

**Patient Safety and Quality Care:  
*Action Required Now  
to Address Adverse Events***  
**— A Background —**

Canadian Healthcare Association

**November 2002**

## Table of Contents

	Page
<i>Acknowledgements</i>	3
<i>Introduction</i>	4
1.0 Crisis, What Crisis? Understanding Patient Safety and Quality Care	6
1.1 Purpose of this Backgrounder	
1.2 Defining Adverse Events	
1.3 Patient Safety as a "Systems" Issue	
2.0 The Facts: What the Experts Have to Say About Patient Safety	9
2.1 Key Academic Studies	
2.2 Government Reports	
2.3 Canadian Coroner's Inquests	
3.0 The Systemic Issues: What Every Stakeholder Needs to Know	18
3.1 Cultural Barriers: Getting Beyond Blame	
3.2 A Systems Approach: The <i>Best</i> Way to Learn from Adverse Events	
3.3 Reporting Adverse Events: The Need for an Evidence-Based Approach	
3.4 Governance and Leadership: Filling the Void	
4.0 The Context for Action: Who's Doing What Now	23
4.1 National Initiatives	
4.2 Provincial/Territorial Initiatives	
4.3 Organizational Initiatives	
5.0 Specific Strategies for Improvement: What We Can Do Now	29
5.1 Organizational Initiatives	
5.2 Provincial/Territorial Initiatives	
5.3 National Initiatives	
<i>Conclusion</i>	33
<i>Reference List</i>	34

## **ACKNOWLEDGEMENTS**

*This background document on patient safety and quality care was conceived, developed, debated and finalized through a synergistic process involving health system managers, trustees of health organizations and health policy analysts at the provincial, territorial and national levels.*

*The Canadian Healthcare Association (CHA) would like to acknowledge the enthusiastic participation of all of those involved in preparing this background document.*

*CEO Forum members had the insight to initially identify patient safety and quality care as an emerging issue that required CHA's immediate attention.*

*CHA appreciates the expertise and insight provided by Elizabeth Carlton, Senior Advisor, Legislation & Policy at the Ontario Hospital Association, and Gina Charos, Policy Researcher at the Canadian Healthcare Association in the writing of the original draft report and in the presentation of this material to the CHA Board of Directors.*

*The lively discussion by the participants at the June 2001 Joint Meeting of the CEOs and Board Chairs of CHA's Member Organizations and the CHA Board of Directors, was critical to shaping the final content and tone of this background document.*

*Finalizing and updating this document was undertaken by Kathie Paddock, CHA Health Policy Analyst, with grace and fortitude. Kathryn Tregunna, CHA Director of Policy Development, provided advice and support throughout the project.*

*The public release of this backgrounder was delayed to capture important events that were unfolding in 2002, including the initiative of the National Steering Committee on Patient Safety and the research of the Canadian Institute for Health Information and the Canadian Institutes for Health Research.*

*Recognition and thanks must also be given to health organizations, governments and associations who are committed to improving patient safety and quality care across the country.*

## ***INTRODUCTION***

In 1999 the U.S. Institute of Medicine (IOM) reported that adverse events ranked as the 8<sup>th</sup> leading cause of death, ahead of motor vehicle accidents, breast cancer and AIDS, costing an estimated \$17 to \$29 billion annually. Medication errors alone were said to account for approximately 7,000 deaths per year. In this report, adverse events (or “error”) were defined as “the failure of a planned action to be completed as intended (e.g., error of execution) or the use of a wrong plan to achieve an aim (e.g., error of planning).”

While the magnitude of these numbers may seem incomprehensible, there is no reason to suggest that the Canadian numbers are proportionally any different. Extrapolating from the U.S. data, adverse events would account for 4,000 to 10,000 deaths per year in Canada. The question is, do we know this to be true? And if true, what can be done about it?

Many groups in Canada have started to answer these questions. For example, the Royal College of Physicians and Surgeons of Canada (RCPSC) held a symposium in 2001 which led to the formation of a National Steering Committee with representation from a broad range of health stakeholders. The Committee’s report entitled *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care* was released in September 2002. The Canadian Coalition on Medication Incident Reporting and Prevention (CCMIRP) with support from Health Canada has also been developing a strategy for improving medication safety. A number of provincial organizations have also been addressing issues related to adverse events. For example, the Continuous Quality Improvement (CQI) Network, the Ontario Hospital Association (OHA), and various professional colleges have held conferences to examine these issues. At the government level, the Quebec Ministry of Health and Social Services commissioned a Ministerial review of patient safety and quality care in the province, releasing its report in March 2001.

While there is benefit to be gained from a multiplicity of efforts across the country, it is arguable that a pan-Canadian approach is warranted, indeed preferable. To address patient safety and quality care in a truly comprehensive way, Canadian health system stakeholders need to work collaboratively to ensure the development and implementation of effective strategies to prevent and minimize adverse events.

The impetus for action is threefold. One, the health system has a moral imperative to ensure the safety of patients. Two, adverse events have a tremendous cost to the system in extended hospital stays and additional medical procedures. Thirdly, adverse events expose health organizations to legal liability and sanctions.

Patient Safety and Quality Care:  
Action Required Now to Address Adverse Events  
*A Background*

The Canadian Healthcare Association (CHA) and our provincial and territorial members are committed to working with others to improve the quality and safety of health services provided to Canadians across the continuum of care. This will require the development and implementation of initiatives at the organizational, provincial/territorial, and national levels.

## **1.0 CRISIS, WHAT CRISIS? UNDERSTANDING ADVERSE EVENTS**

### **1.1 PURPOSE OF THIS BACKGROUNDER**

The purpose of this backgrounder is to provide a context for a discussion and follow-up action related to improving patient safety and quality care in Canada. In this document we will set out the relevant facts; outline some of the common systemic issues underlying the problem; identify a number of potential areas for change; and finally, offer a number of areas for action.

The document is not intended as an exhaustive treatment of the issue, but rather as an overview.

Topics covered include:

- ◆ Crisis, What Crisis? Understanding Patient Safety and Quality Care
- ◆ The Facts: What the Experts Have to Say About Patient Safety
- ◆ The Systemic Issues: What Every Stakeholder Needs to Know
- ◆ The Context for Action: Who's Doing What Now?
- ◆ Specific Strategies for Improvement: What Can We Do Now?

In the appended reference list is a compilation of relevant literature cited in this backgrounder. These studies and reports provide the factual basis for much of this overview and should be consulted for additional information.

### **1.2 DEFINING ADVERSE EVENTS**

Adverse events can occur at almost any stage of a medical procedure — in diagnosis, in the administration of anesthesia, during surgery, post-operatively, or in the dispensing and administration of drugs. Adverse events can also occur anywhere in the health system — in hospitals, clinics, physicians' office, nursing homes, pharmacies and patients' homes. However, to date much of the focus on patient safety has centered on the hospital setting.

Patient safety and quality care are compromised by “adverse events”, a term that is not a static concept *per se*, but rather a generic term that encompasses a number of different categories of events. This backgrounder focuses on those types of adverse events that are

preventable and are within the control of the health system to avoid and correct. This may include adverse events that are the result of what is done to a patient or what is not done, but should have been. It may also include “near misses” (i.e., when an adverse event is prevented just in time).

In health organizations, an adverse event may alternatively be referred to as an “adverse incident” or “medical error”; in legal parlance it is sometimes called a “medical misadventure” or “medical mishap”.

A subset of adverse events is medication error — preventable events in the medication use process. Medication errors need to be distinguished from “adverse drug reactions” which are previously known or newly detected side effects of drugs that may occur in the course of error-free medication use.

As will be discussed later, the absence of a single, unique term for adverse medical events is not without significance. However, for the purposes of this background, we will use the term “adverse events”.

### **1.3 PATIENT SAFETY AS A “SYSTEMS” ISSUE**

Patient safety is hardly new or novel – it has been around as long as medicine has. What has changed however, is the focus of the discussion. While adverse events are largely construed as human error that can be characterized as malpractice or negligence - a taboo subject for many working in the health system - what we now know is that the great majority of incidents may be attributable to what is known as “system error”, i.e., adverse events occurring as a result of a long sequence of events. From this perspective, it is not simply the individual health care practitioner, but also the health organization that falls under scrutiny.

This new twist on patient safety, this emphasis on system error, has been instrumental in pushing the issue to the top of the public agenda and from the back pages of medical journals to the front pages of newspapers. Adverse events are now regarded not so much an issue of negligence and/or liability, but of quality health care and patient safety.

Much of this discussion has its origins in the consumer movement. In this new era of consumerism, health services are regarded as a good or commodity like any other that we pay for (directly or indirectly through taxes). As a consequence, the public is demanding that the health system be held accountable for the services it provides, and more importantly, for how well it provides these services. It follows then, that the incidence of adverse events figures into this equation. Patients, prospective patients and their families want to know the risks of treatment in very real terms. So in essence, what was formerly narrowly construed as an issue of liability and risk management is now widely regarded as one of quality improvement and accountability.

Patient Safety and Quality Care:  
Action Required Now to Address Adverse Events  
*A Backgrounder*

With studies on adverse events gaining critical mass, the issue of patient safety and quality care is now front and center. Over the past several years, a number of academic studies, government reports, and Coroners' inquests have garnered a great deal of public attention around the world. Of particular note are the studies by the U.S. Institute of Medicine, the British National Health Service (NHS), and the Departments of Health in Australia and New Zealand. In Canada, to date, the primary locus for examining adverse events has been through Coroner's inquests, the most notable recent cases being the Sinclair Commission in Manitoba and the Joshua Fleuelling inquest in Ontario. And in Quebec, the government has undertaken a Ministerial Review. The net result has been a growing awareness and heightened visibility of patient safety.

While these international and Canadian studies and reports offer unique perspectives, they are strikingly similar in a number of respects. The authors of these studies attempted to document the incidence of adverse events; identify some of the more salient system processes that contributed to the events; and offer some proscriptive measures to reduce these events in future. But perhaps the most unifying thread among these studies is the alarming incidence and financial cost of adverse events.

For example:

- The U.S. Institute of Medicine estimates that 44,000 to 98,000 people die in hospitals each year as a result of adverse events.
- Australian researchers estimate that each year 18,000 patients die of adverse events, 50,000 patients suffer permanent disability; and that 470,000 admissions are associated with adverse events requiring an additional 3.3 million bed days.
- The NHS study in Britain found that adverse events occurred in 10% of hospital admissions, or at a rate of in excess of 850,000 a year, at a cost of £2 billion annually in additional hospital stays alone.
- The College of Physicians and Surgeons in Saskatchewan estimates that there are 10,000 adverse events in the province each year, 400 of which result in death.

To health service managers and providers faced with the competing pressures of system accountability and continued fiscal restraint, these figures are alarming. It is time to marshal efforts in support of a coordinated and comprehensive response to the problem. The studies and reports summarized below provide a snapshot of where we are, and how far we need to go.

## **2.0 THE FACTS: WHAT THE EXPERTS HAVE TO SAY ABOUT PATIENT SAFETY**

In this section, we review a number of important studies and reports released in the past decade. For each study or report we document key findings in terms of incidence and cost to the health system, and where applicable, recommendations made. Please see the attached Reference List for the full citations of these studies and reports.

### **2.1 KEY ACADEMIC STUDIES**

#### ***Leape et al. (United States, 1991)***

Known as the Harvard Medical Practice Study, Leape et al. examined 30,121 randomly selected records from 51 randomly selected acute care hospitals in New York State in 1984. This retrospective audit based on chart review revealed that adverse events occurred in 3.7% of all hospitalizations, with teaching hospitals having higher rates (4.1%) than rural hospitals (1.0%). Most adverse events resulted in minimal impairment, with 70.5% of the adverse events giving rise to disabilities that lasted less than 6 months.

They further found that 1% of discharges (27.6% of adverse events) were due to negligence and as many of 50% of them were preventable. Drug complications accounted for 19% of the adverse events; wound infections 14%; and technical complications 13%.

#### ***Wilson and Runciman (Australia, 1995)***

Using the Harvard study method with some modifications, the “Quality in Australian Health Care Study” by Wilson and Runciman audited 14,000 admissions to 28 hospitals in New South Wales and South Australia.

Using a slightly more general definition of adverse event than the Harvard study, they found adverse events in 16.6% of hospital admissions, the most common being adverse drug reactions. Some 77.1% of the adverse events the disability was resolved within a year, with 13.7% causing permanent disability; 4.9% of the patients died. Significantly, 51% of these adverse events were deemed to be highly preventable.

Patient Safety and Quality Care:  
Action Required Now to Address Adverse Events  
*A Backgrounder*

In terms of cost to the system, on average, adverse events resulted in 7.1 additional bed days. Extrapolating these data to the entire country for the year of 1992, Wilson and Runciman estimated that 18,000 patients would die of adverse events, 50,000 patient would suffer permanent disability; and that 470,000 admissions would be associated with adverse events requiring an additional 3.3 million bed days

***Lazarou & Pomeranz (United States, 1998)***

This study involved the analysis of 39 prospective U.S. hospital studies over a 30-year period. The results showed serious adverse drug reactions in 6.7% hospital admissions and fatal drug reactions in 0.32% admissions. From this data, the authors estimated adverse drug reactions to be between 4<sup>th</sup> and 6<sup>th</sup> leading cause of death in the United States.

***Thomas, Studdert, et al. (United States, 2000)***

Replicating the Harvard Medical Practice Study, the authors estimated the incidence and types of adverse events in Utah and Colorado. The incidence (2.9% of all hospitalizations) and types of adverse effects was found to be similar to those in New York State in 1984. Operative adverse events comprised 45% of all adverse events, of which 16.9% were deemed preventable and 16.6% resulted in permanent disability. Adverse drug events were the most common type of non-operative adverse event comprising 19.3% of all adverse events. Surgeons had the highest percentage of adverse events (46.1%, 22.3% preventable).

***Vincent, Neale, et al. (UK, 2001)***

This retrospective review reproduced the US and Australian methodologies to estimate the incidence and costs of adverse events in British hospitals. Results showed that 10.8% of patients experienced an adverse event. When the authors included multiple adverse events, the overall rate increased to 11.7%. Approximately half of these were judged preventable and a third led to moderate or greater disability or death. The authors noted that frequent, minor events and infrequent major events together accounted for great costs to the National Health System.

***Baker & Norton (Canada, 2001)***

Drawing on information from the above major epidemiological studies in the U.S., Australia, and the U.K., the authors of “*Making Patients Safer! Reducing Error in Canadian Healthcare*” proposed a conceptual model for understanding the necessary and interrelated elements for improving patient safety. To reduce the incidence of adverse events, a non-punitive error reporting strategy was recommended for effective *measurement* of adverse events. The authors maintain that this strategy is possible only within a *culture of safety*, when blaming and punishment are avoided in favour of

recognition that error is an inevitable aspect of human life. The authors cite Reason (2000) when they note that “we cannot change the human condition, but we can change the conditions under which humans work”. It is within this context that the design of machinery, tools and patient care settings can be altered to reduce the likelihood of error.

Recommendations based on the above model of patient safety and quality care focus on six thematic areas. The first, highlighting the need for leadership, recommended the formation of an expert panel to assess the status quo of patient safety in Canada. This section also emphasized target setting and the development of national standards. The second area described Canada’s informational needs and discussed reporting systems and accompanying legislation that could be proposed. Third, the authors recommended knowledge uptake initiatives such as education programs through the professional colleges. Fourth, the authors recommended a series of demonstration projects funded by federal and provincial governments. The fifth area further emphasized the need for adequate funding in order to initiate patient safety projects. Finally, the authors highlighted the need for knowledge and Canadian expertise and suggested that patient safety and quality care be a cross-cutting theme in the Canadian Institutes of Health Research.

## **2.2 GOVERNMENT REPORTS**

There has been a considerable amount of work undertaken at the governmental level, with reports emerging from the United States, United Kingdom, Australia, and New Zealand, and more recently, here in Canada. The first of these reports, *To Err is Human* by the Institute of Medicine provoked a fair amount of controversy and discussion.

**United States - *To Err is Human: Building a Safer Health System* (Kohn et al. for the Institute of Medicine, National Academies of Sciences, December 1999)**

In a landmark study undertaken by the Committee on Quality in Health Care in America, the authors estimated that there were between 44,000 and 98,000 deaths annually in hospitals as a result of adverse events, 7,000 from medication errors alone. Using the lower estimate, they predicted that more people die from adverse events each year than from highway accidents, breast cancer, or AIDS, making adverse events one of the leading causes of death in the country.

The authors further found that adverse events cost approximately \$37.6 billion each year (about \$17 billion of those costs are associated with preventable events); and approximately half of the expenditures for preventable adverse events are attributable to direct health costs, such as extended hospital stays and/or additional medical procedures.

Patient Safety and Quality Care:  
Action Required Now to Address Adverse Events  
*A Backgrounder*

Perhaps the most surprising finding related to the cause of adverse events. The authors concluded that the majority of adverse events do not result from recklessness on the part of the health practitioner, but from basic flaws in the way the health system is organized - - stocking patient-care units with certain full-strength drugs that are toxic unless diluted and illegible writing in medical records being some common examples. The authors also cited rapid growth of medical knowledge and technology, and a health system evolving so quickly that it lacks coordination, as additional reasons for the incidence of adverse events.

The authors established a minimum goal of 50% reduction in adverse events over the next five years and made the following recommendations in support of that overarching goal:

- That Congress establish a Center for Patient Safety within the Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ; formerly the Agency for Health Care Policy and Research) to set national safety goals, track progress in meeting them, invest in research to learn more about mistakes, and act as clearinghouse for the latest information about patient safety.
- That a nation-wide mandatory public reporting system be established where hospitals and other health organizations would be responsible for reporting [adverse events] to state governments (only a third of states have their own reporting requirements).
- That federal legislation be enacted to protect the confidentiality of certain information so that the information may be used exclusively for the purpose of improving safety and quality and not ultimately used in lawsuits.
- That regulators and accreditation bodies make patient safety a key component of their evaluations.
- That health organizations create an environment in which safety is a top priority; this culture of safety means designing systems geared to preventing, detecting and minimizing hazards and the likelihood of error – not attaching blame to individuals.
- That all hospitals and health organizations implement proven medication safety practices, such as using automated drug-ordering systems.

While the report made clear that there are no “magic bullets” to remedy the problem, it pointed out that each part of the health system needs to take some responsibility for creating a culture of safety. On this point, the report suggested that much could be learned from other high-risk industries such as aviation, nuclear power and mining where

Patient Safety and Quality Care:  
Action Required Now to Address Adverse Events  
*A Background*

safety improvements have been achieved through an ongoing commitment of resources and leadership rather than a one-off effort. Accordingly, the report stressed the need for leadership by executives and clinicians and accountability for patient safety by boards of trustees in creating and adequately funding systems to monitor safety.

In response to the recommendations made in *To Err is Human*, a national summit has been convened to examine research issues, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has implemented new safety and adverse event reduction standards and the Centre for Disease Control (CDC) has announced five year goals to promote patient safety. A number of additional national reports have also been issued.

**United Kingdom - *An Organization with a Memory*  
(Department of Health, June 2000)**

Chaired by the Chief Medical Officer, this study found that adverse events occurred in 10% of hospital admissions, or at a rate in excess of 850,000 a year at a cost of 2 billion pounds annually in additional hospital stays alone. Specifically, it found that every year 400 people die or are seriously injured in adverse events involving medical devices and that nearly 10,000 people report having experienced serious adverse reactions to drugs.

The Chief Medical Officer concluded that the NHS is not adept at learning from adverse events; that local risk reporting systems are variable; incident reporting systems are poorly-developed in primary care; and that systematic reporting of “near misses” is almost non-existent across the NHS.

The report outlines four key areas to be addressed – unified mechanisms for reporting and analysis when things go wrong; a more open culture in which adverse events or service failures can be reported and discussed; mechanisms for ensuring that where lessons are identified the necessary changes are put into practice; and a much wider appreciation of the value of the system approach in preventing, analyzing and learning from adverse events.

Recommendations in this report included mandatory reporting for all adverse incidents and “near misses”, the creation of a single database, and the establishment of targets for specific categories of recurring adverse events. (For example, by 2005 the number of serious errors in the use of prescribed drugs should be reduced by 40%.)

The U.K. Department of Health issued a follow-up report, *Building a Safer NHS for Patients: Implementing an Organisation with a Memory*, and in July 2001 established a National Patient Safety Agency to operate a system for reporting and tracking adverse events and near-misses.

**Australia - *Safety First: Report to the Australian Health Ministers' Conference*  
(Australian Council for Safety and Quality in Health Care, July 2000)**

This is the first report of the Australian Council for Safety and Quality in Health Care established in January 2000 by Australian Health Ministers to facilitate and coordinate national action in safety and quality.

The report cited previous data confirming that inappropriate medication use results in at least 80,000 hospital admissions each year at a cost of around \$350 million; half of which are thought to be preventable (Roughead, 1999).

In terms of remedial action required, the Council identified three priority areas: (1) better use of data to identify, learn from and prevent [adverse events] and system failures, including national reporting systems and promotion of quality and compatibility of national data sets; (2) promotion of effective approaches to clinical governance and accountability which address both the competence of organizations and individuals; and (3) redesigning systems to create a culture of safety within health organizations, including the means to support this new culture, such as the development of practical tools and standards development.

The report also identified some key areas for immediate action:

- Development of standards protocols and data for health professionals and managers.
- Education about health system safety improvement.
- Establishment of a national focus on the development and uptake of standards in collaboration with accreditation bodies.
- Support for lead implementation sites so that best practices are adopted elsewhere in Australia.

The Council committed to developing a national strategy which includes an environmental scan of current safety/quality initiatives to identify partnerships and other opportunities as well as the development of standards and compliance mechanisms in priority areas where they do not exist.

The Council also emphasized the need for dedicated national investment, recommending that Health Ministers allocate \$50 million to support the required national actions over the next five years, with \$5 million flowing in the first year.

**New Zealand - *Review of Processes Concerning Adverse Medical Events*  
(Helen Cull, Q.C. for the Ministry of Health, March 2001)**

This review, initiated in November 2000, focused largely on the adequacy of complaint mechanisms, but made a number of salient observations about patient safety and quality care.

Specifically, Cull's mandate was to report on what lessons can be learned from processes and timeliness of investigation of medical practitioners; any regulatory and institutional barriers that may exist which impede the timely identification and investigation of adverse medical outcomes by medical practitioners; any regulatory and organizational barriers to information sharing and co-ordination regarding adverse medical outcomes between relevant agencies; any improvements necessary to allow patients to better identify and access patient complaint mechanisms; and any legislative, regulatory or procedural changes which could ensure that adverse medical outcomes are identified and appropriate, timely remedial actions is taken.

In her report, Cull observed that fourteen different organizations could potentially be involved in investigating adverse medical events and concluded that there was no streamlined approach to complaint mechanisms, no agency interaction or co-ordination to enable the disclosure of relevant information, and no centralized database to detect repeated poor practice.

Cull recommended a one-stop shopping approach to the complaint process. This new streamlined process would ensure that patients know where to make complaints; all relevant complaints are recorded on a centralized database; one agency would be responsible for handling the principal investigation process; costs incurred as result of the adverse medical outcome could be tracked; the number of investigations and hearings could be minimized; and the time taken to process complaints would be considerably shorter.

**United States - *Crossing the Quality Chasm: A New Health System for the 21<sup>st</sup> Century*  
(Committee on the Quality of Health Care in America for the Institute of Medicine, National Academies of Sciences, March 2001)**

This report is the second report of the Committee on Quality of Health Care in America and a companion report to the first report, *To Err is Human*. While the emphasis of this report is on the need for a commitment to redesign the health care delivery in the United States, it does offer some insights on the subject of patient safety and quality care.

Specifically, the authors argued that use of a computerized medication order entry (CMOE) system could significantly reduce errors in prescribing and dosing drugs. Accordingly, they concluded that a nationwide effort was required to build a technology-

Patient Safety and Quality Care:  
Action Required Now to Address Adverse Events  
*A Backgrounder*

based information infrastructure that would lead to the elimination of most handwritten clinical data within the next ten years.

Finally, the report recommended that the U.S. Department of Health and Human Services monitor, track quality improvements on six key areas – safety, effectiveness, responsiveness to patients, timeliness, efficiency and equity – and report to Congress annually respecting progress made on these fronts.

The Agency of Healthcare Research and Quality (AHRQ), established in response to the first IOM report *To Err is Human*, continues to put IOM recommendations into action by setting the research agenda and funding initiatives in areas such as the use of computers and information technology to prevent adverse events.

**Canada – *Patient Safety and Healthcare Error in the Canadian Healthcare System. A Systematic Review and Analysis of Leading Practices in Canada with Reference to Key Initiatives Elsewhere* (Baker & Norton for Health Canada, 2002)**

This annotated review examined key initiatives, studies, and research papers from the United States, Australia, and the United Kingdom, among others. The review includes international efforts, epidemiological evidence, identification of adverse events, strategies to reduce incidence, and an in-depth examination of the ethical-legal issues around patient safety strategies. Major policy papers, professional education, and lessons from other industries round out the review.

Also included in this paper are the results of telephone and mail surveys carried out with individuals currently working on patient safety initiatives in Canada. Although the response rate was fairly low (only 48, or 33% completed the survey), the authors were able to obtain almost even representation from colleges/associations, and health care facilities. Both telephone and mail surveys captured complementary findings. For example, both identified that historical surveillance systems were not functioning well or were not present in many cases. Also, a strong need for leadership, a coordinated and systematic process to collect information, and education among health care professionals was recognized. Major barriers to progress included limitations on human and financial resources, and fear of litigation or negative repercussions in identifying adverse events.

Based on the literature review and survey results, the authors presented an analysis of the gaps between current patient safety practices in Canadian organizations and programs, and leading work elsewhere. From this analysis, 15 recommendations in the following key areas were developed:

- Build awareness and set priorities to improve patient safety in Canada.
- Develop better reporting systems.
- Build skills, disseminate knowledge and implement systems to improve safety.
- Create organizational and policy level supports for patient safety efforts.

## **2.3 CANADIAN CORONERS' INQUESTS**

Although there have been a number of inquests in which systemic issues have figured prominently, two recent ones are particularly instructive: the Sinclair Commission in Manitoba, and the Fleuelling Inquest in Ontario.

### ***Manitoba - Pediatric Cardiac Surgery Inquest (Sinclair Commission, November, 2000)***

Led by Associate Chief Justice Sinclair, this inquiry involved the deaths of twelve children while undergoing, or shortly after having undergone cardiac surgery at the Winnipeg Health Sciences Centre.

Justice Sinclair found that the Pediatric Cardiac Surgery Program did not provide the standard of care that it was mandated to provide - at least five of the deaths were preventable. Moreover, he found that the program continually undertook cases that were beyond the skill and experience of the surgeon and the team. This was seen to be a direct result of the lines of authority, staffing and case selection.

In his report, Justice Sinclair concluded that there was a failure of quality assurance and monitoring and that nurses were not provided opportunities to voice serious and legitimate concerns because they were never treated as full and equal members of the surgical team. He recommended changes to existing internal and external review and monitoring practices, and the development of ongoing policies of team building, risk management, and quality assurance, among other organizational issues.

### ***Ontario - Joshua Fleuelling Inquest (October 2000)***

This inquest involved the death of an asthmatic teenage boy. At issue in the inquest was the overcrowding of Emergency Departments in hospitals and the resulting use of Critical Care Bypass (CCB).

In reviewing the case, the jury issued a critical assessment of the condition of the health system, stating that the problems encountered were "systemic in nature and are not easily solved". They further concluded that these problems have developed over a period of time and had now reached critical proportions.

The jury made forty-six recommendations to some 16 stakeholders involved in the delivery of care, one of which was the recommendation that the Ministry of Health and Long Term Care and other relevant stakeholders continue to address the overcrowding problem of Emergency Departments in a cooperative and collaborative approach.

### **3.0 THE SYSTEMIC ISSUES: WHAT EVERY STAKEHOLDER NEEDS TO KNOW**

The studies and reports described above document incidence rates and underscore the clinical and financial impact of adverse events. They are also instructive in terms of identifying systemic issues that need to be addressed.

In reviewing these studies, it becomes abundantly clear that there are a number of significant systemic barriers to managing adverse events and enhancing patient safety. Collectively, the authors identify a number of challenges to the health system that can be categorized under four key themes: a punitive culture of blame that drives the issue underground; a failure to adopt a “systems approach” that would enable us to learn more effectively from adverse incidents; antiquated and uncoordinated reporting mechanisms; and a need for committed leadership to move this issue forward.

#### **3.1 CULTURAL BARRIERS: GETTING BEYOND BLAME**

One of the more insidious features of adverse events is the culture of non-disclosure. Many health service providers are wary of disclosing any error because of potential legal liability/insurance ramifications. Moreover, in many instances, they are discouraged from being candid about anything adverse that may have occurred – regardless of whether the mishap was unrelated to professional competence. However, without disclosure and examination of the event, no remedial action can be taken to ensure that in the future similar occurrences are avoided.

As was observed by the Australian Council on Quality and Safety, assigning blame is inherently counterproductive to enhancing safety. Because the vast majority of health service providers already assume a high level of personal and professional responsibility for their patients, assigning blame will only evoke a defensive reaction and lead to a “wall of silence” and cover-up of mistakes. (Australian Council Report, p. 3)

The British NHS similarly concluded that blame is an inappropriate response to adverse events in today’s complex environment:

When things go wrong, whether in health care or in another environment, the response has often been an attempt to identify an individual or individuals who must carry the blame... Yet in the great majority of cases, the causes of serious failure stretch far beyond the actions of the individuals immediately involved. Safety is a dynamic, not a static

situation. In a socially and technically complex field such as health care, a huge number of factors are at work at any one time which influence the likelihood of failure. (NHS Report, ix)

The authors go on to explain that these factors are a combination of failures – unsafe acts committed by those working at the “sharp” end of a system (i.e., health service professionals in giving care) which are usually short-lived and often unpredictable; and errors at the “blunt end” (i.e., at the administrative/system level) attributable to latent conditions that can develop over time and lie dormant before combining with other factors or active failures to breach a system’s safety defenses. In short, the former are largely a product of human error; the latter however are errors resulting from poor design, faulty maintenance, bad management decisions, and poorly structured organizations -- errors that can be identified and remedied before they cause an adverse event.

The crucial first step in managing and reducing adverse events then must be to reframe the events; to remove the stigma of error and the culture of “judgment and blame” and replace it with one of “learning for quality improvement”. Blame cultures can encourage people to cover up errors for fear of retribution and act against the identification of the true cause of failure, because they focus heavily on individual actions and largely ignore the role of underlying systems. Learning or “safety” cultures on the other hand recognize that errors and failures in our systems will inevitably occur everyday, but similarly appreciate that they need to be anticipated and managed in order to provide an environment that encourages free and frank discussions of areas where improvements can be made. (Australian Council Report, p. 3)

*Challenge #1:* In the interests of promoting safety, the health system needs to replace the prevailing culture of blame with a safety culture that encourages openness and objective analysis of adverse events.

### **3.2 A SYSTEMS APPROACH – THE *BEST* WAY TO LEARN FROM ADVERSE EVENTS**

In other high-risk sectors where error is often attributable to long sequence of events, the practice is to examine error from a systems approach. Those who have studied patient safety and quality care believe that the health sector must take a similar approach.

Why adopt a systems approach? Quite simply, because of the complexity of modern day medicine, most adverse events are system-related. Thus, while human error may sometimes be the factor which immediately precipitates an adverse event, there are usually deeper, systemic factors at work which if addressed would have prevented the event or acted as a safety-net to mitigate its consequences. Indeed Leape et al. (1991)

Patient Safety and Quality Care:  
Action Required Now to Address Adverse Events  
*A Backgrounder*

concluded that “a large part of the reason preventable adverse events occur is that today’s medical care is extremely complex, involving a variety of personnel, equipment, and procedures.” In short then, most adverse events occur as a result of a sequence of failures in the complex processes of care.

To date the health sector has done little to recognize this fact and adapt its quality improvement practices accordingly. As Michael Cohen, President of ISMP in the United States observes, “unlike industr[ies] which scrutinize system for error potential, the health care community often waits for accidents to occur before taking appropriate preventative action.” (Institute for Healthcare Improvement, 1998) It would appear that the health sector as a high risk, high reliability industry has much to learn from other sectors in respect of a quality or “systems” approach to safety.

What are the key elements of the systems approach used in other high-risk sectors?

- Business is planned and managed recognizing that errors and failures in production lines are an everyday occurrence.
- Defensive practices are changed into activities that promote learning to do better.
- Capacity is developed to collect and analyze data for patterns of underlying cause of mistakes.
- There is recognition of the need to standardize processes while understanding the importance of flexibility. (Australian report, p. 3)

From a practical standpoint, a systems approach necessitates that information collected is used as a learning resource; that there is a single focal point for information on adverse events; that there is follow-up on recommendations made, including implementation of necessary changes identified in a particular report or inquest; and the appropriate I.T. infrastructure is in place to share information and to analyze system error.

The overwhelming benefit of the “systems approach” then, is the extent to which learning takes place – going beyond simply diagnosing and publicizing the lessons from incidents to ensuring that these lessons are embedded in new policies and practices.

*Challenge #2:* The health sector needs to adopt a systems approach to ensuring safety and quality – to develop ways of proactively analyzing and addressing both mistakes and “near misses”.

### **3.3 REPORTING ADVERSE EVENTS: THE NEED FOR AN EVIDENCE-BASED APPROACH**

One of the most crucial prerequisites for positive change is in the area of reporting practices. As we suggested earlier, a positive organizational culture is vitally important to facilitating transparent reporting practices. However, at a very fundamental level, there needs to be a solid reporting infrastructure. As the authors of the British NHS report observed, the absence of a solid reporting framework represents a fundamental obstacle to learning from adverse events:

Reporting systems are vital in providing a core of sound, representative information on which to base analysis and recommendations. Experience in other sectors demonstrates the value of systematic approaches in recording and reporting adverse events and the merits of quarrying information on the ‘near misses’ as well as events which actually result in harm. (NHS Report, ix)

One of the threshold issues in creating this infrastructure is the matter of defining adverse events. If there is not one accepted standard definition of an adverse event, how can we know what the data mean? (Presuming for a moment that we are able to collect comparable data.) The key then, is to ensure that all health system stakeholders across Canada are working with the same definition of an adverse event and that characterizations of adverse events are consistent across the board.

The second barrier to reporting is the lack of regulatory requirements. In other jurisdictions, the issue has been identified as a significant problem. Without national standards, the matter will remain underground – as the saying goes, you can’t measure what you don’t report. Ensuring that standards are established and that these standards are consistent ones across the country will go a long way in ensuring that we have the data we need to appropriately analyze adverse events and improve patient safety.

Finally, the third challenge on the reporting front is the absence of any oversight authority. While standards are vitally important, they need to be monitored to ensure compliance. At a minimum, this agency could assume the role of a central clearinghouse for data on adverse events. But more importantly, it would ensure that adverse events are consistently reported, analyzed and learned from.

*Challenge #3:* The health system needs to embrace the development and implementation of comprehensive reporting standards and enforcement mechanisms related to adverse events.

### **3.4 GOVERNANCE & LEADERSHIP: FILLING THE VOID**

Are we ready to change or will we procrastinate and dissemble...It may seem to some that the race for patient safety has just begun, but the patience of the public we serve is already wearing thin. They are asking us to promise something reasonable, but more than we have ever promised before: that they will not be harmed by the care that is supposed to help them. (Leape & Berwick 2000, *BMJ* 2000, p. 726)

While the need for a change in organizational culture, the adoption of a systems approach and a better framework for reporting are fundamental to achieving change, perhaps the most overriding need is for leadership.

As discussed earlier, the issue is complex, involving all stakeholders within the health system. While we are all working to improve our performance respecting patient safety and quality care, independent actions by stakeholders are not sufficient. To achieve the desired level of systemic change, there must be cooperation and collaboration.

What is necessary now is a collaborative approach among health service providers, health system managers and trustees, governments and the public. Collaboration also requires coordination, yet at present there is no discernable “lead” organization(s) identified to ensure that the steps necessary to change practices are being taken.

Leadership will ultimately give not only coherence to strategies to reduce adverse events, but may also provide the needed advocacy efforts to address the resource issues – i.e., the research and I.T. infrastructure needed to comprehensively examine patient safety. Moreover, leadership will ensure that accountability rests not only with individual stakeholders and organizations, but is manifested in a very concrete way at the provincial, territorial and national level.

*Challenge #4:* Health service providers, managers and trustees, governments and the public must mount a consolidated effort to ensure that there is a coordinated and effective response to adverse events in Canada.

## **4.0 The Context for Action: Who's Doing What Now**

In the previous section we outlined some of the common systemic challenges posed by adverse events. In this section, we identify current Canadian initiatives. To carve out a purposeful role in the area of patient safety and quality care for the CHA and our member organizations, it is important to first understand the roles and responsibilities of key stakeholders that have assumed a leadership position on the issue.

### ***4.1 National Initiatives***

**The Royal College of Physicians and Surgeons of Canada** hosted a *Roundtable on Patient Safety and Error in Medicine* in September 2001. At this meeting there were 55 participants, including governments (federal and provincial/territorial), health organizations, providers, research organizations and other stakeholders.

A national Steering Committee of nine was formed to develop an integrated national strategy for patient safety. The final objective was the development of a publicly supported and adequately funded multi-stakeholder collaborative network to deal effectively with patient safety issues, and to coordinate interventions and reporting on these issues in Canada. The Steering Committee developed and proposed a framework for a Canadian solution. This included consulting widely to develop specific goals and objectives, a detailed action plan, timeframe and estimated resource requirements (financial and human). Activities were divided into the following 5 distinct working groups:

1. Measurement/Evaluation (how to measure scope and impact)
2. System Issues (improving health system design to reduce human error)
3. Regulatory Issues (regulation and monitoring of individuals and institutions)
4. Education/Professional Development (education to reduce adverse events)
5. Information/Communication (communication between stakeholders and jurisdictions)

An interim update released in April, 2002 included a number of recommendations from the Work Groups and identified several likely barriers to the advancement of the patient safety agenda for all communities involved in its promotion. Next the Steering Committee consolidated the findings from the working groups by distilling recommendations, identifying themes and variables, and also pointing to gaps that may need to be addressed. The Steering Committee gathered more information about

Patient Safety and Quality Care:  
Action Required Now to Address Adverse Events  
*A Backgrounder*

governance, especially in the area of lessons learned, and explored funding options to develop models for the considerable financial support that is needed in order to move forward a Canadian solution to address patient safety. The final proposal was completed and released publicly in September 2002.

**The Canadian Institute for Health Information (CIHI) and the Canadian Institutes for Health Research (CIHR)** are jointly sponsoring an initiative to fund peer-reviewed research to obtain Canadian data on adverse events. The scope of this CIHI-CIHR study, “Adverse Events in Canadian Hospitals” is to determine 1) the extent of adverse events (avoidable and otherwise) in Canadian hospitals, and 2) the availability of routinely collected data that could serve to monitor and reduce adverse events. Teaching, community, and rural hospitals will be selected from study centres in British Columbia, Alberta, Ontario, Quebec, and Nova Scotia. Findings from the study will also provide comparative information between the three types of hospitals and between medical and surgical cases. As part of this initiative, a high-level stakeholder group has been formed to facilitate consultation on the research and dissemination of the findings to those who will be most affected. A final report is expected to be released to the public in 2004. In addition to the CIHI/CIHR study, databases of health information are available from CIHI that may be useful for conducting further research on patient safety and quality care.

**Health Canada** is also involved in the issue of patient safety and quality care. The Health Policy and Communications Branch commissioned a literature review on patient safety and quality care initiatives (see summary in section 2.2 Government Reports). The report entitled “*Patient Safety and Healthcare Error in the Canadian Healthcare System. A Systematic Review and Analysis of Leading Practices in Canada with Reference to Key Initiatives Elsewhere*” included a review of national and international initiatives, major research papers, and results from surveys of individuals working on patient safety in Canada. Based on these findings, the authors identified areas where patient safety strategies could advance and suggested areas for action.

The Therapeutic Products Directorate of Health Canada is coordinating the Canadian Coalition on Medication Incident Reporting and Prevention. This Coalition was established to develop a business plan for a comprehensive, viable, sustainable, and affordable medication incident reporting and prevention system for Canadians. The purpose of the proposed *Canadian Medication Incident Reporting and Prevention System* (CMIRPS) is to:

- ◆ Coordinate the capture, analysis and dissemination of information on medication incidents;
- ◆ Enhance the safety of the medication use system for Canadians; and
- ◆ Support the effective use of resources through the reduction of potential or actual harm caused by preventable medication incidents.

Patient Safety and Quality Care:  
Action Required Now to Address Adverse Events  
*A Backgrounder*

A report is now available from the Coalition, and next steps include focusing on outstanding issues (e.g., legal review, evaluation needs, privacy impact assessment, and funding options) to ensure the future development and successful implementation of the system. The Therapeutic Products Directorate is also responsible for post-market surveillance of drugs and medical devices. Monitoring potential threats to patient safety and notifying health providers and health organizations of such threats is part of this mandate.

The Policy Division in the Policy, Planning and Priorities Directorate is studying health system injury (not error, per se). This will include exploring the antecedents of injuries in the health system. The goal of this study is to identify incentives for developing “learning organizations” (i.e., organizations that learn from their mistakes and take corrective action on their own, not as a result of external forces to do so, such as regulation).

**The Institute for Safe Medication Practices (ISMP) Canada** has played a leading role in addressing patient safety. Working with the Ontario Ministry of Health and Long Term Care and the Ontario Hospital Association, ISMP Canada will put in place Canada’s first Safe Medication Support Service, which will provide advice and support at both a distance and on-site at Ontario’s hospitals. Using the Internet and telephone, ISMP Canada will alert hospitals to potential medication errors and help to ensure that safe drug management processes are in place.

In partnership with ISMP in the United States, ISMP Canada is developing a new software program (“*Analyze-ERR*”) that tracks medication errors and near misses for hospitals, as well as facilitating ‘root-cause’ analysis of these errors. This software provides two separate databases – the first collects objective facts about errors and potential errors; the second suggests contributing possible causes of the reported errors. After the data are entered into the system, the information on possible causes is no longer linked with any specific error in the first database. Reports generated by the software identify areas for system improvement in the organization using it.

ISMP Canada is also testing *The Medication Safety Self-Assessment Program for Hospitals* in 35 Ontario hospitals. Already used successfully in the United States, this self-assessment tool allows hospitals to enter data on-line that subsequently can be analyzed to identify areas for system improvement initiatives and projects. The scoring of the hospital’s self-assessment reflects a level of safety of medication use, and more importantly, can serve as an ongoing health care quality indicator.

ISMP Canada also offers a subscription service to the *Medication Safety Alert! Newsletter*, which consists of two parts: the original ISMP US newsletter and a special alert bulletin supplement by ISMP Canada. Much of the information in the newsletters comes from the error reports received from ISMP US and ISMP Canada. The newsletters

can be used by senior managers, risk managers, pharmacists, and other providers, usually in acute care facilities.

**The Canadian Council on Health Services Accreditation (CCHSA)** has an ongoing interest in patient safety as it relates to quality of health services. CCHSA is committed to moving patient safety forward by building on the existing accreditation program. Improved standards and criteria, references to specific guidelines generated by others and a comprehensive survey process will allow teams in organizations to better detect, prevent, learn and continually improve from patient safety issues.

Complementing the standards work are some key projects on patient safety that include:

- ◆ participating in the Royal College of Physicians and Surgeons of Canada's national strategy for patient safety project;
- ◆ establishing a database based on accreditation survey results that tracks all indicator use by organizations; and,
- ◆ conducting a retrospective study to assess the quality of patient safety indicators used by organizations.

CCHSA is watching closely all patient safety developments to ensure the accreditation program effectively responds and contributes to improving the provision of quality services and care.

#### ***4.2 Provincial/Territorial Initiatives***

Provincial and territorial **Ministries of Health** have an important role to play. For example, in March 2001 a Ministerial Committee of the Quebec Ministry of Health and Social Services released a comprehensive report examining the issue entitled "*La gestion des risques, une priorité pour le réseau*". In its report the Committee identified 14 key recommendations relating to a broad range of issues. Some of these recommendations proposed that:

- Institutions ... boards of directors ... and regional boards be responsible for ensuring the safety of the services offered.
- All institutions to include in their organizational plans ... a multidisciplinary risk management device specifically designed to reduce the occurrence of preventable accidents related to the delivery of services.
- A permanent risk management support committee be created, based on a very close partnership with the regional boards, institutions, professional Orders, universities, insurers, associations of clinicians and biomedical engineers, coroner and user representatives, among others.

Patient Safety and Quality Care:  
Action Required Now to Address Adverse Events  
*A Backgrounder*

- It be an obligation for any institution to adopt a regulation on the duty to divulge to patients and families all pertinent information in case of accident, and that this regulation contain appropriate support measures [for] victims or their families.
- All data gathered ... be sent to the data banks currently managed by the Régie de l'assurance maladie du Québec.
- The Minister create a working group with the mandate to examine the pertinence of setting up a compensation plan not based on liability, to study the feasibility of such a reform, to determine how the new plan would work and to estimate its cost.

An action plan entitled “*Plan d'action ministériel: Comité sur les accidents évitables dans la prestation de soins de santé mise en application des propositions du rapport ministériel*” was released by the Ministerial Committee in January 2002, outlining how these recommendations will be implemented, and providing a status report on work undertaken to date.

Also, various commissions and inquests established by provincial and territorial governments have made recommendations for quality initiatives. For example, in Manitoba, a Review and Implementation Advisory Committee was established to assess the recommendations of the Sinclair Commission report and to identify future actions that should be taken to address the recommendations. In the *Report of the Review and Implementation Committee for the Report of the Manitoba Pediatric Cardiac Surgery Inquest* (2001), the Committee addressed a broad range of issues, including recommendations that:

- Each Program Management division develop an “accountability map” which designates responsibilities and traces the lines of reporting back to the Chief Operating Officer of HSC [Health Sciences Centre].
- The HSC evaluate the performance of its program teams to ensure that they are functioning on the basis of shared leadership and the full utilization of the disciplinary expertise of all members.
- A number of strategies be used in the recruitment and selection process to determine the willingness and demonstrated capacity of physicians and surgeons to work in a team context.
- Stronger risk management strategies and better information on different types of risk be developed.
- HSC and other hospitals in Manitoba develop policies on internal disclosure as part of a broader strategy to promote cultures and climates of openness and

creative-problem solving in which individuals can raise legitimate and reasonably based concerns without fear of reprisal.

This is only a sample of 50 recommendations included in the Committee's report. For the full recommendations, please consult the *Report of the Review and Implementation Committee for the Report of the Manitoba Pediatric Cardiac Surgery Inquest* (2001).

The Saskatchewan Commission on Medicare (i.e., the Fyke Commission) recommended the establishment of a Quality Council for Saskatchewan. Part of the mandate of this proposed Quality Council would include reporting on adverse events, making recommendations and supporting initiatives to prevent and/or reduce its impact.

**Professional bodies** across the country also play a substantial role in managing adverse events. As the organizations responsible for identifying professional misconduct, many have launched quality assurance programs. Some professional organizations have also held conferences and developed programs to educate their members about patient safety and quality care. And, several professional colleges have established statements and guidelines (or recommendations) regarding patient safety. Also at the provincial and territorial level, there are a number of organizations and **networks** focussed on quality issues.

### ***4.3 Organizational Initiatives***

More and more health facilities and agencies are identifying and addressing system issues related to patient safety and quality care, including developing specific policies and procedures, changing organizational culture to focus on non-punitive reporting, educating Boards and staff, and implementing specific changes to day-to-day operations.

.....

It is clear from the summaries above that there are a number of groups and organizations that are interested or engaged in monitoring and preventing adverse events in Canada. The challenge will be to coordinate these initiatives to ensure that the strategies needed to monitor and address adverse events are developed and implemented across the country. These strategies are discussed in more detail in the next section.

## 5.0 Specific Strategies For Improvement: What We Can Do Now

Addressing all of the system issues related to patient safety and quality care is clearly a long-term goal that will not be achieved overnight. While this goal is certainly laudable, we need to ask: “What we can do *now* to effect change?” **Well, the experts tell us that there are a number of strategies that will move us toward improved patient safety.** Broadly speaking, the health system will need to develop the appropriate culture and processes to support the reporting of adverse events in health organizations across the country, establish national standards for reporting adverse events, undertake more education and research, and make better use of information technology.

Some specific actions at the organizational, provincial/territorial and national levels that could contribute to these ends are outlined below.

### 5.1 Organizational Initiatives

#### 1) *Foster a culture of safety.*

- Adopt existing patient safety reporting guidelines or policies.
- Develop the necessary policies and processes to support the reporting and prevention of adverse events and near misses (e.g., establish committees or working groups to make recommendations, dedicate resources, etc.).

#### 2) *Enhance current surveillance practices.*

- Examine current surveillance practices in health organizations and the degree of compliance with existing federal and provincial/territorial regulatory requirements.

#### 3) *Investigate more “proactive” approaches to improving patient safety.*

- Explore information technology capabilities such as computer safeguard features for physician order entry that reduce incidence of adverse events.
- Examine purchasing arrangements for products designed to prevent adverse events (e.g., a drug bottle could be purposefully designed to look different or fit differently into dispensing tools such as syringes so as to reduce the risk of accidentally using it inappropriately).
- Encourage “safety walk-about”, whereby designated teams within or external to the organization tour the facility to identify conditions that could result in adverse events.

Patient Safety and Quality Care:  
Action Required Now to Address Adverse Events  
*A Backgrounder*

- Develop operational policies to prevent adverse events (e.g., a policy could stipulate that the undiluted form of drug X is never allowed on the pediatric ward).
- 4) *Examine organizational procedures and legal issues around reporting adverse events.*
- Educate staff and management regarding the appropriate means to inform a patient and/or the family that an adverse event has occurred.
  - With Canadian professional colleges, explore legal issues including the implications of health organizations NOT reporting an adverse event, and the feasibility of no-fault insurance. The colleges will need to address these issues at a national level (see #17, below).
- 5) *Consider innovative pilot studies respecting patient safety management techniques within the organization.*
- Pilot test innovative new regional and national reporting systems.
  - Evaluate the linkage of discovered adverse events to improvement efforts.
  - Assess the effectiveness of such efforts. This will also need to take place at the provincial/territorial level (see #11 below).
- 6) *Facilitate the development and implementation of information technology tools for patient safety.*
- Support existing and developing national and provincial Adverse Drug Event (ADE) reporting systems.
  - Work to incorporate IT tools to track and/or reduce likelihood of adverse events, such as the Computerized Physician Order Entry (CPOE) software and the Institute for Safe Medication Practice's "Analyze-ERR" software program.

## **5.2 Provincial/Territorial Initiatives**

- 7) *Convene Provincial and Territorial stakeholders to develop a patient safety agenda.*
- Recognize and integrate the work of existing provincial/territorial organizations or networks dedicated to quality and safety.
  - Where there are no existing organizations or networks, establish provincial/territorial group(s) to make recommendations on quality and safety, to coordinate provincial/territorial initiatives, and to act as a resource for patient safety programs and tools relevant to Canadian health care organizations. This will also need to take place at a national level (see #14 below).

Patient Safety and Quality Care:  
Action Required Now to Address Adverse Events  
*A Backgrounder*

- 8) *Establish performance targets for the reduction of adverse events.*
- Identify high priority patient safety issues and performance targets for each province/territory. Examples of priority issues could include falls prevention, data systems and workforce concerns in safety.
  - Convene provincial/territorial expert panels to share ideas and develop an action plan to meet these targets. This will also need to take place at the national level (see #14 below).
- 9) *Work toward a national registry and oversight mechanisms.*
- Lobby provincial/territorial governments for the creation of a national registry and appropriate provincial, territorial and national oversight mechanisms. This will also need to take place at the national level (see #16 below).
- 10) *Educate provincial/territorial stakeholders and the public to increase awareness and understanding of patient safety.*
- Educate the public regarding the reality of adverse events within the context of safety and quality, and within the context of explaining their rights and processes that are available to them.
  - Convene regional meetings for senior leaders in health care and other stakeholders. The meetings should build greater awareness and disseminate expert knowledge about patient safety, effective tools and approaches used in Canada and elsewhere, and the roles of leaders in creating organizational cultures that support patient safety. This will also need to take place at the national level (see #18 below).
- 11) *Develop systems and processes to enhance and integrate standardized reporting in the province/territory.*
- Pilot test innovative new regional and national reporting systems.
  - Evaluate the linkage of discovered adverse events to improvement efforts.
  - Assess the effectiveness of such efforts.
  - Support the development of carefully evaluated demonstration projects in idealized design, system change and patient safety in Canada.
- 12) *Address consistency and interoperability issues among reporting tools.*
- Work with other provincial/territorial governments and the federal government to address consistency and interoperability issues of adverse events data and reporting tools.
- 13) *Encourage the integration of adverse event reporting with other provincial/territorial reporting mechanisms, such as accountability mechanisms.*
- Patient safety programs and initiatives should be integrated into the Canadian Council on Health Services Accreditation standards and other health care accreditation standards. This will also need to take place at the national level (see #16 below).

### **5.3 National Initiatives**

*14) Convene stakeholders to develop a national framework and action plan.*

- Collaborate with stakeholder and professional organizations from each Province and Territory to develop a national framework and action plan to address patient safety. This could include developing a common definition of adverse events and targets for reducing its incidence.
- Work with provincial/territorial networks to share ideas and develop an action plan to meet performance targets for the reduction of adverse events.

*15) Support research regarding the extent of adverse events in Canada and data requirements for monitoring.*

- Encourage safety research and system change as a cross cutting theme at the Canadian Institutes of Health Research and in work at the Canadian Foundation for Health Services Research.

*16) Participate in the development of consensus around national safety standards.*

- Integrate patient safety programs and initiatives into the Canadian Council on Health Services Accreditation standards and other health care accreditation standards.
- Lobby the federal government for the creation of a national registry and appropriate provincial, territorial and national oversight mechanisms. This will include the development of national standards for reporting. Legislation change could enhance reporting of adverse events and near-misses and should be encouraged and supported.

*17) Encourage Canadian professional colleges and organizations to be active in the areas of disclosure policy and legislation.*

- Lobby for appropriate legislation to enable professional colleges to expand their efforts. Legislation change could enhance reporting of adverse events and near-misses and should be encouraged and supported.
- Encourage national provider organizations, such as CNA and CMA, to revise their codes of ethics to include the need to inform patients of adverse events (not simply telling if asked).

*18) Educate stakeholders, including the public, to increase awareness and understanding of patient safety.*

- Through a national conference, monitor and disseminate new developments and strategies, best practices, and ideal designs that improve patient safety.

## ***CONCLUSION***

To say that changing how we manage patient safety is a critical quality issue for stakeholders in the health system today is an understatement. Arguably, few other issues are as visceral or tangible as adverse events are to the public.

It is equally trite to say that the task will be a challenging one. Addressing patient safety and quality care in a systemic way requires an appreciation for the complexity of the issue, a commitment to leadership, the investment of significant resources, and vigilance on the part of all stakeholders to ensure that the necessary changes are made. Moreover, timing is an added pressure.

The Canadian Healthcare Association (CHA) and its provincial and territorial member organizations have a unique opportunity to play a leadership role in changing the status quo. Through commitment, cooperation, and collaboration with other stakeholders, the CHA and its provincial and territorial members can have a profound impact on how the Canadian health system manages adverse events in the 21<sup>st</sup> century.

.....

## ***REFERENCE LIST***

- Australian Council for Safety and Quality in Health Care, *Safety First: Report to the Australian Health Ministers' Conference*, July 2000.
- Baker, G. R., & Norton, P. *Patient Safety and Healthcare Error in the Canadian Healthcare System. A Systematic Review and Analysis of Leading Practices in Canada with Reference to Key Initiatives Elsewhere*. Ottawa: Health Canada, 2002.
- Baker, G. R., & Norton, P. (2001) "Making Patients Safer! Reducing Error in Canadian Healthcare", *Healthcare Papers* 2(1), 10-31.
- Brennan, T.A., et al., (1991) "Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study", *New England Journal of Medicine*, 324(6), 370-76.
- Chief Coroner, Province of Ontario. *Inquest Touching the Death of Joshua Fluelling: Jury Verdict and Recommendations*. Toronto: Office of the Chief Coroner, 2000.
- Committee on the Quality of Health Care in America, *Crossing the Quality Chasm: A New Health System for the 21<sup>st</sup> Century*. Washington: National Academy Press, 2001.
- Cull, H., *Review of Processes Concerning Adverse Medical Events*. Wellington: New Zealand Ministry of Health, 2001.
- Hébert, P., et al., (2001) "Bioethics for clinicians: 23. Disclosure of Medical Error", *Canadian Medical Association Journal*, 164(4), 509-513.
- Kohn, L.T., et al., *To Err is Human: Building a Safer Health System*. Washington: National Academy Press, 1999.
- Lazarou, J. and B.H. Pomeranz, (1998) "Incidence of Adverse Drug Reactions in Hospitalized Patients", *Journal of American Medical Association*, 15, 1200-1205.
- Leape, L.L., & Berwick, D.M. (2000). "Safe Health Care: Are We Up to It?". *British Medical Journal*, 320, 725-726.
- Leape, L.L. et al., (1991) "The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II", *New England Journal of Medicine*, 324(6), 377-384.

Patient Safety and Quality Care:  
Action Required Now to Address Adverse Events  
*A Backgrounder*

Quebec Ministry of Health and Social Services, *La gestion des risques, une priorité pour le réseau. Rapport du comité ministériel*. Québec: Gouvernement du Québec, 2001.

Quebec Ministry of Health and Social Services, *Plan d'action ministériel: Comité sur les accidents évitables dans la prestation de soins de santé mise en application des propositions du rapport ministériel*. Québec: Gouvernement du Québec, 2001.

Review and Implementation Committee for the Report of the Manitoba Pediatric Cardiac Surgery Inquest, *Report of the Review and Implementation Committee for the Report of the Manitoba Pediatric Cardiac Surgery Inquest*. [On-line] May, 2001. Available: <http://www.gov.mb.ca/health/cardiac.html>.

Saskatchewan Commission on Medicare (Commissioner Kenneth J. Fyke), *Caring for Medicare: Sustaining a Quality Health System*. April, 2001

Sinclair, M., *Report of the Manitoba Pediatric Cardiac Surgery Inquest: An Inquiry Into Twelve Deaths at the Winnipeg Sciences Centre in 1994*. Winnipeg: Provincial Court of Manitoba, 2000.

The CQI Network and ISMP Canada, *Breaking the Silence: Error in Healthcare*, Conference Proceedings, April 20-21, 2001, Toronto.

The CQI Network, *Safety & The System: Is Anybody Paying Attention?*, Conference Proceedings, October 23-25, 2001, Huntsville.

Thomas, E.J., Studdert, D.M., et al. (2000). "Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado". *Medical Care*, 38 (3), 261-71.

U.K. Department of Health, *An Organisation with a Memory. Report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer*. London: The Stationary Office, 2000.

U.K. Department of Health, *Building a Safer NHS for Patients: Implementing an Organisation with a Memory*. London: Department of Health, 2001.

Vincent, C., Neale, G., et al. (2001). "Adverse Events in British Hospitals: Preliminary Retrospective Record Review". *British Medical Journal*, 322 (7285): 517-519.

Wilson, R. M. et al., (1995) "The Quality in Australian Health Care Study", *The Medical Journal of Australia* 163(6), 458-476.