, there is the potential for breakthrough types of change, such as the introduction of universal, pre-paid access to physician services in the mid 1960s.

This observation leads to the concept of “windows of opportunity” which received its most sophisticated expression in the theoretical model developed by John Kingdon (1995). His model deals with the role of policy entrepreneurs, located both outside and inside of government, in taking advantage of opportunities to move issues from the informal, wide ranging discussion agenda of society onto the more formal, limited agenda of government. When three streams of variables converge – the problem stream, the policy stream and the politics stream – there is the greater likelihood that issues will make it on to the agenda of governments and become the basis for action. Different types of windows of opportunity were identified by Kingdon, but it is not necessary to describe those here.

The nature of the reception for particular issues and the types of responses they bring from governments depends significantly on the policy field involved and on the distribution of interests and power within that field. Sometimes governments will anticipate the reactions of powerful groups and avoid issues, they may respond mainly with symbolic gestures, they may seek delay to allow time to mobilize political support for actions, or they may seek to co-opt affected groups by putting their leaders in advisory positions. All of these tactics and others have become part of the agenda management process in which governments seek to shape public expectations and to appear to be governing on the basis of a consensus, with low levels of conflict over policy goals and means.

As mentioned earlier, health is primarily a provincial responsibility, but since the post-war period there has been significant policy leadership and financial involvement by the Government of Canada. The introduction of a national hospital insurance scheme in 1957 and the gradual adoption by provincial governments after 1964 of the national medicare programs were the leading examples of fundamental policy reforms involving federal-provincial collaboration. The next such major policy change was probably regionalization within nearly all provincial health systems during the 1990s (Casebeer, 2004; Contandriopoulos, et. al., 2004 and Rasmussen, 2001) Below the regional health authorities in each province are operational institutions which actually deliver services, such as hospitals, long-term care, mental health, home care and other programs. In short, the health care system in each province is both multi-tiered and multi-sectoral making for difficult challenges in terms of the implementation of sweeping policy changes on a top-down basis.

However, the stratified and pluralistic nature of the health policy systems also means there are not only “big” windows of policy opportunity at the national and provincial levels, there are also “small” windows of opportunity at the regional and the institutional level (Exworthy and Powell, 2004). Medium and lower-level policy-making is less “political”, more operational and more often based upon what is considered at the time to be professional “best practice”. For higher levels of health policy-making, the prevailing pattern of change might be incremental with occasional fundamental changes, but the closer one moves to the operational front-lines of health care delivery the pattern of change becomes more continuous, but usually more limited in scope.

Demonstrating the relevance of these ideas of agenda setting to the emergence of patient safety issues is not difficult. While concern for patient safety has always been part of the practice of medicine and the delivery of health care, it is only in the past five years that the issues have achieved prominence on the broad societal agenda and have begun to receive active and serious consideration within government and other parts of the health care policy system,

including the self-regulating health professions. Previously the issues related to the delivery of safe, quality health care were seen as best left to the professionals who possessed the required knowledge and skills (Brennan and Berwick, 1996. Chapter 4). This deferential stance towards health professionals was encouraged by the remarkable progress of health care provision during the 20<sup>th</sup> century, especially the miracles of modern medicine which were responsible for saving and improving the lives of millions of patients. For some members of the medical community there was the belief that death and complications were an inevitable cost of medical breakthroughs, as exemplified by a 1956 article in the *New England Journal of Medicine* entitled “Diseases of Medical Progress”. However, there were also throughout the health care system procedures intended to prevent mistakes and to promote safe practices, such as educational requirements, professional licensing and regulatory programs, hospital accreditation reviews, critical incident reporting, the use of clinical practice guidelines, standards committees and death review procedures, such as morbidity and mortality (M & M) rounds in hospitals. Other procedures could probably be added to this seemingly impressive list. Questions have been raised recently about the effectiveness of these procedures, both alone and in combination. Nevertheless, the remarkable accomplishments of medicine in the second half of the 20<sup>th</sup> century contributed to an image of scientific certainty and perfection within the field and to high public expectations about health care generally. The recent discovery of unintended, but serious harm to patients comes therefore as a greater shock to everyone involved with the system.

Part of this questioning arose out of the quality assurance movement which emerged during the 1980s and gained prominence in Canadian hospitals during the 1990s. The idea behind quality programs is that data from critical incidents can be used to focus on unwanted events, to examine trends, to compare performance and to identify ways to improve care. Critical incident reporting does not provide a full picture of the quality of care; it merely highlights poor quality care. Moreover, having a formal quality program does not guarantee an enduring organizational commitment to continuous quality improvement, which is the essential purpose of such programs.

Quality programs launched with great fanfare during the 1980s and 1990s tended to founder in the wake of budgetary cutbacks, workforce reductions and structural reorganizations. There were other factors which explained the general disappointment with quality initiatives in the hospital sector:

- “quality” is an inherently value-laden and subjective attribute of health service provision so that different care providers, administrators and patients each may have their own definition and criteria of evaluation;
- some physicians had trouble identifying with and committing to quality initiatives, seeing them as a threat to their professional status and autonomy, as a means of managerial control and/or as a method of cost cutting
- there was uncertainty over what structures and processes were necessary to support quality initiatives; e.g. whether quality should be a horizontal staff function or a vertical line department function, and what types of educational efforts were necessary and feasible to introduce quality theory and methods.

By the late nineties the momentum behind the quality movement in health care slowed, with fewer institutions prepared to invest scarce resources in stand-alone quality programs.

To a significant extent, the patient safety movement emerged from the professional debates over quality. Drawing a distinction between safety and quality is not clear cut, but many informed commentators view safe care as the most basic requirement of the health system and

the essential foundation for the achievement of the broader aim of quality patient care (Wachter and Shojania, 2004, 58-61). It seems to be the case that the individuals who became the leading safety crusaders saw the dramatic potential of evidence about deaths and complications from preventable mistakes as a way to regain momentum in the quality field. Initial debates of the early 1990s over patient safety were largely confined to specialized research reports, professional conferences and the academic journals of the various health disciplines. To the extent that one event could be said to have launched the patient safety movement on to the wider public policy agenda, it was the publication in 1999 of a report from the prestigious Institute of Medicine (IOM) in the United States.

The IOM was a research body with the bureaucratic-sounding mandate to provide “objective, timely, authoritative information and advice concerning health and science policy to government, the corporate sector, the professions and the public”. Since its inception in 1970, the Institute had issued approximately 50 reports annually, few of which attracted any interest beyond the small, specialized knowledge communities to whom they were primarily addressed. Therefore, the intense media and public response to its 1999 report *To Err is Human: Building a Safer Health System* was highly unusual. The report was clearly written to grab media headlines and to arouse public concern with statements like: “as many as 98,000 people die in any given year from medical errors that occur in hospitals” and that this was “the equivalent of a jumbo jet crashing everyday” (IOM, 1999). The leading researchers for the report became instant media celebrities when the topic of medical errors became the subject of numerous news reports and documentaries. Often the treatment of the topic was sensational, if not frightening, adding another anxiety to the “culture of fear” which some commentators believe now exists in contemporary societies (Altheide, 2002 and Glassner, 2000). Books with titles like *Internal Bleeding: The Truth Behind America’s Terrifying Epidemic of Medical Mistakes* added to the exaggerated picture of risk involved with using the American health care system.

As a result of all this hoopla, the issues of patient safety suddenly had political salience and governments in the United States were forced to respond. At the national level President Clinton referred the IOM report to the Health Quality Care Commission and subsequently agreed to a set of recommendations to encourage better reporting of errors, to strengthen the hands of consumers, to improve patient safety and to increase accountability within those parts of the health care system controlled by the federal government. Within weeks of the IOM report, congressional hearings on the topic of patient safety were held. The Agency for Healthcare Research and Quality was directed to establish a Centre for Quality Improvement and Patient Safety and to fund research on those topics. Bills to require reporting on critical occurrences in the health care field were passed at the national level and in many states. For example, in July, 2005 President Bush signed into law the long-awaited Patient Safety and Quality Improvement Act which prevents discovery in malpractice litigation of voluntary reports of medical error to Patient Safety Organizations (PSOs). PSOs are expected to analyze data and to develop patient safety improvement strategies. Research centres, conferences, websites, specialized publications and advocacy groups concerned with patient safety appeared almost overnight. Business even got into the act when a consortium of Fortune 500 Companies, the Leapfrog Group, was launched to promote patient safety, mainly through technology-based solutions. Their motivations were a mix of social responsibility, a desire to control costs in a market-based health system (with rising malpractice costs) and the potential to sell their products and equipment.

This flurry of activity arose in response to what was an atypical report from the IOM which usually issued more sombre, scientific documents. *To Err is Human* was based on 1984

data collected in a limited study and the methodology for analyzing that data was hotly disputed. This is not the place to review those disagreements among the experts (Birnbaum and Scheckler, 2002; Localio, et al., 1996; Thomas and Peterson, 2003). Suffice to say that the IOM report represented a defining moment; it served to crystallize a growing public anxiety about a number of aspects of health care in the United States. It also had a demonstration effect, causing other countries to take a closer look at the safety of their health care systems. For example, in Australia a 1995 study found that a higher-than-expected number of admissions to hospitals were associated with adverse events and, boosted by media coverage of the U.S. report, national and state health ministers agreed in 2000 to establish the Australian Council for Safety and Quality in Health Care. In England, a number of high profile cases (particularly infant deaths in the pediatric cardiac program in Bristol in 1995) caused the Labour Government after 1997 to embark on an ambitious programme to improve the safety and quality of the health care provided by the National Health service (Lewis and Fletcher, 2005). This included the establishment in 2001 of the National Patient Safety Agency to provide leadership and the setting of targets for safety improvement. Similarly in other countries, like Denmark and New Zealand, landmark reports helped to galvanize the will to act and provided an agenda for action.

In Canada, federal and provincial/territorial governments, regional health authorities, institutions, the various health professions and other stakeholder groups had, of course, always paid some attention to patient safety issues. Some medical specialties, such as anesthesiologists, were early leaders in voluntary reporting of adverse events. However, the alarming events like the Krever inquiry into tainted blood and the deaths of twelve infants in a pediatric cardiac surgery program in Manitoba brought issues of patient safety to the forefront of public debate. The fact that Canada is exposed non-stop to media coverage and policy debates in the United States meant that, to some not easily measured degree, the swirl of publicity and controversy surrounding the 1999 IOM report affected the timing and content of patient safety initiatives in this country.

In September, 2001 the Royal College of Physicians and Surgeons held a one-day forum which led to the creation of a National Steering Committee on Patient Safety (NSCPS). After establishing five working groups and holding extensive consultations with Health Canada, provincial/territorial ministries of health, 26 health care organizations and many experts the NSCPS released a report in September, 2002. The report made over 20 recommendations, including the creation of a Canadian Patient Safety Institute (CPSI). Agreement to implement the recommendations of NSCPS was part of the 2003 First Ministers Accord on Health Care Renewal and the federal budget of the same year announced the provision of \$10 million annually to support patient safety, including the creation of CPSI. Now headquartered in Edmonton, the Institute is an arms-length, non-profit organization with a mandate to foster knowledge about optimal safety practices, to promote coordination among stakeholders and to modify the health care culture(s) to focus more on prevention and learning and less on blaming. The involvement of Health Canada with patient safety is not limited to CPSI, it also supports initiatives dealing with adverse drug reactions, look alike/sound alike health products, medical device problems, medication incident reporting, health infostructures and health research. After a year of federal-provincial negotiation, the Health Council of Canada was created in December, 2003 with 26 government, expert and public representatives. Its mandate is to monitor the 2003 Accord. The provincial governments of Alberta and Quebec decided not to participate directly in the operations of the Council, which has as part of its mandate ongoing monitoring of patient safety activity.

Further momentum was seen at the provincial level where several jurisdictions have recently established commissions, councils or institutes to monitor, promote and to coordinate initiatives dealing with patient safety. In 2002 Saskatchewan created a Health Quality Council, in 2003 Alberta expanded the mandate of an existing commission and renamed it the Health Quality Council of Alberta. In 2004 Manitoba established the Manitoba Institute for Patient Safety and in British Columbia there has been a task force on patient safety operating for several years. All of these organizations are meant to be independent of government so that they are free to provide objective analysis and advice to improve patient safety in their respective health care systems. Provinces to the east of Manitoba have not established arms-length bodies, but most have taken patient safety initiatives through their ministries of health, such as Ontario's patient safety support service and Nova Scotia's working group on patient safety.

The Canadian patient safety movement received a major boost in terms of media and public attention from the publication in the May 25, 2004 edition of the Canadian Medical Association Journal of "The Canadian Adverse Events Study" (CAES) (Baker, et al., 2004). Based on methods used in other countries, the CAES reviewed adult patient charts randomly selected from 20 acute care hospitals across five provinces. Researchers found that the overall rate of adverse events in 2000 was 7.5 percent for all hospital admissions (not including pediatric, obstetric and psychiatric admissions). Extrapolating from these percentages, it was estimated that 185,000 of almost 2.5 million admissions in 2000 were associated with an adverse event – defined as an unintended injury or complication resulting in death, disability or prolonged hospital stay caused by health care management rather than the patient's underlying medical condition. The majority of adverse events resulted in temporary disability or prolonged hospital stay, but the media focused on the deaths associated with preventable adverse events.

The study's estimate of a range from 9,000 to 24,000 such deaths in 2000 produced a headline in *The National Post* which read "Medical errors kill 24,000 per year; rates double those of the U.S.A." Similarly, *The Globe and Mail* ran a picture of a four year old who died alongside the headline "Study shows that medical mistakes affect 7.5% of patients." In fact, after all the appropriate statistical adjustments were made, the rate of preventable adverse events was 2.8% and an estimated total of 1.6% of people hospitalized in 2000 had an adverse event and died. In the interest of more sensational coverage, most media outlets focused on the higher range estimates, ignored the study's message that care in Canadian hospitals was safe for the vast majority of patients and that system failings, not incompetence or callousness on the part of care providers, were the main source of problems. Public debates of the study's findings were somewhat truncated with the calling of a federal election in June, 2004.

The CAES study dealt with hospitals, but mistakes and adverse events occur in other parts of the health care system. There is some research available, or in progress, on the frequency of mistakes in such other health fields as ambulatory, long-term and home care but much greater data and analysis is needed to achieve understanding of the various types, causes and means of prevention of adverse events. Knowledge of the best ways to improve patient safety is continuously evolving and actions must operate at different levels of the health care system simultaneously. The next section of the paper draws upon implementation theory to identify the challenges involved and to identify a range of policy instruments that could be used to implement the patient safety agenda.

#### **IV A Brief Synopsis of Implementation Theory**

In simple terms, implementation refers to the process whereby policy ideas are translated into practice. Until the early 1970s, implementation was assumed to be a straightforward, unproblematic step in the policy process in which the administrative apparatus carried out the policy decisions made by the elected members of government. In 1973 Pressman and Wildavsky published the seminal book, *Implementation*, which focused on how the high expectations attached to the Great Society programs of the 1960s in the United States were dashed in the process of implementation (Pressman and Wildavsky, 1973). The book illustrated vividly the complexity and uncertainty of joint action in which the national government sought to achieve its social policy goals by working through state and local governments who exercised significant discretion and freedom to apply the policies. Studies in other countries confirmed the slippage between policy intentions and policy results and argued that the gap was caused by the manner in which policies were being implemented.

During the 1970s and early 1980s there followed a flurry of studies utilizing a wide variety of research designs, theoretical models and multiple variables to explain the implementation process and its products (see the comprehensive review in Hill and Hupe, 2002). Any attempt to synthesize or to consolidate the writings on implementation is bound to be simplified and to omit important theoretical perspectives and insights. It is generally agreed that the field has lacked a consistent focus and has failed to build theory through the replication of studies in different contexts. There are both broad range and narrow theories. A proliferation of mainly descriptive case studies has added to an ever growing list of variables deemed to be potentially relevant to implementation.

Theoretical diversity and multiple variables makes it difficult to extract practical lessons for policy-makers. Many of the factors deemed important are obvious and there are few attempts to rank the relative importance of different factors. It might be assumed that different types of programs pose different types of implementation challenges, but there is no refined typology which could provide a guide for practitioners. In fact, the motto of implementation researchers might be described as “it all depends” because so many of the studies emphasize the importance of the context or the environment in which implementation is being attempted. Having opted for a contingency model, few researchers go beyond this to define and operationalize the concept of “context” in a way that would be helpful to practitioners. There is little guidance, in other words, about which contextual factors deserve the most attention and how they might be dealt with in policy planning and implementation. Also, the focus in many academic studies has been on explaining the so-called “implementation gap”, the distance between the original design of policies and programs and what happens in practice. This orientation to failure, describing what doesn’t work as opposed to prescribing how things could be made to work better, also limits the practical utility of available academic research.

Criticizing implementation researchers for not providing useable models that clarify the relationships among causal and manipulable variables is not entirely fair because most academics writing on the topic are interested in making theoretical advancements and creating more comprehensive understanding rather than generating ideas for immediate application. However, at the peak of the popularity of the implementation field there was the hope, often explicitly expressed, that studies could provide specific advice to practitioners about to handle concrete circumstances to achieve more successful implementation. This aspiration has been largely unfulfilled, but this is not to say that the field is completely without value to the practitioner community. As O’Toole noted in two articles which surveyed the implementation literature for policy recommendations, there are several lines of inquiry and potential syntheses of existing

knowledge which could yield practical insights, depending upon the circumstances in which implementation is being undertaken (O'Toole, 2004 and O'Toole, 2000). Applying selective implementation perspectives to the case of patient safety in Canada will hopefully demonstrate the relevance of theory to the movement of the policy ideas identified earlier into practice.

One of the theoretical debates in the field is whether implementation represents a distinctive, identifiable stage within the policy process. It must be acknowledged that the idea of a linear sequence of events leading from problem identification to policy formulation and then to policy implementation involves some artificiality since in "the real world" there is a blurring among the various stages, with policy often being refined as it is being applied. Also, policies seldom represent pure innovation (Hogwood and Gunn, 1984 and Peters and Hogwood, 1982). With so many policies accumulated from the past and with policies intersecting with one another in unpredictable ways, there is more policy succession happening than completely new policies being implemented. Even acknowledging these realities, the idea of stages has both theoretical and practical value because it highlights different contexts, institutions, individuals and issues involved as policies are applied, lessons are learned and policy refinements are introduced.

For many years the leading theoretical debate was between top-down and bottom up approaches to the study of policy implementation (see Hill and Hupe, 2002, for a full review of the debate). Top-down models focused on the capacity of central policy authorities to direct and control the behaviour of implementing agencies. To determine if implementation was working as intended required an examination of whether policy directions, prescribed procedures and timetables were being followed and the desired outcomes were being achieved in the real world. Explanations for implementation failure focused on a number of factors: lack of clear policy direction; a multiplicity of agencies and actors involved; inter- and intra-organizational differences in interests and values; problems of communication and coordination among the various actors and the basic limits of administrative control when autonomy and discretion were necessary to allow for the creative use of specialized knowledge and skills. Failure to achieve the implementation of stated policy goals was regarded as a problem to be corrected by stricter parameters for lower-level policy-making, tighter procedures and guidelines, performance measurement and sanctions for non-performance.

In contrast, the bottom-up approach documents and endorses flexibility for lower-level program officials to allow for choices about the use of scarce resources under pressures of various kinds. Also explored was the use of discretion to negotiate policy modifications among the participating agencies and actors. In short, there was a shift away from a focus on formal organizational hierarchies and control mechanisms and more attention was given to the interplay of interests, including power relationships. The goal of this research perspective was to build from the bottom up a picture of the "implementation structure", the pattern of interactions among agencies and actors which shaped, to some not easily specified degree, the policy outcomes.

The top-down versus bottom-up debate partly revolved around the question of whether implementation studies were meant to be mainly prescriptive or descriptive. Top-down approaches emphasized what ought to happen whereas bottom-up approaches sought to explain implementation processes and outcomes without offering prescriptions. The debate also had practical implications for how best to achieve improved performance while maintaining accountability. As noted later in this article, the top-down versus bottom-up distinction is highly relevant to the implementation process for patient safety. Managing this duality is one of the keys to success.

Earlier implementation studies had tended to assume that public organizations and their managers had the knowledge and skills to carry out policy as set forth by political authorities. However, with the recognition that all public organizations face pressures for more fundamental and continuous change, there was during the 1990s a surge of interest in the concept of organizational learning. Put simply, the concept suggests that organizations must read the signals from their external and internal environments, recognize the necessity for certain kinds of changes, develop the knowledge and skills needed to bring about change and then apply new ideas and approaches. Organizational learning is seen as more than the cumulative effects of individual learning; it is seen as a process of social interaction involving the shared production of useable knowledge and the use of teamwork to translate that knowledge into action (Fry and Griswold, 2003; Koffman and Senge, 1995). The concepts of organizational learning and the learning organization clearly have relevance to the challenges facing health care organizations today, most of which operate in complex, dynamic and unpredictable environments. A recent study of the introduction of capital investment appraisal into the National Health Service in the U.K. demonstrated persuasively that the development of new knowledge and skills was a key requirement for the implementation of what were relatively ambiguous policy directives coming from the political level (Schofield, 2004). Implementing most patient safety initiatives is more multi-faceted, involving a wider range of institutions and actors, than the adoption of a fairly straightforward financial management tool.

## **V Obstacles to Implementation of the Patient Safety Agenda**

There are a wide range of obstacles to the achievement of the policy goals of the patient safety movement. Implementation in this field must involve both “top-down” policy direction as well as the creation of policy from the “bottom up”. With respect to top down policy direction, those institutions and individuals responsible for carrying out policy directives are not merely passive recipients; they have discretion about how to apply policy and they have their own perceptions, values and interests in relation to proposed changes. Creating a receptive environment and the conditions necessary for change will require the support of key players at all levels throughout the health care system. Selecting from among a range of potential policy instruments to effect change is at this stage somewhat experimental because of imperfect knowledge of the problems of patient safety and what will work best to produce improvement. Statutory, regulatory, organizational, procedural, technological, scientific, financial, leadership and cultural changes will all be involved in moving the patient safety agenda forward and sustaining momentum.

One of the initial obstacles is the varying perceptions of the problem of medical errors. According to recent surveys in a number of countries (unfortunately Canada is not among them), there is a tendency by health providers, administrators and the public to underestimate the size of the patient safety problem and to disagree about its causes. For example, a survey of physicians and the public in the U.S.A. (reported in *The New England Journal of Medicine* on December 12, 2002) found that a majority of respondents believed that 5,000 or fewer deaths annually in hospitals were due to avoidable medical error (Blendon, et al., 2002). This compared to the much higher IOM estimate of between 44,000-98,000 such deaths. A similar under-estimation of the problem was found in a 2004 survey of nurses, doctors and administrators in the U.K. in which two out of five respondents believed the number of avoidable deaths in hospitals was between 1,000 to 10,000, one quarter of the estimate from the leading study in that country. In

terms of causes, the 2002 study in the U.S.A. found divergent perspectives between physicians and the public. Offered eleven possible causes of medical error, only two (understaffing and overwork/stress) were thought by at least half of the physicians to be very important. In the case of the public respondents, seven of the eleven causes were thought to be very important, with the following being leading examples: lack of time with physicians (72%), overwork/stress (70%), failure of health professionals to work as a team (67%), and understaffing of nurses in hospitals (65%). Neither group of respondents accepted the explanation that “the system” was to blame. In the case of surgical errors, for example, both the public and the physicians thought the surgeon should be held responsible and the public was more likely to blame the institution as well. The public’s insistence that someone and/or some institution should pay a price when things go wrong, will make it difficult to achieve the “blame free” environment that patient safety experts advocate.

As the survey results suggest, there is a need to change the several professional cultures which operate within the health care field if the aims of patient safety are to be strongly embraced. At the risk of over simplification, the strengths of the existing professional health cultures are a background of extensive education based upon scientific inquiry, a strong sense of individual responsibility and self criticism and a reluctance to acknowledge mistakes. The culture of perfection expressed by the maxim “first do no harm” becomes an obstacle for health professionals to examine honestly and to learn from adverse events. Until providers of care (physicians, nurses and others) accept that error-free health care is unattainable, the type of reporting and dialogue needed to achieve a learning culture will be difficult to develop and sustain (Carroll and Quijada, 2004). Prevailing approaches to the enforcement of accountability and liability reinforce existing cultural tendencies, as is discussed below.

The requirements for new professional cultures would include the following components: an understanding and commitment to patient safety, a recognition of interdependencies and willingness to work in teams, an openness towards the examination of unwanted events, an avoidance of blame and an acceptance of a compact of mutual, collective accountability. Often the required cultural shift is described as a movement away from “naming, blaming and shaming” towards an open, fair and just culture of safety. It is generally accepted that such a fundamental cultural change will be a difficult, slow and uncertain process because we do not know precisely which types of legal, policy, educational, structural, procedural and financial reforms will deliver the greatest amount of cultural change. Also, the health care system has been under constant pressure over the past three decades to undertake fundamental reforms and there is a significant amount of disillusionment, fatigue and fear of recrimination that changes will not go as planned. Surveys suggest that patient safety changes are not seen by providers or patients as the most pressing issues facing Canada’s health care systems today.

Putting in place the right incentives and removing disincentives at the level of the individual health care provider, the group/team, institutional and the overall policy environment is another requirement for successful implementation. This is too large a topic to be fully explored in the space available here. As noted above, hospitals have been the focus of most patient safety research because the sickest, most vulnerable patients depend on those institutions and the risks of harm are greater in these settings. Hospitals were developed and still function to a significant degree as independent institutions, despite regionalization which was intended to integrate them into the wider delivery system. Therefore, the obstacles and disincentives to improvement in that setting will be examined.

Hospitals are complex environments – especially large, acute care hospitals with emergency departments and those which handle the most difficult, severe cases. Many factors can potentially contribute to adverse events within hospitals. A recent synthesis of the research (Wong and Beglaryan, 2004) identified five major causes: flaws in equipment design, communications breakdowns, staff shortages, complex, high-pressured environments and punitive cultures which discourage reporting and learning. Change on several levels were identified as required to address patient safety issues in the hospital setting.

The belief within individual hospitals that patient safety concerns do not apply to us and that internal review processes for adverse events work as intended, can represent impediments to improvement. Fear of bad publicity and litigation can lead to silence about mistakes. Hospitals tend to have dual hierarchical structures based upon clinical program lines and administrative processes, which complicates coherent approaches and communication. A lack of trust and fear of reprisal may lead to a reluctance to report mistakes and near misses. Despite much talk of team work, physicians remain in charge of the delivery of most medical services. Many doctors insist on professional autonomy based upon the belief that each case is unique and requires specialized knowledge which only they possess. Doctors are usually not employees of the hospital, they tend to be reluctant to contribute fee-for-service time to patient safety issues and they are conscious of the professional regulatory (peer review investigation, license suspension, loss of income) and legal (malpractice suits, higher premiums and loss of income) consequences of reporting medical mishaps. In the most serious cases of patient harm, the legal and financial interests of the hospital and the physician may diverge. In summary, the orientation of physicians toward patient safety reflects their educational backgrounds, the behavioural norms of professional practice and the constraints/incentives of the contexts in which they work. With rare exceptions, it is not incompetence or indifference which limits their full participation in safety matters. Indeed, when harm to patients occurs, often they pay a significant psychological and sometimes a professional price because they have harmed the very person they are there to serve.

In institutions which have been experiencing budgetary and staff reductions, money and time to devote to patient safety efforts are often scarce. Of course, this begs the question: If patient safety is a clear priority, why is more money and time not assigned to improvement. As implied above, health care institutions may pursue their own organizational interests despite declared public policy goals related to patient safety. Without new funding, health institutions may believe they cannot divert scarce resources from direct programme delivery. Despite the present alarms about the safety of healthcare, governments will face difficulty providing large sums of new money for systems and education intended to produce non-events, i.e. fewer cases of harm to patients. Health institutions face an ever-multiplying number of patient safety requirements and standards. Yet, as one recent study noted, the numerous, recommended safe practices threaten to overwhelm the capacity of institutions to implement change safely and the cost-effectiveness of most proposed improvements remains unknown. The study concluded that: “Unless we collect information on cost-effectiveness and use it to prioritize both safety improvement initiatives and new safety research, society will not gain the maximum return (in terms of safety) for whatever resources are put into error reduction. This would be a bad thing” (Warburton, 2005, p. 227).

There is growing interest in the concept of a “business case” for patient safety and quality. This would involve comparing the cost of patient safety initiatives to the costs connected with an injury, such as additional procedures, prolonged hospital stays, damage

claims, reduced productivity, harm to professional and institutional reputations and loss of public trust and confidence. All of this does not include, of course, the suffering of patients and their families. Even if there is a “business case” for safety initiatives, politicians and the public are likely to insist that safe, quality care is to be expected, not something for which large amounts of new money must be found.

As noted above, understaffing, fatigue and stress are perceived as contributing factors to the occurrence of mistakes, lapses and slips in the delivery of health services. There are, in fact, studies which confirm a relationship between nursing staff levels and the frequency of critical occurrences, but the optimal levels of staffing remain unclear (Needleman and Baerhaus, 2003). Often clinical and administrative leaders in health institutions are faced with making trade offs in the face of incomplete information: What is a better investment – additional shifts of nurses to avoid fatigue and lapses or the purchase of new technology like a computerized physician order entry system to reduce medication errors? As noted above the evidence to guide such choices is limited.

Technology represents a driver and enabler of change, but it also poses its own risks in terms of patient safety (Kimmel and Sensmeier, 2002). In the hospital sector, popular technology solutions include web access to patient information, computerized physician order entry, bar codes for medications and computer-based incident reporting. In the future, computer-based simulations of various surgical and other health procedures will be used more widely to reduce the risks to patients arising from the learning curve involved with the mastery of new procedures (Canadian Patient Safety Institute, Patient Simulation in Canada, 2005). How technology works in practice depends significantly upon the organizational context, including the power structure, and upon human factors (Vincente, 2004). Today technological innovation in the health field is occurring so rapidly that there is no way for health care providers to fully understand its potential and risks. A lack of adequate training and time to learn how to use technology safely and effectively can be another problem. The lack of standardization in the design of technology can increase risks and, of course, technical malfunctions also occur. Finally, not all patient safety issues can be addressed through technological means.

Coordination represents another challenge to the implementation of the patient safety agenda. At present, there are hundreds of diverse initiatives being undertaken in the name of patient safety on the policy, legal, institutional, strategy, program and individual level. Hospitals have been the main targets of such initiatives but new activities are also underway in ambulatory, long-term, home care and elsewhere. Ideally, coordination involves the harmonization of policies and strategies to support patient safety aims and the integration of service delivery to avoid gaps and mistakes in the provision of health care. With multiple institutions operating on different levels, there is the risk that interdependencies will not be captured and that “best practice” learning will not occur.

Two broad approaches to greater coordination are possible. Achieving complementary action can occur on a top-down, hierarchical basis through some supervisory body with the authority to set policy directions and to monitor compliance. Alternatively, coordination can be based upon interaction, communication, information sharing and joint decision-making in which different parts of the health care system learn from one another and take the actions of others into account in their own decisions and activities. The creation of the Canadian Patient Safety Institute and the various provincial counterpart organizations is clearly meant to serve coordination purposes, but to do so on the basis of persuasion and influence, not real power. Such arms-length bodies will be successful in advancing the patient safety agenda mainly on the

basis of having good ideas, good timing and modest amounts of money, not by exercising regulatory control or through direct, operational involvement in health care delivery. It will be necessary in the future to evaluate whether such advisory bodies are effective in achieving concerted action across organizations of various types in pursuit of patient safety goals.

As noted above, patient safety is a complex, multi-faceted and multidisciplinary field. Health care has a foundation in medical science and other fields of inquiry, but it involves more uncertainty than is popularly acknowledged. Many procedures continue to be performed for which the scientific basis is questionable. In terms of developing a science for understanding and dealing with patient safety. As a June, 2005 article noted, “what we know about errors and how to prevent them is quite limited. Medical injury research to date has centered heavily on estimating the prevalence of injuries and categorizing them” (Mello, Kelly and Brennan, 2005). Research on causes of preventable injuries to patients is just getting underway, funding to support such research is limited and its future is uncertain since patient safety will not always enjoy its current prominence on the health policy agenda. Few physicians have the appropriate educational backgrounds and analytical skills to conduct such social-science based research, yet this is usually the group who are asked to review research projects and to decide whether findings are integrated into practice. Compared to other risky industries like aviation, health care has a poor record of generating, disseminating and implementing evidence-based knowledge related to safety matters. Driven by recent scary headlines, governments felt compelled to invest in research, but as the health system gets safer there will be less incentive to fund studies of non-events; i.e. accidents which do not happen.

A “best practices” philosophy has long been prominent in the field of medicine. Over time, with expanding knowledge, certain practices emerged as “tried and true” based upon available evidence. The same best practices approach is being recommended for the field of patient safety. Dissemination, knowledge transfer and learning strategies are at the centre of the best practice approach. There is a need, therefore for coordination of research, data collection and analysis and the creation of a clearinghouse of best practices. Both inter-organizational and intra-organizational learning will be needed. There are various kinds of enablers and barriers to knowledge transfer within and between organizations. There is also the risk of generalizing too freely from what appears to work in one health care institution but which may be inappropriate or unaffordable in another context. The replication of best practices is not straightforward and a more realistic approach might be labeled “smart practices”, where the leadership of the recipient organization recognizes the limits of its capacity and expertise.

Committed and effective leadership on a number of levels within the healthcare policy system will be required to achieve patient safety goals. Leaders will have to adopt an “opportunity-seeking” mentality looking for ways to create and to take advantage of opening and closing windows of opportunity to act on patient safety concerns. Given the distinctive context of a health care system, which is decentralized with a diffuse power structure, leadership cannot be based upon single individuals with forceful personalities who drive other actors to follow their direction. Rather, leadership must be more collective in character, a group process in which individuals motivate and influence others to work towards the shared goals of patient safety. Leadership will involve both top-down and bottom-up initiation. It will require the capacity to lead across organizational boundaries, which means less reliance upon formal authority and more use of informal types of influence. Skills in encouraging, motivating and persuading people and institutions will be required, as will skills in negotiation, mediation and compromise. Such activities will require a strategic approach to communication as a basis for proposed activities.

It is realistic to anticipate that achieving the active and sustained commitment of the physician community will be the biggest leadership challenge to successful implementation. By training, the nature of their work and the culture of medicine, most physicians are not well prepared to work in collaborative undertakings. Their individualistic tendencies are reinforced by fee-for-service remuneration systems which mean that time is a scarce commodity and time devoted to patient safety activities potentially represents lost income. It must be emphasized that the difficulty of engaging physicians arises not from indifference on their part, but rather from gaps in their current professional competencies and the constraints of the systems in which they work. It is also the case that the patient safety discourse provides language and knowledge that opens medical practice to surveillance and potential control by non-medical expert groups (Waring, 2004). If the patient safety movement is seen as a way to cut doctors down to size, it will encounter real resistance in the physician community. The only viable strategy is to work from the outset in partnership with physicians.

With leadership comes responsibility and accountability. It is too large a topic to explore fully here, but prevailing approaches to accountability stand in the way of progress towards safer health care systems. There are currently multiple forms of accountability within the health care system – political, legal/professional, hierarchical, procedural, contractual, financial, performance-based and patient-centered. Each type of accountability has its own mechanisms of enforcement, its own standards for judgement and its own range of consequences. Provision of health care is too complicated, involving too many institutions with diverse types of relationships and leading potentially to such serious consequences, that simplification and clarification of the accountability picture is difficult and probably ill advised given the extra protection offered by overlap and redundancy. The more serious problem with current approaches to accountability is the strong emphasis on a retrospective, individualistic, blaming and punitive approach rather than a more prospective, collective, learning and remedial approach.

It is useful in terms of clarity to think in terms of stratified layers of accountability within the health care system, but it must also be recognized that decisions and actions taken on one level can have consequences for performance and accountability on other levels. There are also “spillovers” in terms of outcomes in adjoining domains of health care affecting other parts of the system.

In the congested, interdependent world of the health care system, it is increasingly impossible and inappropriate to focus responsibility accountability on a single individual or institution. There is a need to think more in terms of a mutual, collective responsibility/accountability. Such a new approach would be more informal and cultural than the prevailing approaches which are formal and legal/organizational and procedural in nature.

There has been much written about the need to create a blame-free learning culture of safety. This would be done in part by requiring in legislation the mandatory reporting of adverse events, but at the same time providing physicians and other health care providers with qualified protection of confidentiality for peer review processes in the event of legal damage claims (Thomas 2006, b). Finding the appropriate balances between voluntary versus mandatory reporting to professional bodies, discretionary or mandatory disclosure to patients and families, and the generation of data to understand patient safety issues with the need to protect personal privacy, are all sensitive issues related to accountability.

In calling for a more blame free approach, there cannot be any implication of the complete abandonment of individual professional and organizational accountability in legal, regulatory and political terms. On the other hand, individuals and institutions cannot be fairly

held to account for events over which they had no control or could not reasonably foresee, either because of system deficiencies or because of the inherent uncertainties of health care delivery. Achieving greater reliance on a collective and constructive approach to accountability will be difficult because of the public's perception of bias, the suspicion of cover-ups and the refusal to accept the explanation that "the system" made an error. When something goes wrong, the normal response arising from the political process, the media and the public is to insist that an identifiable individual(s) and/or institution(s) pay a significant price and that new accountability measures be put in place. There is a reluctance in public debates to acknowledge that multiple accountability mechanisms will not in themselves contribute all that much to safer, higher quality health care. At best, they will prevent some types of unwanted behaviour and galvanize the norms of responsibility of all care providers. No matter how many external control and monitoring mechanisms are created, society will ultimately depend most on the internalized, subjective sense of responsibility of everyone in the health care system to ensure safe, quality, ethical and respectful health care.

There is mounting evidence that patients and their families can play a significant role in ensuring that health care is safe (Crawford et al., 2003; Laine and Davidoff, 1996; Vincent and Coulter, 2002). Increased patient awareness can be an important part of risk prevention and a source for the identification of problems. Surveys suggest that patients are not nearly as involved in decisions-making about their health care as they would like to be. Facilitating an active partnership between patients and health care providers should be an important component of a patient safety strategy. However, the level of patient involvement will vary according to the willingness of healthcare authorities and healthcare providers to share knowledge and to seek the active participation of patients. Obviously, the complexity of the issues involved and the educational backgrounds of patients will affect their ability to contribute to some debates. There are usually both technical, clinical issues and subjective value judgements associated with healthcare decision-making. Even on clinical issues there is a tendency to underestimate the capacity of patients to understand and, when values are at stake, their judgements are as legitimate as those of the professionals. In the past, patients were mainly cast in the passive role of being grateful recipients of care. The language of health care was heavily paternalistic – creating superior-subordinate relationships in the process. As part of the movement towards patient autonomy and patient empowerment, more patients see themselves as having rights and power. When it comes to the patient safety agenda, healthcare institutions must develop more and better ways to obtain patients' accounts of their experiences and their understandings of why something went wrong. There is the further challenge of how we integrate and balance these patients' perspectives with what is currently seen as more "scientific" evidence derived from research and professional practice.

In summarizing the above discussion, it can be observed that the implementation requirements in the field of patient safety involve much more than simply moving agreed upon ideas and approaches into practice. The obstacles to implementation reflect the complexity of the health care system, including the constraints of the wider political process. The obstacles include: divergent perspectives about the size and nature of the problem, imperfect understanding of clinical outcomes and possible solutions to adverse events, deeply entrenched professional health cultures which emphasize perfection and discourage the acknowledgement of mistakes, financial and regulatory incentives which reinforce a culture of silence, the reality and the perception of resource (financial, human, time, etc.) scarcity which places productivity concerns above safety concerns, the risks of error involved with combining technological

innovation and fallible human beings in a complex system under stress, the problems of “turf protection” and the need for coherence / coordination in a dispersed system where there are multiple potential points of resistance to change, the need for informed and committed leaders at all levels, the requirement to shift from an almost exclusive reliance upon an “accountability-as-blaming” approach to a much greater reliance upon an “accountability-as-learning” approach and the need to make patient-centered healthcare more the reality. In short, even if there is commitment to patient safety, there are a series of substantive and procedural obstacles or challenges involved with translating that commitment into action. This point can be illustrated by the case study of the creation of the Manitoba Institute for Patient Safety.

## **VI The Case of the Manitoba Institute for Patient Safety (MIPS)**

MIPS was created as an independent non-profit corporation under the Corporations Act of Manitoba in May, 2004. It was brought into existence through the initiative of the Government of Manitoba. The concept of a patient safety institute had been recommended in 2003 by a government-appointed advisory committee chaired by Dr. John Wade, former Dean of Medicine at the University of Manitoba and former Deputy Minister of Health. The decision and the timing to create MIPS reflected a history of episodes in the province involving death or harm to patients in a number of healthcare settings; most notably the deaths of twelve infants in a pediatric cardiac surgery program at the province’s largest teaching hospital, the Health Sciences Centre (HSC) located in Winnipeg. An inquest report (known as the Sinclair Report) issued in 2000 and a review / implementation report issued in 2001 (known as the Thomas Report) both used the tragic events of the “baby deaths” to call for numerous reforms to the safety and quality of the Manitoba healthcare system. Some significant improvements flowed from the Sinclair and Thomas reports: an improved informed consent policy, greater critical occurrence reporting and more disclosure to patients / families, the publication on-line of physician profiles, significant investments in quality improvement and risk management and a greater reliance on multi-disciplinary program management on a regional basis. Given the province’s checkered history of safety problems and the fact that the Minister of Health in the New Democratic Party government had in opposition strongly supported the families who lost children at HSC, meant there were pressures to do something when the Canadian adverse events study reported in June, 2004 that as many as 24,000 Canadians die annually in hospitals from preventable mistakes. The government’s response was to establish MIPS as an arms length body to promote patient safety, as well as to develop greater capacity and knowledge in the Manitoba Health (MH) department to pursue a patient safety agenda. The relationships between MIPS and MH are among a number of coordination challenges involved with moving forward with patient safety activities.

The mandate of MIPS is to stimulate and coordinate activity related to patient safety, to coordinate activities across the system and to provide advice to government and other stakeholders in the healthcare system. The Institute is currently governed by a twelve member Board of Directors, appointed initially by the Minister of Health and by the executive of the department. Eventually, the departmental appointees will be replaced by individuals nominated by health organizations who pay a modest fee to become members of the Institute and from this list of nominees directors will be elected for staggered terms at the annual general meeting of MIPS. There will always be a minority group of directors appointed by the Minister including the Chair.

At this point, MIPS obtains nearly all of its funding in the form of an annual grant for 2005-2006 of approximately \$500,000 from the Government of Manitoba. However, the Institute is expected to diversify its revenues in various ways, both to enable it to undertake more extensive activities and to lessen its dependence upon government support. MIPS will always be a small organization. Currently its full-time staff consists of an Executive Director, a policy analyst, and administrative support with a small number of other people hired on short-term contracts to help with particular projects.

It is important to indicate what MIPS does not do. It does not operate any health care programs. It is not a professional regulatory body and will not pre-empt or interfere with such professional regulatory organizations as the College of Physicians and Surgeons of Manitoba (CPSM), the College of Registered Nurses of Manitoba (CRNM) and the Pharmaceutical Association of Manitoba (PAM). While MIPS has “patient” in its title, it is not a watchdog or ombudsman-like organization which becomes involved with the investigation and resolution of complaints about clinical or administrative problems in health care. As a matter of Board policy, the Institute welcomes submissions from the public about their healthcare experiences as one “window” into the operation of the system, but it refers individuals with specific complaints to the appropriate authorities. In summary, with a limited budget and staff capability, no operational responsibility, no regulatory authority and no mandate to investigate specific cases, there are definite limits to the impact MIS can have on Manitoba’s complicated and dispersed healthcare system.

The challenges facing MIPS in terms of advancing the patient safety agenda in Manitoba include all the factors mentioned in the earlier discussion of the sources of implementation failure and others. Embedding patient safety into the dynamic healthcare policy agenda will be difficult. That agenda shifts constantly in response to social, economic, technological and political developments, including new parties in office, new ministers and new people in key locations throughout the healthcare system. Even with institutions in existence to promote patient safety goals, there is no guarantee that the present support and momentum in favour of a system-wide change will be sustained. In a small, less affluent province like Manitoba, in which over 40 percent of the provincial budget is spent on healthcare, there is strong competition within the health field and with other public policy fields for scarce tax dollars, for knowledgeable personnel and even for continuing attention within organizations driven by crises, urgent problems and media headlines.

Sustained leadership and commitment to patient safety at the provincial level, particularly from the Minister and Manitoba Health, will be crucial for the successful implementation of the patient safety agenda. Only the provincial government can provide the core funding needed for investments in patient safety across the system and on a multi-year basis. There is mounting evidence that a “business case” for investments in patient safety can be made in institutional settings like hospitals and long-term care facilities as the means to avoid such costs of adverse events as additional medical procedures, prolonged hospital stays, lost productivity and law suits. However, the cost-effectiveness calculations of the provincial government must be broader than this. It is only the provincial government that can calculate and take into account the wider social benefits of patient safety, such as the future well-being of patients, public trust in the healthcare systems and the general, negative economic impacts of adverse events. As persuasive as the case for significant provincial investment in patient safety sounds in theory, it runs up against the practical, political problem that spending money on preventing future mistakes ranks lower than

dealing with urgent, immediate problems and, with the health budget growing six to eight percent annually, there is resistance to redirecting more money from other policy fields.

MIPS was given a broad and general mandate from the provincial government. Its budget of just over \$500,000 is modest in relation to both the breadth of its mandate and overall spending on healthcare in the province which was approximately \$4 billion in 2005-2006. The expectations attached to the role of the Institute must accordingly be realistic. The Board of Directors and staff of MIPS must identify practical solutions to problems of patient safety that can be acted upon immediately, as well as longer-term changes that will support safer healthcare in the future. As an independent body created to provide advice to the provincial governments and other institutions in the health field, MIPS must ensure that its activities are relevant to contemporary policy, legal, institutional and service delivery debates, while avoiding entanglements in short-term political controversies and not neglecting the need to anticipate medium-range future requirements in the field of patient safety.

Of necessity, MIPS has adopted an “opportunity-seeking” approach to implementing its mandate to stimulate, support and to coordinate activities in the field of patient safety. The Institute began its development by staging a province-wide consultation exercise to seek direction on its first strategic plan and to heighten its profile in the Manitoba health policy community. The planning exercise was useful to gain a better understanding of patient safety issues in different healthcare contexts, to develop an inventory of existing patient safety initiatives and to identify opportunities where MIPS could make a distinctive contribution or add value to the work of others. An effort is being made to reflect the strategic priorities identified in the plan in the allocation of scarce budgetary and staff resources. Formal planning has benefits in terms of anticipation of future developments, providing focus and discipline to guide activities and encouraging communication across levels and sectors within the healthcare system. However, in practice, the future evolution of the Institute is more likely to resemble strategic improvisation than the textbook image of following a detailed blueprint contained in a strategic plan.

Most of the first year of the Institute’s existence was taken up with all the practical, concrete requirements of getting established and staging the strategic planning exercise. MIPS now has an agenda of future, potential initiatives that it would like to pursue. How soon and on how large a scale it undertakes those initiatives will depend greatly upon resource availability and finding partners with whom to collaborate. Over the long term MIPS will have influence by generating its own ideas for improvement, recognizing and supporting the good ideas of others and working collaboratively with others to move those ideas into practice. Given its reliance upon influence, rather than direct operational or regulatory authority and its need to work with and through other institutions and individuals, MIPS will face serious conceptual and analytical challenges in tracking its progress, measuring and attributing improvements in the field of patient safety to its own activities. Yet, this is something that the Institute must do to develop credibility, to retain financial support from the provincial government and to meet the requirements of the policy system in which it operates (such as potential reviews by the provincial Auditor General).

As noted above, the causes of unsafe healthcare are seen by most experts to be systemic in nature and, as also indicated, system-wide change in Canadian healthcare is a slow and uncertain process. There are simply so many points in a pluralistic complicated and fragmented system (some would say “non-system”) where breakdowns in communication and coordination can occur and where resistance to change can arise. Therefore MIPS must approach its communications and coordination efforts in a strategic manner based on an assessment of the

situational context, the type of issue(s) involved, the institutions and groups most directly affected and their likely response to proposed changes. Finding allies and overcoming resistance will be part of the process. Lacking authority and resources to follow a “top-down”, unilateral approach, MIPS must encourage the harmonization of activities and the spread of “best practices” through the creation of forums for information sharing, knowledge transfer, consultation and consensus building among a wide range of stakeholders. To perform effectively in this role, MIPS must become more visible, develop a reputation for objectivity and gain credibility as a source of sound and feasible ideas in the field of patient safety.

Probably the most difficult, long-term challenge in the patient safety field is the transformation of the multiple professional and institutional cultures in the health field. Culture represents the “taken-for-granted” assumptions, values, beliefs, norms of behavior and informal “rules of the game” which shape, to some not easily measured degree, the thinking and behavior of institutions and individuals.

As mentioned above, the traditional healthcare culture treats adverse events as isolated incidents, as caused by human error and as the focus for investigations leading to blame and punishment. In contrast, the proposed new safety culture sees adverse events as arising from flawed systems and multiple causes, which require analyses of the interactions of structures, processes, conditions, technologies and human factors in the context of a just culture of mutual accountability which leads to learning rather than blaming (Morath and Leary, 2004). Of all the professional health cultures that of medicine is the most entrenched, dominant and difficult to change. Physicians have the scientific knowledge base of medicine and the skills to look after individual patients, but too few have the knowledge/skills to work in teams with other health professionals, researchers, managers and patients and to understand and to analyze healthcare delivery as a process which can be measured and improved on the basis of evidence.

Professional colleges are committed to improving patient care. There are champions of patient safety found in all health professions and in many institutions. Making the patient safety ethos central to the healthcare culture will require not only leadership, but also the use of “positive” and “negative” incentives to encourage modified behavior and to promote the adoption of improvements. MIPS does not directly control the incentive systems in healthcare, but it can lend its support to positive changes as it did in 2005 by publicly endorsing provincial legislation (Bill 17) to require mandatory reporting of critical occurrences in healthcare situations. The establishment of committees within those institutions to conduct investigations of such adverse events and the granting of “qualified privilege” to the proceedings of those committees which prohibits their use in disciplinary and legal actions. By compelling disclosure of serious harms to patients and offering some protection against punishment to individuals who report critical occurrences, the legislation seeks to promote a more open and honest dialogue about adverse events. It is one of many steps that will be taken to change the cultures of healthcare. MIPS is also working with the relevant higher education authorities and the professional colleges to develop patient safety components within professional education and training. Communicating about patient safety in a variety of forums (like co-hosting an annual provincial patient safety conference) and in the media is another way that MIPS is promoting cultural change. Rather than challenge or oppose the existing culture(s), it probably makes more sense to build on existing cultural strengths and to promote a shift and merge of old and new cultures.

Strengthening the voice of patients in debates over patient safety, enabling them to make better informed decisions about their care and ensuring disclosure and redress when something

goes wrong is a key challenge for MIPS. To date the Institute has engaged citizen members of advisory councils to RHAs in its consultation exercise, participated in a national “Speak Up” campaign intended to encourage patient involvement in their care and staged a forum on mandatory reporting, disclosure and privacy and access to information in relation to adverse events and the use of personal health information. “Patient-centered care” has become a popular phrase to cover a range of activities from patient involvement in health policy discussions to shared decision-making in their care. Only a small minority of patients will ever be directly involved in the planning and organization of service delivery, but virtually all will come into contact with health services on an individual level. MIPS must develop a strategy for capturing the patient experience, engaging them in policy debates, promoting a realistic approach to patient involvement with professional groups and managers and building awareness of the redress mechanisms available to obtain explanations and remedies when things go wrong.

## **Conclusions**

Improving patient safety has become a major issue on the already crowded healthcare policy agenda. However, knowledge of the causes of adverse events and of the best ways to prevent harm to patients is still evolving. There is an impatience among patient safety advocates to move quickly on a number of reforms which are widely accepted to represent part of the solution to the problem. This article highlights the complications involved with the implementation process whereby policies, structures and procedures are translated into practice.

Implementation theories are plentiful. There is a lack of consensus about conceptualization of implementation as a stage in the policy process and even whether the model of sequential stages fits with realities of policy-making in the real world. Both “top down” and “bottom up” models seem to provide accurate descriptions of the implementation process depending upon the policy field involved. The number of variables potentially relevant to the outcomes of the implementation process are identified in the literature as numerous. There is a negativity bias to much of that literature in the sense that researchers focus on the sources of implementation failure and/or the slippage between the declared policy goals and the actual impacts of policy. Apart from some common sense kinds of observations about the conditions necessary for successful implementation, the academic literature provides only limited, general advice for decision makers in the real world. This maybe unfair criticism because academics by nature of their professional role are more interested in the “why” than the “how” of the implementation.

Applying the more common sense propositions of the implementation literature was helpful in identifying many of the obstacles and challenges involved with moving the patient safety agenda forward within healthcare systems which are complicated, dispersed and turbulent. The usefulness of both top down and bottom up perspectives is clear to understanding how decision-makers on different levels make choices about the use of scarce resources (financial, human, time, political etc.) under a range of pressures and constraints. Finding the appropriate balance between top-down and bottom-up approaches is a challenge. Improvement cannot be imposed from the top down without taking into account the realities of professional work and the prevailing conditions within healthcare organizations. On the other hand, change will continue to be slow, spotty and disconnected unless bottom-up commitment is combined with system wide leadership from governments, regulatory bodies, RHAs, chief executives, educational bodies and professional associations.

The barriers to successful implementation are many, especially when a systems-wide approach is being followed. There are “big” and “little” windows of opportunity which open and close at different times within Canada’s multi-tiered health care system. Among the variables affecting the success of implementation efforts, the following are seen as key in the case of patient safety: agreement on the objectives, a valid theory of the causes and solutions to adverse events, the clarity and consistency of the policy directions, the availability of adequate resources, the role played by incentives in terms of encouraging support or resistance to changes, the relative authority resources and credibility of the multiple agencies involved with the adoption of patient safety reforms, the disposition and response (comprehension, acceptance, rejection) of the multiple stakeholders within the health policy community and the multi-dimensional cultures of the healthcare system which can lead to support or resistance for change. There are, in effect, multiple contexts for change on the policy, legal, institutional, group and individual levels. Actions to improve patient safety must operate at all levels of the healthcare system simultaneously, which involves the risks of contradictions, overlaps and gaps in how implementation proceeds.

The general ideas contained in the implementation literature are useful up to a point, but the practical advice is vague and inconsistent. This reflects in part the diversity of the contexts and settings in which implementation is undertaken. As O’Toole observes:

“Implementation settings in the real world typically face considerable uncertainty and complexity, particularly in networked contexts, and especially at the initial stages of implementation, when routines for interaction are not yet in place, modes of coordination and many aspects of implementation action are under negotiation and considerable learning must take place” (O’Toole, p.322).

This description describes quite accurately the experience of MIPS as I have experienced and observed it as Chair of the Board of Directors during the first eighteen months of the Institute’s existence. There has been uncertainty about how to define and to pursue the broad mandate of the Institute in a situation where it lacks authority and resources and must network with partners who are well established and have direct, operational and regulatory roles in the healthcare system. It has been necessary to develop shared understandings and routines of interaction with a range of institutions and individuals, such as the Minister and Manitoba Health, the Regional Health Authorities across the province, the various health professions regulatory bodies, and the groups and individuals leading safety and quality initiatives on all levels and in all parts of the system. Relations with the media and the public have posed a challenge because of the tendency to see the Institute as an advocate on behalf of patients’ right and/or as a kind of specialized ombudsman for complaints about health matters. While committed to strengthening the involvement of patients in healthcare decision-making on a number of levels, MIPS has neither the mandate nor the resources to assume either a direct advocacy or ombudsman role. As part of its learning efforts, MIPS has looked at the experience in other jurisdictions, including other countries like Australia, the UK and the USA and has networked with safety/quality councils in Western Canada and with the Canadian Patient Safety Institute. There are definitely lessons to be learned from other jurisdictions, but determining what activities are relevant and feasible for an Institute assigned only a safety (not a quality) mandate, with limited resources and operating in a smaller “have-less” province is a practical challenge faced by MIPS.

There cannot be “top ten rules” about how to structure and carry out the implementation of patient safety ideas. Rather, it involves being sensitive to and responding to the problems, opportunities, and constraints found in different contexts. In my own experience with MIPS, the literature on governance and organizational change has proven to be more valuable in practical terms than the implementation literature. Governance is about more than government and as an activity of direction setting and change within society it involves interactions based upon interdependence and persuasion, not upon hierarchy and top-down control. This fits with the circumstances of the field of patient safety. Successful governance involves all of the key components of organizational change: reading “signals” from the environment, planning combined with improvisation, dispersed, shared leadership, the ethical use of power and constructive conflict management, the transformation of cultures, the creative use of incentives and the evaluation of progress towards goals. Identifying and deploying mechanisms of implementation of patient safety cannot be done on a standardized format, it will require strategic analysis, creative thinking and perseverance.

### **Bibliography**

- Akins, Rolitsa B. and Bryan R. Cale. 2005. “Barriers to Implementation of Patient Safety Systems in Healthcare Institutions: Leadership and Policy Implications” *Journal of Patient Safety*. 1, 1, 9-16.
- Altheide, David 2. 1999. *Creating Fear: News and the Construction of Crises* New York: Aldine.
- Baker, G. Ross and Peter G. Norton. 2005. “Next Steps for Patient Safety in Canadian Healthcare” *Healthcare Papers*. 5, 3, 75-80.
- Baker, G. R. and Norton, P. G., *et. al.* 2004. “The Canadian Adverse Events Study: The Incidence of Adverse Events Among Hospital Patients in Canada” *Canadian Medical Association Journal* 170, 11, 1678-86.
- Berta, Whitney Blair, and Ross Baker, 2004. “Factors That Impact the Transfer and Retention of Best Practices for Reducing Error in Hospital” *Health Care Management Review* 29, 2, 90-8.
- Birnbaum, David and William Scheckler. 2002. “Beware of the patient safety juggernauts” *British Journal of Clinical Governance* 7, 4, 282-85.
- Blendon, Robert J. *et. al.* 2002. “Views of Practicing Physicians and the Public on Medical Errors” *The New England Journal of Medicine* 347, 24, December 12, 2002. 1993-1940.
- Brennan, Troyen A. and Donald M. Berwick. 1996. *New Rules: Regulation, Markets and the Quality of American Health Care*. San Francisco: Jossey-Bass Publishers.

- Carroll, J. S. and M. A. Quijada. 2004. "Redirecting traditional professional values to support safety: changing organizational culture in health care." *Quality Safe Health Care* 13, ii16-ii21.
- Contandriopoulos, Damien, Jean Louis Denis, Ann Langley and Annick Valette. 2004. "Governance Structures and Political Processes in a Public System: Lessons from Quebec" *Public Administration* 82, 3. pp. 627-655.
- Casebeer, Ann. 2004. Regionalizing Canadian Healthcare: The Good – The Bad – The Ugly" *Healthcare Papers* 5, 1 pp1-5.
- Crawford, Mike J., et. al. 2002. "Systematic review of involving patients in the planning and development of health care" *British Medical Journal* 32, 5, 1263-8.
- Devers, Kelly J., H. H. Pham and G. Lin, 2004. "What is Driving Hospitals' Patient-Safety Efforts." *Health Affairs* 23, 2, 103-115.
- Entwistle, V. A., A. J. Bowden and I. S. Watt, 1998. "Evaluating interventions to promote patient involvement in decision-making: by what criteria should effectiveness be judged" *Health Services Research and Policy* 3, 2, 100-7.
- Exworthy, Mark and Martin Powell. 2004. "Big Windows and Little Windows: Implementation in the 'Congested State'". *Public Administration* 82, 2. 263-81.
- Forster, Alan J., Kaveh G. Shojania and Carl van Walraven, 2005. "Improving patient safety: moving beyond the 'hype' of medical errors" *Canadian Medical Association Journal* 173, 8, 1503-11.
- Fry, Brian R. and J. Samuel Griswold. 2003. "Defining and Implementing the Learning Organization: Some Strategic Limitations" *Public Administration Quarterly* 27, 3/4. pp. 311-36.
- Glassner, Barry. 2000. *The Culture of Fear: Why Americans Are Afraid of the Wrong Things* New York: Basic Books.
- Hill, Michael and Peter Hupe, 2002. *Implementing Public Policy: Governance in Theory and Practice* London: Sage.
- Hogwood, Brian W. and Lewis A. Gunn. 1986. *Policy Analysis for the Real World* Oxford: Oxford University Press.
- Howlett, Michael and M. Ramesh, 2003. *Studying Public Policy: Policy Cycles and Policy Subsystems* Don Mills, ON: Oxford University Press.
- Kimmel, Kathleen Covert and Joyce Sensmeier. 2002. "A Technological Approach to Enhancing Patient Safety" Health Information and Management Systems Society. 1-7.

- Kingdon, John W. 1984. *Agendas, Alternatives and Public Policies* Boston: Little, Brown.
- Koffman, Fred and Peter M. Senge. 1995. "Communities of Commitment: The Heart of Learning Organizations" in S. Chawla and J. Renesch (eds.) *Learning Organizations: Developing Cultures for Tomorrow's Workplace* Portland: Productivity Press.
- Laine, C. and F. Davidoff. 1996. "Patient-centered medicine. A professional evolution" *JAMA*. 275, 2, 293-300.
- Lewis, R. Q. and M. Fletcher, 2005. "Implementing a national strategy for patient safety: lessons from the National Health Service in England" *Quality, Safe Health Care* 14, 135-9.
- Mello, Michelle M., Carly N. Kelly and Troyen A. Brennan. 2005. "Fostering Rational Regulation of Patient Safety". *Journal of Health Politics, Policy and Law* 30, 3 375-426.
- Needleman, Jack and Peter Buerhaus. 2003. "Nurse staffing and patient safety: current knowledge and implications for action". *International Journal for Quality in Health Care* 15, 275-77.
- Okumus, Fevzi. 2003. "A framework to implement strategies in organizations". *Management Decision* 41, 9, 871-82.
- O'Reilly, Patricia. 2000. *Health Care Practitioners: An Ontario Case Study in Policy Making*. Toronto: University of Toronto Press.
- O'Toole, Laurence J. 2004. "The Theory-Practice Issue in Policy Implementation Research" *Public Administration* 82, 2, 309-29.
- O'Toole, Laurence J. 2000. "Research on Policy Implementation: Assessment and Prospect" *Journal of Public Administration Research and Theory* 10, 263-88.
- Peters, B. Guy and Brian W. Haywood. 1982. *Policy Dynamics: The Policy Succession Process*. New York: St. Martins Press.
- Pressman, J. L. and A. Wildavsky. 2003. *Implementation*, 3<sup>rd</sup> ed. Berkley, Ca: University of California Press.
- Schofield, Jill. 2004. "A Model of Learned Implementation" *Public Administration* 82, 2. 283-308.
- Smith, P. and N. York. 2004. "Quality incentives: the care of the U.K. general practitioner. *Health Affairs*. 23, 112-8

- Thomas, Paul G. 2006a. "Changing Approaches to Governance, Leadership and Accountability in Canadian Policy Making: The Case of Healthcare." in M. Wallace, M. Fertig and E. Schneller (eds) *Managing Change in the Public Sector* Oxford. Blackwell.
- Thomas, Paul G. 2006b. "Patient Safety and Personal Health Information: Reporting, Disclosure, Privacy and Access" Winnipeg: Manitoba Institute for Patient Safety.
- Tuohy, Carolyn. 1999. *Accidental Logics: The Dynamics of change in the Healthcare Arena in the United States, Britain and Canada* New York: Oxford.
- Vincent, C. A. and A. Coulter. 2002. "Patient safety: What about the patient?" *Quality and Safe Health Care* 11. 76-80.
- Vincente, Kim. 2004. *The Human Factor: Revolutionizing the Way We Live with Technology* Toronto: Vintage Canada.
- Wachter, Robert M. and Kaveh G. Shojania. 2004. *Internal Bleeding: The Truth Behind America's Terrifying Epidemic of Medical Mistakes* New York: Ruggedland.
- Walshe, K. and S. Shortell. 2004. "When things go wrong: how health care organizations deal with major failures" *Health Affairs*, 23, 1003-11
- Warburton, Rebecca Nunn. 2005. "Patient safety – how much is enough?" *Health Policy*, 71, 223-32.
- Wong, Dr. Jiahui and Hasmik Beglaryan, 2004. *Strategies for Hospitals to Improve Patient Safety: A Review of the Research* Toronto: The Change Foundation".
- Waring, Justin J. 2005. "Patient safety: new directions in the management of health service quality." *Policy and Politics* 33, 4. 675-92.
- "Making the Health Care System Safer: Second Annual Patient Safety Research Conference." 2003. Agency for Healthcare Research and Quality. Rockville, MD.