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

---

A Report to Health Canada

By
G. Ross Baker & Peter Norton

1. The views expressed in this report are those of the authors and do not necessarily represent those of Health Canada.
2. The surveys conducted in this report are pilots and the sample sizes are small.
3. This report is 160 pages long. It is divided into Chapters as follows for ease of printing.

Table of Contents

Executive Summary

Patient safety has become an important healthcare issue in Australia, the United States and the United Kingdom. There is limited knowledge about the incidence of adverse events and healthcare error in Canadian healthcare, and little knowledge about current initiatives to improve patient safety. This report addresses these issues through three major components. First, we provide a literature review that examines published materials on patient safety in the health care system, both generally and in Canada. Second, we report the results of telephone and mail surveys that we carried out with individuals currently working on patient safety efforts in Canada. Third, based on these materials, we present an analysis of the gaps between current patient safety practices of the Canadian organizations, programs and individuals, and leading work elsewhere.

The definitions of the terms used in the area of patient safety are not yet standardized. We have included the definitions that are used in this report in Appendix F.

The literature review is extensive and annotated with particular attention paid to the Canadian literature. We also include a specific examination of the medical-legal literature that discusses relevant issues in patient safety and liability such as the privileging of healthcare information.

The survey and interview instruments were designed to identify key activities in patient safety in Canada. They captured both qualitative and quantitative data from organizations that deliver care, professional organizations, and those involved with policy in this area. The two methods, mailed questionnaires and telephone interviews, produced consistent and complementary findings that give a picture of the present efforts and challenges in patient safety in Canada. These findings include:

- There are pleas for leadership at local, regional and national levels.
- The current limitations on human and financial resources addressed to patient safety concerns appear to be a major barrier to progress.
- Fear of litigation is an important issue in many organizations but is less dominant than might be expected from anecdotal information.
- Punishment, fear and possible professional censure are major barriers to identifying and investigating adverse events at the local level.
- There are few coordinated and systematic processes to collect information on adverse events and errors in Canadian healthcare organizations.
- There is little information available about programs and techniques to enhance patient safety in Canadian healthcare organizations.
- Some see improved computerized information services as an important improvement, but costs for such services are viewed as prohibitive.

- Large numbers of organizations reported that historical surveillance systems – death reviews, incident analysis, etc. – were not functioning well or were not present at all.
- Relatively few Canadian organizations are improving existing efforts or adopting new interventions to improve safety in Canadian healthcare organizations.
- Almost 50% of health care delivery organizations felt that they could not effectively enhance patient safety.
- Respondents identified the need for formal training in specific tools like Root Cause Analysis.
- Respondents identified the need to develop systems to allow regional and national sharing of changes made to improve safety.
- There was an identified need for education among health care professionals concerning patient safety issues.
- Respondents stated that we need to "go up stream", focusing on systems and the prevention of error.

There are substantive patient safety activities currently underway in Canada including:

- The recently funded CIHI/CIHR study "Improving the Quality of Health Care in Canadian Hospitals" that will establish a Canadian acute care error rate.
- The founding of the National Steering Committee on Patient Safety (NSCPS).
- The cross Canada interest in patient safety.
- Important local initiatives.

Based on this work and from the results of the surveys, the literature, and the authors own experience and expertise, the following series of recommendations are made. These recommendations will provide guidance for future directions useful to those interested in patient safety and will serve to accelerate the work in this area.

The recommendations are:

<u>Build awareness and set priorities to improve patient safety in Canada</u>

1. Governments and other stakeholders should convene an expert committee representing clinical disciplines and management with knowledge of patient safety systems, tools and other resources. This committee would develop an agenda for addressing patient safety issues in Canadian healthcare, including a list of approaches to and sources for methods and tools for patient safety relevant to Canadian health care organizations. This list would be of interest to provincial ministries of

health, regional authorities, healthcare organizations and accrediting agencies.

2. An invitational meeting should be convened for senior leaders in healthcare. The meeting, conducted with input from the Federal/Provincial/Territorial Conference of Ministers of Health and linked with activities of the National Steering Committee on Patient Safety, should build greater awareness and disseminate 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.

Develop better reporting systems

3. New regional and national reporting systems and mechanisms should be pilot tested and evaluated. Key evaluation points must include the linkage of discovered adverse events to improvement efforts. Pilot projects should be undertaken to assess the effectiveness of such efforts. While most work to date has occurred in acute care facilities, new systems to identify adverse events and errors should be tested at all levels of the system – acute, chronic and community.

4. There should be expanded support for the existing and developing national and provincial Adverse Drug Event (ADE) reporting systems.

Build skills, disseminate knowledge and implement systems to improve safety

5. Healthcare organizations should be strongly encouraged and supported in heightening their focus on errors, adverse events and near misses and to link this to improvement work and system change.

6. Three to five high priority patient safety issues should be identified. National expert panels should be convened to share ideas and develop national strategies in each area. Examples of priority issues could include falls prevention, data systems and workforce concerns in safety.

7. A series of regional meetings or workshops should be held to disseminate knowledge about these best practices, improvement strategies and ideal designs for making improvements in priority areas to reduce adverse events.

8. Support should be made available to create carefully evaluated demonstration projects in idealized design, system change and patient safety in Canada.

9. Support should be provided to develop curricula and learning experiences in patient safety at all educational levels (undergraduate and post graduate and continuing professional education).

10. A one-year “safety fellowship” program should be developed. Two or three representatives (at least one MD along with one or two other health professionals) from each province and territory should be named and supported as fellows. The purpose of this fellowship would be to develop these individuals’ knowledge and skills in all aspects of patient safety to enhance Canadian capacity in this area.

11. Safety research and system change should become a cross cutting theme at the Canadian Institutes of Health Research and emphasized in work at the Canadian Foundation for Health Services Research.

Create organizational and policy level supports for patient safety efforts

12. Canadian professional colleges and organizations should be encouraged to be active in the areas of disclosure policy and legislation and to lobby for appropriate legislation to enable them to expand their efforts.

13. Patient safety programs and initiatives should be integrated into the Canadian Council on Health Services Accreditation standards and other healthcare accreditation standards.

14. Legislation change could enhance reporting of errors and near-misses and should be encouraged and supported.

15. Effective strategies for risk management and risk management programs need to be investigated. Current risk management efforts focus on reducing risk and safeguarding institutional assets. More “proactive” approaches to improving patient safety that are under development elsewhere need to be undertaken in Canada.

Acknowledgements

The authors would like to thank those individuals and organizations that answered our surveys. We would also like to thank Health Canada for their support of this project under contract HC-3-030-0121.

The two surveys were developed with the aid of Smaller World Communications of Toronto. This company also carried out the surveys and assisted in the analysis of the data. We would like to thank the project team from Smaller World Communications for their exceptional efforts: Jennifer Yessis, Ph.D., Research Director; Vanessa Blount, M.Sc., Project Leader; Barb van Maris, M.Sc., Company Leader; Phoebe Lawton, Research Assistant; and Ada Hui, Research Assistant.

Finally we acknowledge the hard work of two research assistants, Fatima Chatur and Claire Nguyen, who assisted with literature reviews.

1. Background

In the last few years the issues of patient safety and healthcare error have become important topics in health policy and healthcare practice in several countries, including the United States, Australia and Great Britain (Baker and Norton, 2001; National Health Service, 2000; Wilson RM, Runciman WB, et. al., 1995; Leape LL, Brennan TA, et. al., 1991). These concerns stem from a set of research studies and organizational and policy initiatives generated by these studies. The epidemiological research that sparked these efforts has demonstrated a consistently high level of error across these jurisdictions, although the focus has been almost entirely on acute care settings (Leape LL, Brennan TA, et. al., 1991; Bates DW, Spell N, et. al., 1997) so a full assessment of the incidence of adverse events and errors is not available. Similar work has not been done in Canada, although many acknowledge the likelihood of comparable levels of error in Canadian facilities (Millar, 2001; Ohlhauser and Schurmann, 2001). There is every indication that the interest shown in patient safety and healthcare error will continue to grow, stimulated by knowledge of current initiatives in the US and elsewhere.

Australia, the US, and the UK have initiated focused efforts to reduce healthcare errors and improve patient safety. These efforts are based in health services delivery organizations, in regulatory and accreditation bodies, among suppliers, and at policy levels, including government and non-governmental organizations. There is limited knowledge about the extent to which Canadian healthcare organizations have addressed patient safety efforts. Knowledge about current efforts to improve surveillance and reporting together with new ideas for creating safer systems and care processes will assist policy makers and organizational leaders. Better understanding about current efforts will help identify activities that could be strengthened and spread. Study of Canadian efforts and those underway elsewhere will assist in developing an analysis of gaps in current activities.

The changes needed to increase patient safety in Canada must take into account the current structures and resources of the Canadian healthcare systems. Limited growth or cuts to healthcare budgets in many provinces have reduced the resources available for new initiatives. Reviews in several provinces and at the federal level are underway to address issues of sustainability of the healthcare system under the current funding and governance arrangements. A number of varying options for increasing revenues and for increasing efficiencies are under intense study. Attention to these important macro policy and funding issues should not distract concern with the issues of adverse events and patient safety that are addressed in this report. Rather, we believe, that greater efforts to increase safety are likely to maintain confidence in healthcare organizations and caregivers. Reducing healthcare errors and adverse events will improve outcomes for patients, families and communities. Such efforts will require additional resources. However, they are

also likely to reduce current costs for dealing with what has been termed, the "hidden epidemic" of error.

1.1 Project Goals and Objectives

This project has three major components: a literature review, telephone and mail surveys, and a gap analysis of current activities in light of efforts underway in various Canadian locations and abroad. The literature review examines published materials on patient safety in the health care system. This literature has been identified using a search of MEDLINE, CINAHL, and HEALTHSTAR, complemented by a hand search of major Canadian journals. In addition, a special review of legal literature has been carried out to identify issues in this area.

The second component of this project is telephone interviews and a mail survey of samples of Canadian organizations, programs and individuals. The telephone interviews were held with individuals currently working on patient safety efforts. These interviews examined the nature of these efforts and their benefits. The mail survey is directed toward a random sample of healthcare delivery organizations and professional associations and colleges. The purpose of the survey was to gauge the level of knowledge about and engagement of these organizations in patient safety activities.

The third component of the report is an analysis of the gaps between current practices of the Canadian organizations, programs and individuals and leading work elsewhere. Based on the identification of "best practices" and "leading edge activities" in Canada, and efforts identified in the UK, Australia and the US through the literature review, we outline key activities for advancing efforts to identify healthcare error and improving patient safety in Canada.

1.2 Focus of Inquiry

This project aims at identifying initiatives in Canada to reduce adverse events and errors in health care settings and to improve patient safety. James Reason, the British expert on human error, defines error as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim (Reason, 1990; Reason, 1997). Adverse events are injuries caused by medical management (rather than underlying disease) (Bates et al., 1997). Not all adverse events are preventable. Patient safety is freedom from accidental injury (Kohn, et al., 1999). The (US) Institute of Medicine in its 1999 report notes, "[t]his definition recognizes that this is the primary safety goal from the patient's perspective." (Kohn, et al., 1999: 3)

While the new emphasis on patient safety has heightened our awareness of the need for greater attention to this issue, there is a long history of concern with ensuring that patients experience as little risk as possible. The Hippocratic maxim, “first, do no harm,” dating back more than 2000 years, suggests that caregivers need to consider that treatment may pose risks as well as benefits. There are many activities that individual professionals and healthcare organizations use to identify risk and reduce the potential for injury. These include Morbidity and Mortality (M&M) rounds, autopsy, risk management, infection control, quality assurance and external reviews by accrediting and other agencies. There are many organizations, including professional associations and licensing bodies, accrediting agencies, and government ministries, among others, that have a mandate to safeguard patients and the public, to improve professional practice and healthcare delivery, and to ensure that healthcare services meet the highest standard of practice possible, given the resources available.

These efforts have contributed to important safeguards and high levels of performance. However, data on adverse events suggests that these levels of performance need to be improved. Efforts made in aviation and other high-risk industries have led to major improvements in performance that are not yet evident in healthcare. We need to acknowledge that healthcare professionals and provider organizations face important challenges in making these improvements. Patients who enter care are often vulnerable because of their illnesses and disabilities. The variation in disease progression and patients’ responses to treatment limits diagnostic accuracy and the effectiveness of therapeutic interventions. Finally, the complexity of healthcare services and the need for coordination across a wide range of individuals, organizations and settings create barriers to introducing the tools and methods used in other industries.

Despite these barriers, individuals and organizations in several countries are making concerted efforts to identify adverse events and healthcare errors, and to improve practices and systems to reduce these events and errors. Baker and Norton (2001) have suggested that efforts are needed in three complementary areas. First, efforts are needed to improve measurement to increase the detection of adverse events and to guide interventions to improve care processes and systems. Second, new system tools and change strategies are required to redesign care, implement solutions that have been shown to be effective, and support teams and individual practitioners in identifying and preventing adverse events. Third, there needs to be visible leadership and supportive cultures that encourage the reporting of adverse events and the implementation of new systems and tools to reduce adverse events, assist in intercepting those adverse events that occur, and mitigating the impact of the adverse events that escape detection.

The broad nature of patient safety and the wide range of activities that may influence safety create a challenge in focusing this research. While we acknowledge that many activities contribute to creating safer healthcare practices and organizations, we have focused on new initiatives to improve the reporting of adverse events, the implementation of system tools and strategies, and the creation of more "resilient" cultures that reduce errors. Efforts to strengthen and invigorate existing programs of risk management, quality improvement and adverse event reporting that have a positive impact on patient safety have also been identified.

1.3 Overview of International Efforts

Exemplary efforts to improve patient safety are underway in three countries: Australia, the United States, and the United Kingdom.

1.3.1 Australia

The Quality in Australian Health Care study (QAHCS) published in 1995 heightened attention to adverse events and iatrogenic injury in Australian healthcare. The study identified that 16.6% of patients whose hospital charts were reviewed suffered an adverse event (Wilson et al., 1995). The data from the QAHCS revealed a much higher level of adverse events than was evident in the Harvard study of hospital adverse events in New York state published several years earlier, in part because the Australian study focused on prevention and quality of care, rather than negligence and malpractice concerns that were key to the US study. The Australian data clearly demonstrated that morbidity in healthcare was a major public health problem (Vincent, 1999). More recent analyses have revealed that over 70% of the adverse events identified were the result of failures in technical performance; failures to decide or act appropriately based on available information; failures to investigate or consult; and a lack of care or failure to attend (Vincent, 1999; Wilson, Harrison, Gibberd, & Hamilton, 1999).

The publication of the Australian study caused considerable controversy in Australian healthcare and in the press. Several years of planning by a National Taskforce on Quality in Australian Health Care produced a comprehensive plan to address these issues. Recommendations from the Taskforce were widely supported, and the Australian state and federal governments have allocated considerable funding for quality improvements. A National Expert Advisory Group on Safety and Quality in Australian Healthcare was established in 1997 and its recommendations led to the formation of the Australian Council for Safety and Quality in Healthcare. In its most recent report the new Australian Council identified a number of key initiatives and achievements:

- The publication of two reports to the Health Ministers outlining a five year plan to improve safety and quality
- Holding of workshops to formulate a vision for safer healthcare, and set priorities for action
- Launching a “blueprint for action” jointly with the Commonwealth and New South Wales Health Ministers
- Developing communications plans, including a web site and commissioned reports
- Surveying health professionals on barriers and opportunities for safer delivery of health care in hospitals (Australian Council for Safety and Quality in Healthcare, 2001)

In addition to these efforts to create greater awareness of system issues and to target improvements on these issues, new systems for monitoring and analyzing adverse events have been developed in Australia. Initial efforts were focused on monitoring adverse events in anaesthesia. Government funding led to the establishment of the Australian Incident Monitoring System – Anaesthesia in 1993. Following the publication of the QAHCS this system was broadened and now includes all public health facilities in South Australia. The system has also been adopted by New Zealand. The Australia Patient Safety Foundation has responsibility for the incident monitoring system and has also developed a classification system for coding and reporting of incidents and adverse events (Runciman, Helps, Sexton, & Malpass, 1998).

1.3.2 United States

The Institute of Medicine (IOM), a private, non-governmental organization created to advise the US federal government on scientific and technical matters, published an important report on healthcare errors in 1999 that stimulated considerable political effort and organizational activities around error. The report, *To Err is Human*, identified healthcare error as a major public health issue leading to the death of at least 44,000 and perhaps as many as 98,000 Americans each year in US hospitals. These estimates were based on the groundbreaking Harvard Medical Practice study, published in 1991, and more recent work using similar methods in Utah and Colorado. The report authors recommended a four tiered approach and sought to balance regulatory and market-based initiatives. The recommendations included:

- Establishing a national focus to create leadership, research, tools and protocols to enhance the knowledge base about safety;
- Identifying and learning from errors through mandatory and voluntary reporting efforts;
- Raising the standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers and professional groups; and

- Creating safety inside health care organizations through the implementation of safe practices in the delivery of care.

In the two years since the IOM report was released there has been a flurry of congressional hearing and proposed legislation, at both state and national levels. Federal agencies involved in health care, including funding agencies such as Medicare and provider agencies such as the Veterans Administration have created a Quality Interagency Coordination Task Force (QUIC) to coordinate responses by US federal agencies on improving patient safety. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has implemented new patient safety requirements for hospitals accredited by this agency. Employers, including many large Fortune 500 companies, have begun to see patient safety as important criteria for selecting healthcare providers who offer care for their employees. The "Leapfrog Group," a group of large companies, has identified several key efforts that may reduce adverse events, including the implementation of computerized physician order entry systems, and will be creating market-based incentives for providers to adopt such systems.

1.3.3 United Kingdom

The National Health Service (NHS) in Britain published a report in June 2000, *An Organisation with a Memory* (National Health Service, 2000), identifying the important impact of adverse events in the NHS. The report was prepared by an expert committee chaired by the chief medical officer of the NHS and focused on how the NHS can more effectively learn from failures in clinical care. The report concluded that the picture of error in Britain was incomplete but that there was a serious problem. For example, existing data, although admittedly poor, indicated that at least 400 patients died or were seriously injured in adverse events involving medical devices in 1999 and that nearly 10,000 people are reported to have experienced serious adverse reactions to drugs (not all of which are preventable). Since the publication of that report, Vincent and colleagues have published a pilot study of adverse events in two acute care hospitals in London using methods similar to those used in the Australian and the US studies (Vincent, Neale, & Woloshynowych, 2001). The researchers found that 10.8% of patients in these hospitals experienced an adverse event during their hospital stays. About one-half of these events were judged to be preventable. The authors state that these results suggest that adverse events are a serious source of harm to patients and a large drain on NHS resources.

More recent analyses of the UK pilot study indicate that less than 20% of preventable adverse events were directly related to surgical operations or invasive procedures and less than 10% to misdiagnoses. Fifty-three percent (53%) of preventable adverse events occurred in general ward care (including initial assessment and the use of drugs and intravenous fluids) and 18% in care

at the time of discharge. The authors suggest that probable contributory factors in these errors included dependence on diagnoses made by inexperienced clinicians, poor records, poor communication between professional caregivers, inadequate input by consultants into day-to-day care, and lack of detailed assessment of patients before discharge (Neale, Woloshynowych, & Vincent, 2001).

The NHS expert panel recommended instituting a national system for reporting adverse events (National Health Service, 2000). More recently the National Health Service announced that it would establish a reporting system to enable actions to reduce risk and prevent reoccurrence of adverse events. In addition, the NHS has indicated that it would establish an independent body, the National Patient Safety Agency. This agency would:

- collect and analyze information on adverse events from local NHS organizations, NHS staff, and patients and caregivers;
- assimilate other safety-related information from a variety of existing reporting systems and other sources in this country and abroad;
- learn lessons and ensure that they are fed back into practice, service organization and delivery;
- where risks are identified, produce solutions to prevent harm, specify national goals and establish mechanisms to track progress (National Health Service, 2000).

The National Patient Safety Agenda was launched in 2001 and linked to a new national system for reporting adverse events, medical errors and near misses. In addition, the previous overlapping mandates and inconsistencies in investigating incidents were addressed by clarifying responsibilities of local health services, the Department of Health, the Commission for Health Improvement, and professional colleges (Department of Health, 2001).

Specific targets for action to improve patient safety in the NHS have been established based on the analysis in *An Organization with a Memory*. These targets include reducing to zero the number of patients being paralyzed by mal-administered spinal injections by the end of 2001 and reducing by 40% the number of serious errors in the use of prescribed drugs by 2005, among other issues. More general targets to improve clinical practice, build safety into the broader environment of care, and encourage clearer roles for patients have also been articulated (Department of Health, 2001).

1.4 Summary

Considerable activity is underway in Australia, the United States and the United Kingdom to reduce the incidence of adverse events and medical errors. Each of these countries has established a high profile committee with a mandate to

examine the issue, improve reporting, and develop recommendations to address system deficiencies. These efforts have included strong support from the federal governments (and state governments in Australia). In addition, a variety of professional groups, employers, regulators and healthcare providers have initiated a wide range of efforts to address this issue.

1.5 References

Australian Council for Safety and Quality in Healthcare. (2001). Safety in Practice: Making Health Care Safer.

Baker, G. R. and P. Norton (2001). "Making Patients Safer! Reducing Error in Canadian Healthcare." Healthcare Papers 2(1): 10-31.

Bates, D. W., Spell, N., Cullen, D. J., Burdick, E., Laird, N., Petersen, L. A., Small, S. D., Sweitzer, B. J., & Leape, L. L. (1997). The costs of adverse drug events in hospitalized patients. JAMA, 277(4), 307-311.

Department of Health [UK]. (2001). Building a Safer NHS for Patients: Implementing An Organization with a Memory. London: Department of Health. www.doh.gov.uk/buildsafenhs

Kohn, L. T., J. M. Corrigan, et al., Eds. (1999). To Err is Human: Building a Safer Health System. Washington, DC, National Academy Press.

Leape, L. L., Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes BA, Hebert L, Newhouse JP, Weiler PC, Hiatt H (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.
Millar, J. (2001). "System performance is the real problem." Healthcare Papers 2(1): 79-85.

National Health Service (2000). An organisation with a memory: Report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer. Norwich, UK, Department of Health**:** 91.

Neale, G., Woloshynowych, M., & Vincent, C. (2001). Exploring the causes of adverse events in NHS hospital practice. J R Soc Med, 94(7), 322-330

Ohlhauser, L. and D. P. Schurman (2001). "National Agenda: Local Leadership." Healthcare Papers 2(1): 77-78.

Reason, J. (1990). Human Error. New York, NY: Cambridge University Press.

Reason, J. T. (1997). Managing the Risks of Organizational Accidents. Aldershot, England: Ashgate Publishing.

Runciman, W. B., Helps, S. C., Sexton, E. J., & Malpass, A. (1998). A classification for incidents and accidents in the health-care system. Journal of Quality in Clinical Practice, 18(3), 199-211.

Vincent, C. (1999). The human element of adverse events. The Medical Journal of Australia, 170, 404-405.

Vincent, C., Neale, G., & Woloshynowych, M. (2001). Adverse events in British hospitals: preliminary retrospective record review. BMJ, 322(7285), 517-519.

Wilson, R. M., Harrison, B. T., Gibberd, R. W., & Hamilton, J. D. (1999). An analysis of the causes of adverse events from the Quality in Australian Health Care Study. The Medical Journal of Australia, 170(9), 411-415.

Wilson, R. M., Runciman, W. B., Gibberd, R. W., Harrison, B. T., Newby, L., & Hamilton, J. D. (1995). The Quality in Australia Health Care Study. The Medical Journal of Australia, 163(6 (November)), 458 - 476.

2. Methods

The reader's attention is drawn to Appendix F where we have included the definitions of many of the terms that are used in this report.

2.1 Literature Review

The U.S. National Patient Safety Foundation [www.npsf.org] has been identifying rapidly growing literature in this area for several years and publishes an annual bibliography. The number of items included in this bibliography now totals several thousand. The bibliography for this report was constructed to include recent readings in key areas along with "classic" articles and books. Special emphasis was placed on including Canadian materials, that is, materials related to Canadian practices and organizations, as well as articles written by Canadian authors that focus on patient safety issues in a broader context. The present annotated literature review provides a list of key readings in patient safety, with descriptions of each reading and overviews for each topic highlighting key issues in selected areas.

There is no standard listing of the topics and areas included under "patient safety." The topic can be defined narrowly to include only readings specifically related to the study of adverse events and their prevention, or, more broadly to include any aspect of health care and health services that may lead to patient injury, and any interventions, including clinical, organizational and policy changes to reduce injury. These interventions could include improved reporting of adverse events, efforts to reduce the likelihood of injury or lower the impact of injuries that do occur, and policy and research initiatives related to patient safety and healthcare error. Since almost any change in health care delivery may have an impact on adverse events, the potential literature base for this review is extremely large. For example, it is well known that many heart attack patients do not receive appropriate medications, including beta-blockers and non-steroidal anti-inflammatory drugs. Any efforts aimed at improving such prescribing and the compliance of patients with these regimens has benefits in reducing injury. In order to limit this bibliography, we have focused on identifying key literature related to understanding the factors and conditions that promote safer healthcare, at an individual, organizational and policy level, and on the identification of adverse events. We have excluded literature on specific practices and interventions to improve such practices that would reduce injuries for specific clinical conditions and procedures (such as the use of guidelines to improve the prescribing of beta blockers for heart attack patients).

The authors developed the headings in this bibliography based on their knowledge of the literature. Readings for each topic were selected based on personal knowledge of the literature, and on a review of bibliographies created by the National Patient Safety Foundation, the Agency for Healthcare Research and Quality, and the Salzberg Seminar on Medical Error and Patient Safety. A

search of MEDLINE, HEALTHSTAR and CINAHL was carried out to identify additional materials. Terms used for this search include: patient safety, adverse events, medical error, and risk management. In addition, these databases were searched for Canadian materials, and a hand search was conducted of major Canadian medical, nursing and healthcare journals.

The draft literature review was circulated to several experts for feedback on the topics and readings included and potential omissions. Based on this review additional readings were added and changes made to clarify the descriptions of the topics and readings.

2.2 The Surveys

The main work in this study comprised two surveys. One was a semi-structured phone survey and the other a mailed questionnaire in two forms. The purposes of the surveys were:

- to identify specific issues of concern about patient safety or health system error;
- to identify emerging or potential safety issues identified by organizations;
- to identify patient safety tools, programs, and surveillance systems that are in use; and
- to identify leading practices in Canada.

The questionnaires were created by Drs. Peter Norton and Ross Baker with the assistance of Smaller World Communications (SWC). Two forms of the mailed questionnaire were required: one for healthcare facilities (such as hospitals, homecare organizations, and long term care facilities) and one for healthcare colleges and associations. Different versions of the questionnaire were developed because these organizations have different mandates and roles with regards to patient safety and the prevention of healthcare errors. One questionnaire for the telephone methodology was developed. Details of the development and testing of these instruments are included in the supplemental volume of this report.

2.2.1 Sample for the Mail Survey

The mail surveys were developed for the following groups: community health centres (CHCs), community hospitals, homecare organizations, large teaching hospitals, long term care facilities, small hospitals, government organizations, national organizations, and professional organizations and professional colleges. The organizations were identified by two strategies. First, we searched the World Wide Web for these specific organizations across Canada, and then others were identified from the referrals of organizations contacted from the initial search of the

World Wide Web. Overall, there were 69 associations and colleges, and 102 healthcare facilities that were sent questionnaires.

The final sampling frame was as follows:

Table 1.

Organization Type	Atlantic	British Columbia	Ab., Sas. & Man.	Ontario	Quebec	**Total**
Community (CHC)	2	2	3	3	3	13
Community hospitals (non-teaching)	4	4	6	6	8	28
Governments	2	1	2	1	1	7
Home Care	2	2	2	5	2	13
Large Teaching Hospitals	2	2	2	3	5	14
Long Term Care	2	2	2	3	2	11
National organizations	0	0	0	0	0	21
Professional Associations	4	4	4	4	5	21
Professional Colleges	4	4	4	4	4	20
Small Hospitals	4	4	4	5	6	23
Totals	26	25	29	34	36	171

The Dillman method (Dillman, 1978) was used to maximize the questionnaire response rate. Initial questionnaires were mailed August 21, 2001. A reminder card was sent September 4th, and a third mailing was sent September 18th to all participants who had not yet responded to the initial questionnaire. During the week of October 8th, participants who had not yet responded received a follow-up phone-call to encourage participation, and also to inquire about reasons for non-response. Those who received a questionnaire were given the option of mailing the questionnaire and additional materials to SWC in the pre-stamped, self-addressed envelope or faxing their response.

2.2.2 Sample for the Telephone Survey

The telephone survey sample was generated by the 'snowball' technique (Fink, 1995). First, Drs. Norton and Baker contacted leaders in the area of patient safety and healthcare error across the country. These experts were asked to identify two or three individuals and/or organizations involved in innovative practices and projects for identifying errors and improving patient safety. The first list comprised 46 key informants. These key informants were then asked at the end of the interview to identify 2 or 3 individuals they thought were using best practices in the area of patient safety and healthcare error. These referrals then became part of the sample. The same question was asked of participants in the mail survey. As a result, referrals from the mail survey participants were also included in the sample. People who were referred were included in the next round of interviewing if they represented a different organization, were in a region that was not well represented, and had not already been contacted for an interview (some organizations and/or individuals were referred more than

once). The number of referrals that were selected to participate was 33. The total number of participants contacted for an interview was 79.

The final sample was as follows:

Table 2.

	Alberta	Atlantic	British Columbia	Sask. & Manitoba	National	Ontario	Quebec	**Total**
1st line contacts	5	3	3	9	6	14	6	46
Referrals	1	3	3	9	4	12	1	33

During the interviewing, a three call back design was utilized. This means that each of the phone numbers provided was called up to three times to ensure that everyone had the opportunity to participate in the survey. The interviewer also requested interviews through e-mail whenever e-mail addresses were available.

The interviews began the week of September 10th and continued until October 26th. Each informant was interviewed using the semi-structured interview found in Appendix A. Interviews ranged from 20 to 45 minutes in length.

As part of the interview, respondents were asked to submit documentation from their organization that was relevant to the study. If such information was available, SWC couriered a return postage paid envelope to the respondent.

2.2.3 Data Analysis for the Surveys

Quantitative data from the mail surveys were entered into the Statistical Package for the Social Sciences (SPSS). Two quality checks were in place to ensure the accuracy of data entry. First, the data entry system included range checks. If a number that was not within the acceptable range for a specific question was entered, the computer did not accept it and the operator was prompted for a new entry. Accuracy was also verified through reentry of 10% of the data. These methods revealed and entry error rate of less than 1%.

Open-ended questions from the mail surveys were transcribed verbatim into tables in a word processor. All written comments were reviewed and organized into themes to identify key issues, resources, and gaps. Drs. Norton and Baker then reviewed themes in collaboration with the research staff involved in the project.

All telephone interviews were audio taped, and each interview was transcribed verbatim. All transcripts were then imported into the QSR NUD*IST 4.0 program (Qualitative Solutions and Research – Non-numerical Unstructured Data

Indexing Searching and Theorizing) (Richards and Richards, 1991). QSR NUD*IST is a program to aid in coding qualitative data into an index system, to search text and/or determine patterns in the coding.

Transcripts of audiotapes were read several times at the beginning of data analysis to get an overall understanding of the data. Next they were analyzed using the constant comparative analysis method (Glaser and Strauss, 1967), Lincoln and Guba (1985), as well as Lofland and Lofland's (1995) suggestions for initial coding and memoring.

Categories evolved as the transcripts were more thoroughly analyzed. After a number of main points and themes were identified using the final index system, summaries of each of were written. The final main points and themes considered were most pervasive across the interviews.

2.3 Review of Legal Issues

Consultation with two professors at the Faculty of Law at the University of Calgary who have been involved in the teaching of courses in medical jurisprudence led to the identification of two key resources for our review of legal issues. The first is the standard text on legal liability in Canada, by E. I. Picard and G.B. Robertson, *Legal Liability of Doctors and Hospitals in Canada* (1996). The second resource is the landmark report on liability and compensation in Canadian healthcare, by J.R.S. Prichard, *Liability and Compensation in Health Care : A Report to the Conference of Deputy Ministers of Health of the Federal/Provincial/Territorial Review on Liability and Compensation Issues in Health Care* (1990).

The Prichard document offers an extensive and comprehensive review of the area to 1990 while the Picard and Robertson text covers developments to about 1995. To complement these, a search strategy was devised with the aid of librarians at the Law Library at the University of Calgary. The purpose of this search was to identify key areas of change since 1990. We conducted a limited search focusing on the Canadian situation. During this work we discovered the proceedings of a conference on tort reform that was hosted by the Canadian Medical Protective Association in Toronto on November 5, 1998. We reviewed the proceedings of this conference in detail.

A variety of other articles identified through the literature search were also reviewed as part of this overview of legal issues.

2.4 References

Canadian Medical Protective Association (1998). Tort Reform Conference. Toronto, Ontario, November 5, 1998. Proceedings are accessible at http://www.cmpa.org/cmpaweb/public/english/tort-e.cfm

Dillman, Don A. (1978). Mail and Telephone Surveys: The Total Design Method. New York: Wiley-Interscience.

Fink, A. (1995). How to Sample in Surveys. The Survey Kit, Volume 6. Thousand Oaks, California: Sage.

Glaser, B., & Strauss, A. (1967). The discovery of grounded theory: strategies for qualitative research. New York: Aldine de Gruyer.

Lincoln, Y., & Guba, E. (1985). Naturalistic Inquiry. Newbury Park, California: Sage.

Lofland, J., & Lofland, L. (1995). Analyzing social settings: a guide to qualitative observations and analysis. Belmont, California: Wadsworth Publishing.

Picard, E. I. and G. B. Robertson (1996). Legal Liability of Doctors and Hospitals in Canada, 3rd Edition. Scarborough, Ont., Carswell Publishing.

Prichard, J. R. S. (1990). Liability and compensation in health care: a report to the Conference of Deputy Ministers of Health of the Federal/Provincial/Territorial Review on liability and compensation issues in health care. Toronto, University of Toronto Press.

Richards, L., & Richards, T. (1991). The NUD*IST Qualitative data analysis system. Qualitative Sociology, *14*, 307-324.

3. Results

The reader's attention is drawn to Appendix F which contains the definitions of the terms used in this report.

3.1 Literature review

3.1.1 Safety and Error: General Texts and Overviews

Reason, J., Human Error. 1990, New York, NY: Cambridge University Press.

Reason's book is the classic text on error written by one of the leading experts on error and human performance. The book provides an introduction and summary of the basic ideas, methods, research traditions and background studies on error in a broad range of human endeavors. The first chapters provide an introduction to the nature of error and research on error, outlining two traditions of research in the natural sciences and engineering (or "cognitive science"). Chapters 3 to 5 present a view of basic error mechanisms and the processes that give rise to different types of error. The concluding chapters focus on the consequences of human error: error detection, accident contribution and remedial measures. In particular, Reason establishes the important distinction between active errors and latent errors. The former have an immediate impact on systems and are usually created by pilots, doctors and other actors at the "sharp end". By contrast, those at the "blunt end" of the system, including managers, policy makers and system designers, most often generate latent errors. An examination of six case studies, including Three Mile Island, Challenger, and others suggest that latent rather than active failures pose the greatest threat to safety in high technology systems. The final chapter reviews various techniques for assessing and reducing the risks of error, including human reliability techniques, memory aides and decision support systems.

Bogner, M.S. (ed.) (1994). Human Error in Medicine. Hillsdale, N.J.: Lawrence Erlbaum Associates.

Bogner's volume includes a number of classic papers on error including work by Leape, Senders, Gaba, Helmreich, and Cook and Woods.

Cook, Richard I. and David D. Woods (1998). A Tale of Two Stories: Contrasting Views of Patient Safety. Chicago: National Patient Safety Foundation

This monograph is based on a workshop that explored the technical issues in improving patient safety and the contrast between the infamous “celebrated” cases and other more detailed investigations of safety failures that have implicated a wide range of system issues contributing to these incidents. A narrow focus on practitioners at the “sharp end” hinders the ability to understand how to improve systems; and a focus on safety in isolation ignores the complex nature of those organizations.

Kohn, L.T., J.M. Corrigan, and M.S. Donaldson, eds. (1999). To Err is Human: Building a Safer Health System. National Academy Press: Washington, DC.

This report, issued by the Committee on Quality of Health Care in America of the U.S. Institute of Medicine (IOM) provides a summary of key epidemiological studies of healthcare error, examines the implications of those studies and reviews the leadership, reporting strategies and system changes necessary to reduce the incidence and impact of error in American healthcare. Based on this analysis a series of recommendations are presented to achieve a “threshold improvement in quality over the next 10 years”. The recommendations focus on a four aspects: “(1) establishing a national focus to create leadership, research, tools and protocols to enhance the knowledge base about safety; (2) identifying and learning from errors through the immediate and strong mandatory reporting efforts, as well as the encouragement of voluntary efforts; both with the aim of making sure the system continues to be made safer for patients; (3) raising standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups; and (4) creating safety systems inside health care organizations through the implementation of safe practices at the delivery level. This level is the ultimate target of all the recommendations.” The IOM Report was the most important stimulus to the greatly increased attention to healthcare error in the last two years in the U.S. Following this report, then President Clinton ordered all federal agencies with responsibilities for healthcare to develop plans to reduce errors. Numerous legislative hearings have been held and several proposed bills have been offered to address various aspects of this problem.

Leape, L. L. (1994). “Error in Medicine.” JAMA **272**(23): 1851-1857.

Leape extrapolates the impact of the Harvard Medical Practice study to the US, and notes that if these rates are typical, then the analogous impact would be the equivalent of a jumbo jet crashing every 2 days. Leape then discusses why the error rate in medicine is so high, focusing on the impact of the “culture of medical practice” on physicians and other staff. He notes the emphasis on error-free practice in the socialization of physicians and the assumption that if

errors do occur they are the fault of individuals. Striving for infallibility leads to attempts to conceal mistakes least individuals who report them be regarded as incompetent or careless. Yet concealing errors extracts an emotional toll on physicians, and limits efforts to increase safety. This situation gives rise to a paradox where "the standard of medical practice is perfection…[but] all physicians recognize that mistakes are inevitable."
The emphasis on perfection also means that efforts to prevent or reduce errors are based on training and motivation of individuals, and punishment of those who make mistakes. This approach differs from other industries where human error is often seen as resulting from factors beyond individual control. Systems that rely on error-free performance are doomed to fail. If physicians and nurses want to reduce error they must change the way they think about error.
Research in human factors and cognitive psychology provides some useful ideas for reducing error. While there are not simple or universal strategies, the key to reducing error lies in systemic changes, including attention to the design of health care work to make it difficult for individuals to commit errors. Since errors will inevitably occur, systems need to be designed to provide feedback and have built-in buffers and redundancies that limit the impact of these errors. Standardization and simplification of work processes also reduces the opportunities for error. These strategies have not been widely adopted in medicine, unlike aviation and other high-risk industries. Physicians and nurses need to accept the notion that error is inevitable and that the design of systems must be altered to reduce errors.

Spath, P.L., ed. (2000). Error Reduction in Health Care: A Systems Approach to Improving Patient Safety. Jossey-Bass: San Francisco.

Spath's book provides several very good reviews of key topics, including strategies for "error-proofing" work processes, investigating adverse events, carrying out root cause analyses and reducing errors through improved teamwork. The chapters build on the systems approach to reducing error, through the identification of latent factors and situational issues that contribute to error. Using human factors principles to design tasks, work processes and systems is outlined, and approaches to error measurement and root case analysis are offered as ways to improve current approaches to reducing error.

Cook, R. I. and D. D. Woods (1994). Operating at the Sharp End: The Complexity of Human Error. In M. S. Bogner. Human Error in Medicine. Hillsdale, NJ, Lawrence Erlbaum: 255-310.

This chapter provides a rich introduction to understanding of system failure and the ways in which human error is linked to human factors and cognitive psychological mechanisms. A model for human performance is presented that identifies three areas of cognitive factors that govern how people form intentions to act. The three factors are: knowledge factors (factors related to the knowledge that can be drawn on when solving problems in context), attentional

dynamics (factors that influence the attention and mental workload as situations evolve), and strategic factors (the trade-offs between goals that conflict, especially when the practitioners act in uncertain situations or under the pressure of limited resources.) These interlocking elements operate within the context of available resources and constraints, at the blunt end, and across a range of actors coordinating activities at the sharp end. In the first part of the chapter the authors present and analyze three examples from anesthesiology, examining how errors in human performance are linked to complex patterns of human behavior and system function. The second part of the chapter addresses large system failures in medicine and other domains. The authors argue that problems of cognitive processing are similar across these different domains. The third part of the chapter focuses on the consequences of these ideas for attempts to eliminate human error as a cause of large system failures. One solution for enhancing human performance is training, including simulators that allow practitioners to experience infrequently encountered, but realistic scenarios. Technology, including automation is a second solution, but can be a mixed blessing. Technology can reduce workload, but "clumsy automation" increases workload at peak workload times leading to degradation of human performance. The authors conclude that failures in complex systems are inevitably linked to demands, particularly cognitive demands, on human performance. Strategies that enhance performance (training and some technology) rather than simply trying to minimize human error (rules, policies and sanctions) are keys to effective human performance.

Senders, J. W. (1991). Human Error: Cause, Prediction and Reduction. Hillsdale, NJ, Lawrence Erlbaum Associates.

A collection of papers from the 2nd Conference on the Nature and Source of Human Error (1983, Bellagio, Italy). Several papers develop taxonomies of error and identify strategies for prediction and reducing error. The introduction provides a valuable overview of the field.

Baker, G. R. and P. Norton (2001). "Making Patients Safer! Reducing Error in Canadian Healthcare." Healthcare Papers **2**(1): 10-31.

This paper addresses the implications of epidemiological studies of healthcare error in Australia and the US. There are no similar studies in Canada, but little reason to expect that the situation differs markedly from the other countries that have rigorously studied the problem. These studies have created widespread concern that an epidemic of error exists in healthcare. Three key strategies are outlined for addressing the problem of healthcare error. First, better information about the numbers and types of errors that occur is needed to help pinpoint change efforts. Non-punitive reporting policies must be put in place, to assist in altering the traditional culture of blame that has discouraged error reporting. Second, the practices and strategies shown to reduce error, such as physician-order entry and medication administration systems, need to be piloted and

adopted. Third, healthcare organizations need to work to create more effective cultures oriented toward preventing errors and intercepting errors that inevitably occur. These cultures will require a new emphasis on teamwork, a continual focus on redesigning care systems, particularly in high risk areas such as operating rooms, intensive care units and emergency rooms. These are not easy tasks and will require investments in new equipment and new skills. These steps are essential if we are to maintain public confidence in healthcare.

Zipperer, L. and S. Cushman, Eds. (2001). Lessons in Patient Safety. Chicago, IL, National Patient Safety Foundation.

The National Patient Safety Foundation produced this edited volume that includes a series of brief overviews on key issues and underlying concepts. The book includes several essays on important concepts and underlying disciplines. Other chapters offer readers' guides to the literature, for example on administrative challenges, environments prone to error, learning from responses to error and system contexts for safety. This volume is a highly readable introduction to the topic and literature.

3.1.2 Epidemiology of Healthcare Error

Major Incidence Studies of Error

Brennan, T. A., L. L. Leape, et al. (1991). "Incidence of adverse events and negligence in hospitalized patients." The New England Journal of Medicine **324**(6): 370 - 384.

As part of an interdisciplinary study of medical injury and malpractice litigation, the authors report the result of a large study of adverse events in hospital patients in New York State in 1984. Based on a review of over 30,000 randomly selected patient charts they estimate the incidence of adverse events, defined as injuries caused by medical management, and of the subgroup of such injuries that resulted from negligent or substandard care. Adverse events occurred in 3.7 percent of the hospitalizations and 27.6 percent of the adverse events were due to negligence. Although 70.5 percent of the adverse events gave rise to disability lasting less than six months, 2.6 percent caused permanently disabling injuries and 13.6 percent led to death. The percentage of adverse events due to negligence was markedly higher among the elderly. This study, the Harvard Medical Practice Study, was based on methods developed earlier to review adverse events in California. The results have been widely cited and were a major contribution to the analyses in the IOM report. The methods from this study have been further adapted and applied by researchers in Australia, the UK and New Zealand studies cited below.

Leape, L. L., Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes BA, Hebert L, Newhouse JP, Weiler PC, Hiatt H (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.

A second report on the Harvard Medical Practice Study. This article provides an analysis of these adverse events and their relation to error, negligence, and disability. Two physician-reviewers independently identified the adverse events and evaluated them with respect to negligence, errors in management, and extent of disability. One of the authors classified each event according to type of injury. The authors found that drug complications were the most common type of adverse event (19 percent), followed by wound infections (14 percent) and technical complications (13 percent). Nearly half the adverse events (48 percent) were associated with an operation. Adverse events during surgery were less likely to be caused by negligence (17 percent) than nonsurgical ones (37 percent). The proportion of adverse events due to negligence was highest for diagnostic mishaps (75 percent), noninvasive therapeutic mishaps ("errors of omission") (77 percent), and events occurring in the emergency room (70 percent). Errors in management were identified for 58 percent of the adverse events, among which nearly half were attributed to negligence. The authors conclude that the prevention of many adverse events must await improvements in medical knowledge, but the high proportion that are due to management errors suggests that many others are potentially preventable now. Reducing the incidence of these events will require identifying their causes and developing methods to prevent error or reduce its effects.

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

A review of the medical records of over 14000 admissions to 28 hospitals in New South Wales and South Australia revealed that 16.6% of these admissions were associated with an "adverse event", which resulted in disability or a longer hospital stay for the patient and was caused by health care management; 51% of the adverse events were considered preventable. In 77.1% the disability had resolved within 12 months, but in 13.7% the disability was permanent and in 4.9% the patient died. This report has had a major impact on the development of policy and organizational initiatives to reduce health care error in Australia.

Vincent, C., G. Neale, et al. (2001). "Adverse events in British hospitals: preliminary retrospective record review." BMJ **322**(7285): 517-519.

This article reports a British replication of the US and Australian methods to detect adverse events through record review in British hospitals and to make preliminary estimates of the incidence and costs of adverse events. Like the previous studies, the researchers conducted a retrospective review of 1014 medical and nursing records. in two acute hospitals in Greater London area. The results found that 110 (10.8%) patients experienced an adverse event, with an overall rate of adverse events of 11.7% when multiple adverse events were

included. About half of these events were judged preventable with ordinary standards of care. A third of adverse events led to moderate or greater disability or death. These results suggest that adverse events are a serious source of harm to patients and a large drain on NHS resources. Some are major events; others are frequent, minor events that go unnoticed in routine clinical care but together have massive economic consequences.

Thomas, E. J., D. M. Studdert, et al. (2000). "Incidence and types of adverse events and negligent care in Utah and Colorado." Medical Care **38**(3): 261-71.

This study reports a replication of the Harvard Medical Practice Study to estimate the incidence and types of adverse events and negligent adverse events in Utah and Colorado. The researchers selected a representative sample of hospitals in the two states and then randomly sampled 15,000 nonpsychiatric 1992 discharges. Each record was screened by a trained nurse-reviewer for 18 criteria associated with adverse events. If one or more criteria were present, the record was reviewed by a trained physician to determine whether an adverse event or negligent adverse event occurred and to classify the type of adverse event. Adverse events were found in 2.9+/-0.2% (mean+/-SD) of hospitalizations in each state. In Utah, 32.6+/-4% of adverse events were due to negligence; in Colorado, 27.4+/-2.4%. Death occurred in 6.6+/-1.2% of adverse events and 8.8+/-2.5% of negligent adverse events. Operative adverse events comprised 44.9% of all adverse events; 16.9% were negligent, and 16.6% resulted in permanent disability. Adverse drug events were the leading cause of nonoperative adverse events (19.3% of all adverse events; 35.1% were negligent, and 9.7% caused permanent disability). Most adverse events were attributed to surgeons (46.1%, 22.3% negligent) and internists (23.2%, 44.9% negligent). The authors conclude that the incidence and types of adverse events in Utah and Colorado in 1992 were similar to those in New York State in 1984.

Davis P, Lay-Yee R, Schug S, Briant R, Scott A, Johnson S, Bingley W. (2001). Adverse events regional feasibility study: indicative findings. New Zealand Medical Journal. May 11; 114(1131):203-5.

This study reports the findings of research applying the Australian protocol to identify adverse events in three Auckland (NZ) hospitals. Using a two-stage review, 142 cases were identified as AEs (10.7% of 1,326 screened records). In 102 cases, 7.7% of all screened records, it was considered to be more likely than not that health care management contributed to the AE. About half the reported AEs occurred before the index admission, the majority outside hospital. Over half of all events resulted in disability that was resolved within a month. An average 6.7 extra days stay in hospital were attributable to AEs. For 60% of AEs the evidence for preventability was either low or nonexistent. Areas of potential prevention were predominantly educational. Over half of all AEs occurred in a surgical context. Medical AEs were more likely to have occurred

outside hospital, to be drug-related, to be associated with an acute admission, to be classified as highly preventable, and to have a greater impact on hospital stay. The researchers conclude that although the data generated by a feasibility study must be treated with caution, the pattern of results is consistent with comparable Australian findings and is of potential clinical and managerial significance.

Thomas, E. J., D. M. Studdert, et al. (2000). "A comparison of iatrogenic injury studies in Australia and the USA. I: Context, methods, casemix, population, patient and hospital characteristics." International Journal for Quality in Health Care **12**(5): 371-8.

This article focuses on understanding the reasons contributing to the differences between two iatrogenic injury studies of hospitalized patients in 1992 which used ostensibly similar methods and similar sample sizes, but had quite different findings. The Quality in Australian Health Care Study (QAHCS) reported that 16.6% of admissions were associated with adverse events (AE), whereas the Utah, Colorado Study (UTCOS) reported a rate of 2.9%. Both studies reviewed charts of hospitalized patients. A review of the methods in both study and a reanalysis of the QAHCS data using UTCOS methods were carried out. Five important methodological differences were found: (i) QAHCS nurse reviewers referred records that documented any link to a previous admission, whereas UTCOS imposed age-related time constraints; (ii) QAHCS used a lower confidence threshold for defining medical causation; (iii) QAHCS used two physician reviewers, whereas UTCOS used one; (iv) QAHCS counted all AEs associated with an index admission whereas UTCOS counted only those determining the annual incidence; and (v) QAHCS included some types of events not included in UTCOS. When the QAHCS data were analysed using UTCOS methods, the comparative rates became 10.6% and 3.2%, respectively. CONCLUSIONS: Five methodological differences accounted for some of the discrepancy between the two studies. Two explanations for the remaining three-fold disparity are that quality of care was worse in Australia and that medical record content and/or reviewer behaviour was different.

Runciman, W. B., R. K. Webb, et al. (2000). "A comparison of iatrogenic injury studies in Australia and the USA. II: Reviewer behaviour and quality of care." International Journal for Quality in Health Care **12**(5): 379-88.

This study is a companion piece to the Thomas study aiming to identify the remaining three-fold disparity between adverse event (AE) rates in the Quality in Australia Health Care Study (QAHCS) and the Utah-Colorado Study (UTCOS) after methodological differences had been accounted for. The researchers used a previously developed classification to assign all AEs to 98 exclusive descriptive categories and then compared the relative rates between studies; they also compared the severity of these AES and frequency of death. For 38 categories, representing 67% of UTCOS and 28% of QAHCS AEs, there

were no statistically significant differences. For 33 other categories, representing 31% and 69% respectively, there was seven times more AEs in QAHCS than in UTCOS. Rates for major disability and death were very similar (1.7% and 0.3% of admissions for both studies) but the minor disability rate was six times greater in QAHCS (8.4% versus 1.3%). The researchers observe that a similar 2% core of serious AEs was found in both studies, but for the remaining categories six to seven times more AEs were reported in QAHCS than in UTCOS. They hypothesize that this disparity is due to different thresholds for admission and discharge and to a greater degree of under-reporting of certain types of problems as AEs by UTCOS than QAHCS reviewers. The biases identified were consistent with, and appropriate for, the quite different aims of each study. No definitive difference in quality of care was identified by these analyses or a literature review.

Hofer, T.P. and E.A. Kerr (2000). What is an error? Effective Clinical Practice 3(6): 261-269.

The authors investigate the variation in how “error” has been defined in the medical literature. They note that errors have sometimes been defined in terms of failed care processes without any link to subsequent harm. Only a few studies have actually measured errors and these have not described the reliability of the measurement. No studies have directly examined the relationship between errors and adverse events. The authors suggest that the value of pursuing latent system errors using case studies or root cause analysis has not been demonstrated in either the medical or non-medical literature.. They suggest that better epidemiological research is necessary to guide efforts to reduce errors.

Other Incidence Studies

Kohn, L. T., J. M. Corrigan, et al., Eds. (1999). To Err is Human: Building a Safer Health System. Washington, DC, National Academy Press. Chapter 2, Errors in Health Care: A Leading Cause of Death and Injury.

Chapter 2 offers a good review of various epidemiological studies of error in the context of assessing their impact on US healthcare.

Donchin, Y., D. Gopher, et al. (1995). “A look into the nature and causes of human errors in the intensive care unit.” Critical Care Medicine **23**(2): 294-300.

This study examines the nature and causes of human errors in an intensive care unit of a university hospital. Two types of data were collected: errors reported by physicians and nurses immediately after an error discovery; and activity profiles based on 24-hr records taken by observers with human engineering experience on a sample of patients. During the 4 months of data collection, a total of 554 human errors were reported by the medical staff. Errors were rated for severity and classified according to the body system and type of medical activity involved. There was an average of 178 activities per patient per day and an estimated number of 1.7 errors per patient per day. For the ICU as a whole, a severe or potentially detrimental error occurred on the average twice a day. Physicians and nurses were about equal contributors to the number of errors, although nurses had many more activities per day. The authors conclude that a significant number of dangerous human errors occur in the ICU. Many of these errors could be attributed to problems of communication between the physicians and nurses

Orser, B. A., R. J. Chen, et al. (2001). “Medication errors in anesthetic practice: a survey of 687 practitioners.” Canadian Journal of Anaesthesia **48**(2): 139-46.

This study examines whether anesthesiologists had experienced a medication error and, if so, the causal factors linked to these errors. A survey was mailed to members of the Canadian Anesthesiologists' Society (n = 2,266). Respondents provided free-text descriptions of medication errors and answered fixed response questions. Surveys from 687 anesthesiologists (30% response rate) revealed that 85% of the participants had experienced at least one drug error or "near miss". Although most errors (1,038) were of minor consequence (98%), four deaths were reported. The commonest error involved the administration of muscle relaxants instead of a reversal agent. "Syringe swaps" (70.4%) and the misidentification of the label (46.8%) were common contributing factors. Anesthesiologists (97.9%) reported that they read the ampoule label "most of the time" although the label colour was an important secondary cue. Approximately half of the participants would report the error if a reporting program existed and 84% agreed that improved standards for drug labels would reduce the incidence of error.

Wanzel, K. R., C. G. Jamieson, et al. (2000). “Complications on a general surgery service: incidence and reporting.” Canadian Journal of Surgery **43**(2): 113-7.

This Canadian study examined the incidence and nature of complications on a general surgery service compares these results with pre-existing institutional recording and reporting methods. A single observer prospectively monitored the presence and documentation of complications for 192 general surgery inpatients, which comprised all patients admitted to the general surgery service at the Wellesley Central Hospital over a 2-month period. The observer carried out daily chart reviews, attended rounds and surgical operating rooms, made frequent patient visits on the ward and interviewed the health care team members. Seventy-five (39%) of the 192 patients suffered a total of 144 complications. Two complications (1%) were fatal, 10 (7%) were life threatening, 90 (63%) were of moderate severity and 42 (29%) were trivial. Of these 144 complications, 26 (18%) were deemed potentially attributable to error. One hundred and twelve (78%) of the complications occurred during or after a surgical operation and were related directly or indirectly to it. Only 9 (6%) complications were not documented in the progress notes of the patients' charts. However, 115 (80%) were not presented at weekly morbidity and mortality rounds, and 95 (66%) were not documented on the face sheet of the patients' final medical records. The authors conclude that complications are common and are underreported by traditional methods. Strategies to improve the recording and reporting of complications must be developed.

Weingart, S.N., A.N. Ship, and M.D. Aronson. (2000). Confidential clinician-reported surveillance of adverse events among medical inpatients. Journal of General Internal Medicine 15: 470-477.

The authors interviewed house officers in a medicine unit of a teaching hospital during morning rounds and via e-mail. The house officers were asked about adverse events that occurred and to identify factors that contribute to iatrogenic injury. One hundred and ten events were identified affecting 84 patients. The most common events were inadequate evaluations of patients, failure to monitor or follow up and failure of the laboratory to perform a test. Adverse events were identified in 2.6% of admissions. The hospital incident reporting system detected only one house officer reported event.

Medication Error Studies

Bates, D. W. (1999). “Frequency, consequences and prevention of adverse drug events.” Journal of Quality in Clinical Practice **19**(1): 13-7.

Iatrogenic injuries are important because they are frequent and many may be preventable; those caused by therapeutic drugs are among the most frequent. While medication errors are common, most have little potential for harm. However, some errors, such as giving a patient a drug to which they have a known allergy, are more likely to cause injury. Error theory provides insights into the changes required to reduce medication error injury rates. Data from the Adverse Drug Event (ADE) Prevention study suggest that most serious errors occur at the ordering and dispensing stages, while another, smaller, proportion occur at the administration stage. These data suggest that physician computer-order entry, where physicians write orders on-line with decision support, including patient-specific information and alerts about potential problems, has the potential to significantly reduce the number of serious medication errors.

Bates, D. W., L. L. Leape, et al. (1993). “Incidence and Preventability of Adverse Drug Events in Hospitalized Adults.” Journal of General Internal Medicine **8**(6): 289-294.

The researchers in this study aimed to evaluate the incidence and preventability of adverse drug events (ADEs) and to determine the yield of several strategies for identifying them. They searched for ADEs on all patients on seven units, including two medical, two surgical, and two obstetric general care units and a coronary intensive care unit in an urban tertiary care hospital. Events were identified in three ways: 1) logs were placed on each unit and satellite pharmacy for nurses and pharmacists to record incidents; 2) a research nurse solicited reports of incidents twice daily on each unit; and 3) the nurse reviewed all charts at least daily. They found the rate of drug- related incidents was 73 in 2,967 patient-days; 27 incidents were judged ADEs, 34 potential ADEs, and 12 problem orders. Fifty different drugs were involved. Physicians were primarily responsible for 72% of the incidents, with the remainder divided evenly between nursing, pharmacy, and clerical personnel. Of the 27 ADEs, five were life threatening, nine were serious, and 13 were significant. Fifteen (56%) of the 27 were judged definitely or probably preventable. Incidents were discovered about equally often from the log and by chart review. The authors conclude that ADEs are not infrequent, often preventable, and usually caused by physician decisions. In this study, solicited reporting by nurses and pharmacists was inferior to chart review for identifying ADEs, but was effective for identifying potential ADEs. Optimal prevention strategies should cover many types of drugs and target physicians' ordering practices.

Classen, D. C. and S. L. Pestotnik (1997). “Adverse drug events in hospitalized patients: Excess length of stay, extra costs and attributable mortality.” JAMA **4**(301-306).

This study aimed to identify the excess length of stay, extra costs, and mortality attributable to adverse drug events (ADEs) in hospitalized patients using a matched case-control study. Patients in LDS Hospital, a tertiary care health care institution in Salt Lake City, UT who experienced an ADE were matched with controls. The authors found that 2.43 per 100 admissions to the LDS Hospital during the study period experienced an ADE. The crude mortality rates for the cases and matched controls were 3.5% and 1.05%, respectively (P<.001). The mean length of hospital stay differed significantly between the cases and matched controls (7.69 vs 4.46 days; P<.001) as did the mean cost of hospitalization ($10,010 vs $5355; P<.001). The extra length of hospital stay attributable to an ADE was 1.74 days (P<.001). The excess cost of hospitalization attributable to an ADE was $2013 (P<.001). A linear regression analysis for length of stay and cost controlling for all matching variables revealed that the occurrence of an ADE was associated with increased length of stay of 1.91 days and an increased cost of $2262 (P<.001). In a similar logistic regression analysis for mortality, the increased risk of death among patients experiencing an ADE was 1.88 (95% confidence interval, 1.54-2.22; P<.001). The authors conclude that the attributable lengths of stay and costs of hospitalization for ADEs are substantial.

Just Ebbesen, Ingebjørg Buajordet, et al. (2001). “Drug-Related Deaths in a Department of Internal Medicine.” Archives of Internal Medicine **161**: 2317-2323.

This study assesses the incidence of fatal ADEs in a major medical department and identifies possible patient characteristics signifying fatal ADE risk. The authors used clinical records, autopsy results, and findings from premortem and postmortem drug analyses to investigate all 732 patients who died during a 2-year period under the care of the Department of Internal Medicine, Central Hospital of Akershus, Nordbyhagen, Norway. These patients represented 5.2% of the 13 992 patients admitted to the department. The researchers found that 18.2% of the patients (133/732) (95% confidence interval, 15.4%-21.0%), deaths were classified as being directly (64 [48.1%] of 133) or indirectly (69 [51.9%] of 133) associated with 1 or more drugs (this equals 9.5 deaths per 1000 hospitalized patients). Those with fatal ADEs (cases) were older, had more diseases, and used more drugs than those without fatal ADEs (noncases). In 75 of the 133 patients with fatal ADEs, autopsy findings and/or drug analysis data were decisive for recognizing the ADEs; in 62 of the remaining 595 patients, similar data proved necessary to exclude the suspicion of a fatal ADE. Major culprit drugs were cardiovascular, antithrombotic, and sympathomimetic agents. The researchers conclude that fatal ADEs represent a major hospital problem, especially in elderly patients with multiple diseases. Autopsy results and the findings of premortem and postmortem drug analyses were important for recognizing and excluding suspected fatal ADEs.

Cohen, M. R., Ed. (1999). Medication Errors. Washington, DC, American Pharmaceutical Association.

An excellent selection of articles by leaders in the field, including Lucian Leape, Michael Cohen, John Senders, and others. The articles include reports on research on the incidence of medication errors, the use of tools such as Failure Mode and Effects Analysis (FMEA), prevention of errors in dispensing and administration of medications, the role of pharmaceutical trademarks and drug packaging and labeling, and specific experiences in dealing with medication errors in cancer chemotherapy, pediatrics and immunology.

Lesar, T. S., L. Briceland, et al. (1997). “Factors related to errors in medication prescribing.” JAMA **277**(4): 312-7.

The researchers in this study sought to quantify the type and frequency of identifiable factors associated with medication prescribing errors. They undertook a systematic evaluation of every third prescribing error detected and averted by pharmacists in a 631-bed tertiary care teaching hospital between July 1, 1994, and June 30, 1995. Each error was concurrently evaluated for the potential to result in adverse patient consequences. Each error was retrospectively evaluated by a physician and two pharmacists and a factor likely related to the error was identified. They found a total of 2103 errors thought to have potential clinical importance during the 1-year study period. The overall rate of errors was 3.99 errors per 1000 medication orders, and the error rate varied among medication classes and prescribing services. A total of 696 errors met study criteria (i.e., errors with the potential for adverse patient effects) and were evaluated for a likely related factor. The most common specific factors associated with errors were decline in renal or hepatic function requiring alteration of drug therapy (97 errors, 13.9%), patient history of allergy to the same medication class (84 errors, 12.1%), using the wrong drug name, dosage form, or abbreviation (total of 79 errors, 11.4%, for both brand name and generic name orders), incorrect dosage calculations (77 errors, 11.1%), and atypical or unusual and critical dosage frequency considerations (75 errors, 10.8%). The most common groups of factors associated with errors were those related to knowledge and the application of knowledge regarding drug therapy (209 errors, 30%); knowledge and use of knowledge regarding patient factors that affect drug therapy (203 errors, 29.2%); use of calculations, decimal points, or unit and rate expression factors (122 errors, 17.5%); and nomenclature factors (incorrect drug name, dosage form, or abbreviation) (93 errors, 13.4%). The authors conclude that several easily identified factors are associated with a large proportion of medication prescribing errors. By improving the focus of organizational, technological, and risk management educational and training efforts using the factors commonly associated with prescribing errors, risk to patients from adverse drug events should be reduced.

Lazarou, J., B. H. Pomeranz, et al. (1998). “Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies.” JAMA **279**(15): 1200-5.

This article reports the results of a meta-analysis of studies on the incidence of serious and fatal adverse drug reactions (ADR) in hospital patients using four electronic databases. Data from 39 prospective studies from US hospitals were analyzed. To obtain the overall incidence of ADRs in hospitalized patients, the incidence of ADRs occurring while in the hospital plus the incidence of ADRs causing admission to hospital were combined. Errors in drug administration, noncompliance, overdose, drug abuse, therapeutic failures, and possible ADRs were excluded. Serious ADRs were defined as those that required hospitalization, were permanently disabling, or resulted in death. Based on this analysis, the overall incidence of serious ADRs was 6.7% (95% confidence interval [CI], 5.2%-8.2%) and of fatal ADRs was 0.32% (95% CI, 0.23%-0.41%) of hospitalized patients. The authors estimate that in 1994 overall 2216000 (1721000-2711000) hospitalized patients had serious ADRs and 106000 (76000-137000) had fatal ADRs, making these reactions between the fourth and sixth leading cause of death. The authors caution that their analysis needs to be viewed with circumspection because of heterogeneity among studies and small biases in the samples. Nevertheless, these data suggest that ADRs represent an important clinical issue.

3.1.3 Identifying and Addressing Errors in Healthcare Organizations

Incident Reporting

Battles, J. B., H. S. Kaplan, et al. (1998). “The attributes of medical event-reporting systems: experience with a prototype medical event-reporting system for transfusion medicine.” Archives of Pathology & Laboratory Medicine **122**(3): 231-8.

The authors report on the design and development of a prototype medical event-reporting system for use in transfusion medicine. Such a system can help to identify weaknesses in operating systems. An interdisciplinary panel of experts from aviation safety, nuclear power, cognitive psychology, artificial intelligence, and education and representatives of major transfusion medicine organizations participated in the development process. A working prototype event-reporting system was recommended and implemented. The system has seven components: detection, selection, description, classification, computation, interpretation, and local evaluation. Its unique features include no-fault reporting initiated by the individual discovering the event, who submits a report that is investigated by local quality assurance personnel and forwarded to a nonregulatory central system for computation and interpretation.

Cullen, D. J., D. W. Bates, et al. (1995). “The Incident Reporting System Does Not Detect Adverse Drug Events - a Problem for Quality Improvement.” Joint Commission Journal on Quality Improvement **21**(10): 541-548.

The authors compare the numbers and types of adverse drug events identified by nurse and physician reviewers versus hospital incident reports. All patient admitted to five patient care units (one medical intensive care unit, two surgical intensive care units, and two medical general care units) in one academic tertiary care hospital were studied between February and July 1993. The main outcome measures used were adverse drug events (ADEs) and IRs. Consensus voting was used by senior hospital administrators, nursing leaders, and staff nurses to determine whether an adverse drug event should have been reported and would have been reported. For the 54 adverse drug events identified by the study, the researchers found only 3 patients (6%) had a corresponding incident report submitted to the hospital's quality assurance program or called into the pharmacy hotline. One additional ADE was identified by an IR, but not by the ADE study. Of the 55 ADEs, 15 were preventable, and 26 were serious or life threatening, yet only 2 of the 26 led to an incident report. The three voting groups agreed that most ADEs justified an IR, but judged that in actual practice, an IR would infrequently have been filed. The authors conclude that voluntary reporting identified only a small fraction of ADEs. Using IRs for quality assurance/quality improvement will lead to significant bias when assessing quality of care.

Karson, A. S. and D. W. Bates (1999). “Screening for adverse events.” Journal of Evaluation in Clinical Practice **5**(1): 23-32.

The authors note that adverse events (AEs) in medical patients are common, costly, and often preventable. Development of quality improvement programs to decrease the number and impact of AEs demands effective methods for screening for AEs on a routine basis. In this article they describe the impact, types, and potential causes of AEs and review various techniques for identifying AEs. They evaluate the use of generic screening criteria in detail and describe a recent study of the sensitivity and specificity of individual generic screening criteria and combinations of these criteria. In general, the most sensitive screens were the least specific and no small sub-set of screens identified a large percentage of adverse events. Combinations of screens that were limited to administrative data were the least expensive, but none were particularly sensitive, although in practice they might be effective since routine screening is currently rarely done. As computer systems increase in sophistication sensitivity will improve. They also discuss recent studies that suggest that programs that screen for and identify AEs can be useful in reducing AE rates. They conclude that while tools for identifying AEs have strengths and weaknesses, they can play an important role in organizations' quality improvement portfolios.

Andrews, L., C. Stocking, et al. (1997). “An alternative strategy for studying adverse events in medical care.” Lancet **349**(9048): 309-313.

The authors report the results of an assessment of adverse events during the care of all patients admitted to three units of a large, urban teaching hospital events using a prospective, observational design. Ethnographers trained in qualitative observational research attended day-shift, weekday, regularly scheduled attending rounds, residents' work rounds, nursing shift changes, case conferences, and other scheduled meetings in three study units as well as various departmental and section meetings. They recorded all adverse events during patient care discussed at these meetings and developed a classification scheme to code the data. Data were collected about health-care providers' own assessments about the appropriateness of the care that patients received to assess the nature and impact of adverse events and how health-care providers and patients responded to the adverse events. Of the 1047 patients in the study, 185 (17.7%) were said to have had at least one serious adverse event; having an initial event was linked to the seriousness of the patient's underlying illness. Patients with long stays in hospital had more adverse events than those with short stays. The likelihood of experiencing an adverse event increased about 6% for each day of hospital stay. 37.8% of adverse events were caused by an individual, 15.6% had interactive causes, and 9-8% were due to administrative decisions. Although 17.7% of patients experienced serious events that led to longer hospital stays and increased costs to the patients, only 1-2% (13) of the 1047 patients made claims for compensation. Based on this study, the authors suggest that health care providers' own discussions of adverse events can be a good source of data for proactive error prevention.

Accreditation Systems

Joint Commission on Accreditation of Healthcare Organizations [JCAHO]. 2001. Revisions to Joint Commission Standards in Support of Patient Safety and Medical/Health Care Error Reduction. Oakbrook Terrace, IL: JCAHO. www.jcaho.org/standard/fr_ptsafety.html

This document outlines the patient safety standards adopted by the JCAHO for US hospitals. the standards focus on leadership effort to implement patient safety programs, identify and manage sentinel events, create a proactive strategy for identifying risks and reducing errors, and creating a performance improvement approach to error reduction.

Near Miss Systems

Barach, P. and S. D. Small (2000). "Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems." BMJ **320**(7237): 759-63.

Based on a search of the literature and interviews with directors of reporting systems and experts, the authors identified 25 non-medical incident reporting systems. These systems reported different types of data and varied in their definition and counting of adverse events. 12 of the systems are compared in terms of the types of information sought and the ways in which reporting occurred. Ten of the systems were confidential and two are anonymous. The authors identify a number of legal, cultural, regulatory and financial barriers to reporting adverse events and their impact on individuals, organizations and the broader society. They conclude that six factors are important in determining the quality of incident reports and the success of incident reporting systems: immunity (as far as practical); confidentiality or data de-identification (making data untraceable to caregivers, patients, institutions, time); independent outsourcing of report collection and analysis by peer experts; rapid meaningful feedback to reporters and all interested parties; ease of reporting; and sustained leadership support.

3.1.4 Strategies to Reduce Error

Training and Staffing

Beney, J., L. A. Bero, et al. (2000). “Expanding the roles of outpatient pharmacists: effects on health services utilisation, costs, and patient outcomes.” Cochrane Database of Systematic Reviews (3): CD000336.

The authors examine the information from existing health services research literature on the effect of expanding outpatient pharmacists' roles on health services utilization, costs, and patient outcomes. Specifically, they reviewed twenty five studies involving more than 40 pharmacists and 16,000 patients These studies indicate that utilization of pharmacists could decrease the rate of hospital and emergency room admissions as well as decreasing the use of other professionals. Improvements in the targeted patient condition were reported in 10 of 13 studies that measured patient outcomes but patients' quality of life did not seem to change. However, the authors note concerns about the generalizability of the studies, the poorly defined interventions, and the lack of cost assessments and patient outcome data, and indicate the need for more rigorous research to document the effects of outpatient pharmacist interventions.

Leape, L. L., D. J. Cullen, et al. (1999). “Pharmacist participation on physician rounds and adverse drug events in the intensive care unit.” JAMA **282**(3): 267-270.

This study measured the effect of pharmacist participation on medical rounds in the ICU on the rate of preventable adverse drug events (ADEs) caused by ordering errors. Seventy-five patients were randomly selected from each of 3 groups: all admissions to the study unit from February 1, 1993, through July 31, 1993 (baseline) and all admissions to the study unit (postintervention) and control unit from October 1, 1994, through July 7, 1995. In addition, 50 patients were selected at random from the control unit during the baseline period. A senior pharmacist made rounds with the ICU team and remained in the ICU for consultation in the morning, and was available on call throughout the day. Preventable ADEs were identified by review of medical records of the randomly selected patients during both preintervention and postintervention phases. Pharmacists recorded all recommendations, which were then analyzed by type and acceptance. The researchers found that the rate of preventable ordering ADEs decreased by 66% from 10.4 per 1000 patient-days (95% confidence interval [CI], 7-14) before the intervention to 3.5 (95% CI, 1-5, P<.001) after the intervention. In the control unit, the rate was essentially unchanged during the same time periods: 10.9 (95% CI, 6-16) and 12.4 (95% CI, 8-17) per 1000 patient-days. The pharmacist made 366 recommendations related to drug ordering, of which 362 (99%) were accepted by physicians. They conclude that the presence of a pharmacist on rounds as a full member of the patient care

team in a medical ICU was associated with a substantially lower rate of ADEs caused by prescribing errors.

System Design and Technology

Cooper, J. B., R. S. Newbower, et al. (1978). “Preventable anesthesia mishaps: a study of human factors.” Anesthesiology **49**(6): 399-406.

The authors report on a systematic approach to developing useful data on errors in anesthesia. A modified critical-incident analysis technique was used in a retrospective examination of the characteristics of human error and equipment failure in anesthetic practice. The objective was to uncover patterns of frequently occurring incidents that are in need of careful prospective investigation. Forty-seven interviews were conducted with staff and resident anesthesiologists at one urban teaching institution, and descriptions of 359 preventable incidents were obtained. Twenty-three categories of details from these descriptions were subjected to computer-aided analysis for trends and patterns. Most of the preventable incidents involved human error (82 per cent). Overt equipment failures constituted only 14 per cent of the total number of preventable incidents, but equipment design was indictable in many categories of human error, as were inadequate experience and insufficient familiarity with equipment or with the specific surgical procedure. Other factors frequently associated with incidents were inadequate communication among personnel, haste or lack of precaution, and distraction.

Leape, L. L., D. W. Bates, et al. (1995). “Systems-Analysis of Adverse Drug Events.” JAMA **274**(1): 35-43.

The authors identify and evaluate the systems failures that underlie errors causing adverse drug events (ADEs) and potential ADEs. They studied all admissions to 11 medical and surgical units in two tertiary care hospitals over a 6-month period examining errors, proximal causes, and systems failures. Errors were detected by interviews of those involved and classified according to proximal cause and underlying systems failure by multidisciplinary teams of physicians, nurses, pharmacists, and systems analysts. During this period, 334 errors were detected as the causes of 264 preventable ADEs and potential ADEs. Sixteen major systems failures were identified as the underlying causes of the errors. The most common systems failure was in the dissemination of drug knowledge, particularly to physicians, accounting for 29% of the 334 errors. Inadequate availability of patient information, such as the results of laboratory tests, was associated with 18% of errors. Seven systems failures accounted for 78% of the errors; all could be improved by better information systems. The authors conclude that hospital personnel are able to identify underlying systems failures. Systems changes to improve dissemination and display of drug and patient data should make errors in the use of drugs less likely.

Nolan, T. W. (2000). “System changes to improve patient safety.” BMJ **320**(18 March): 771-773.

Many errors are attributable to characteristics of human cognition, and their risk is predictable. Systems can be designed to help prevent errors, to make them detectable so they can be intercepted, and to provide means of mitigation if they are not intercepted. Tactics to reduce errors and mitigate their adverse effects include reducing complexity, optimizing information processing, using automation and constraints, and mitigating unwanted effects of change.

Proceedings of Re-engineering the Medication-use System: An Interdisciplinary Conference (2000). American Journal of Health System Pharmacy 57: 537-601.

The proceedings report on the results of a three-day meeting held to describe and analyze problems in medication systems. Participants identified key issues, potential system and technical solutions and ways to implement and evaluate these changes.

Computerized Medication and Decision Support Systems

Evans, R. S., S. L. Pestotnik, et al. (1998). “A computer-assisted management program for antibiotics and other antiinfective agents.” New England Journal of Medicine **338**(4): 232-8.

Optimal decisions about the use of antibiotics and other antiinfective agents in critically ill patients require access to a large amount of complex information. The authors have developed a computerized decision-support program linked to computer-based patient records that can assist physicians in the use of antiinfective agents and improve the quality of care. This program presents epidemiologic information, along with detailed recommendations and warnings. The program recommends antiinfective regimens and courses of therapy for particular patients and provides immediate feedback. They prospectively studied the use of the computerized antiinfectives-management program for one year in a 12-bed intensive care unit. During the intervention period, all 545 patients admitted were cared for with the aid of the antiinfectives-management program. Measures of processes and outcomes were compared with those for the 1136 patients admitted to the same unit during the two years before the intervention period. The use of the program led to significant reductions in orders for drugs to which the patients had reported allergies (35, vs. 146 during the preintervention period; $P<0.01$), excess drug dosages (87 vs. 405, $P<0.01$), and antibiotic-susceptibility mismatches (12 vs. 206, $P<0.01$). There were also marked reductions in the mean number of days of excessive drug dosage (2.7 vs. 5.9, $P<0.002$) and in adverse events caused by antiinfective agents (4 vs. 28, $P<0.02$). In analyses of patients who received antiinfective agents, those treated during the intervention period who always received the regimens

recommended by the computer program (n=203) had significant reductions, as compared with those who did not always receive the recommended regimens (n= 195) and those in the preintervention cohort (n = 766). The cost of antiinfective agents was lower for those treated during the intervention period (adjusted mean, $102 vs. $427 and $340, respectively; P<0.001), as were total hospital costs (adjusted mean, $26,315 vs. $44,865 and $35,283; P<0.001), and the length of the hospital stay days (adjusted mean, 10.0 vs. 16.7 and 12.9; P<0.001). The authors conclude that a computerized antiinfectives-management program can improve the quality of patient care and reduce costs.

Bates, D. W., L. L. Leape, et al. (1998). “Effect of computerized physician order entry and a team intervention on prevention of serious medication errors.” JAMA **280**(15): 1311-1316.

This study evaluated the efficacy of 2 interventions for preventing non-intercepted serious medication errors, defined as those that either resulted in or had potential to result in an ADE and were not intercepted before reaching the patient. The researchers compared all patients admitted to a stratified random sample of 6 medical and surgical units in a tertiary care hospital over a 6-month period, with all patients admitted to the same units and 2 randomly selected additional units over a subsequent 9-month period. The interventions were a physician computer order entry system (POE) for all units and a team-based intervention that included changing the role of pharmacists, implemented for half the units. Comparing identical units between phases 1 and 2, non-intercepted serious medication errors decreased 55%, from 10.7 events per 1000 patient-days to 4.86 events per 1000 (P=.01). The decline occurred for all stages of the medication-use process. Preventable ADEs declined 17% from 4.69 to 3.88 (P=.37), while non-intercepted potential ADEs declined 84% from 5.99 to 0.98 per 1000 patient-days (P=.002). When POE-only was compared with the POE plus team intervention combined, the team intervention conferred no additional benefit over POE. The authors conclude that physician computer order entry decreased the rate of non-intercepted serious medication errors by more than half, although this decrease was larger for potential ADEs than for errors that actually resulted in an ADE.

Monane, M., D. M. Matthias, et al. (1998). “Improving prescribing patterns for the elderly through an online drug utilization review intervention: a system linking the physician, pharmacist, and computer.” JAMA **280**(14): 1249-52.

Since some medications are less appropriate for older patients, systems approaches to improving pharmacy care may be an effective way to reduce inappropriate medication use. This study sought to determine whether a computerized drug utilization review (DUR) database linked to a telepharmacy intervention can improve suboptimal medication use in the elderly. A total of 23269 patients aged 65 years and older throughout the United States receiving prescription drug benefits from a large pharmaceutical benefits manager were

studied for a 12-month period. The researchers evaluated the use of provider prescribing through a computerized online DUR database using explicit criteria to identify potentially inappropriate drug use in the elderly. Computer alerts triggered telephone calls to physicians by pharmacists with training in geriatrics, whereby principles of geriatric pharmacology were discussed along with therapeutic substitution options. They found a total of 43007 alerts were triggered. From the 43007 telepharmacy calls generated by the alerts, they were able to reach 19368 physicians regarding 24 266 alerts (56%). Rate of change to a more appropriate therapeutic agent was 24% (5860), but ranged from 40% for long half-life benzodiazepines to 2% to 7% for drugs that theoretically were contraindicated by patients' self-reported history. Except for rate of change of beta-blockers in patients with chronic obstructive pulmonary disease, all rates of change were significantly greater than the expected baseline 2% rate of change. The researchers conclude that using a system integrating computers, pharmacists, and physicians improved prescribing patterns and quality of care and thus provides a population-based approach to advance geriatric clinical pharmacology.

Teich, J. M., P. R. Merchia, et al. (2000). “Effects of computerized physician order entry on prescribing practices.” Archives of Internal Medicine **160**(18): 2741-7.

This study assesses the impact of an inpatient computerized physician order entry system on prescribing practices. A time series analysis was performed at an urban academic medical center at which all adult inpatient orders are entered through a computerized system. When physicians enter drug orders, the computer displays drug use guidelines, offers relevant alternatives, and suggests appropriate doses and frequencies. The researchers found that for medication selection, use of a computerized guideline resulted in a change in use of the recommended drug (nizatidine) from 15.6% of all histamine(2)-blocker orders to 81.3% (P<.001). Implementation of dose selection menus resulted in a decrease in the SD of drug doses by 11% (P<.001). The proportion of doses that exceeded the recommended maximum decreased from 2.1% before order entry to 0.6% afterward (P<.001). Display of a recommended frequency for ondansetron hydrochloride administration resulted in an increase in the use of the approved frequency from 6% of all ondansetron orders to 75% (P<.001). The use of subcutaneous heparin sodium to prevent thrombosis in patients at bed rest increased from 24% to 47% when the computer suggested this option (P<.001). All these changes persisted at 1- and 2-year follow-up analyses. The researchers conclude that computerized physician order entry is a powerful and effective tool for improving physician prescribing practices.

Usability and Reliability Engineering

Cook, R. I. and D. D. Woods (1996). “Adapting to new technology in the operating room.” Human Factors **38**(4): 593-613.

New technologies may pose burdens as well as benefits on performance. To study the impact of new technology on skilled practitioner performance, the authors observed the introduction of a new, highly integrated, microprocessor-based physiological monitoring system for use in cardiac anesthesia. The new computer system differed from its predecessors in method of display, human interface, level of integration, and automation of functions. Practitioners experienced a series of problems with the new computer system. Computer system characteristics relative to the specific context of cardiac surgery created new cognitive and physical burdens that tended to congregate at times of high demand, the characteristic feature of clumsy automation. Practitioners as individuals and as a group tried to overcome these problems by adapting the computer system (system tailoring) and their behavior (task tailoring) as they learned about the interaction between characteristics of the new system and characteristics of their field of practice.

Gosbee, J. and I. Lin (2000). The Role of Human Factors Engineering in Medical Device and Medical Systems Errors. Clinical Risk Management: Enhancing Patient Safety. C. Vincent. London, BMJ Books.

The authors describe human factors engineering and its use in medical device, medical software and healthcare work area design. Poorly designed systems constitute latent errors. These design flaws include inadequate functional requirement definition, inadequate attention to user interface design, inadequate usability testing and inadequate training. The authors outline several preventative strategies that incorporate human factors engineering principles into risk management approaches. These include pre-purchase assessment of products, ongoing auditing of troublesome and risk-related devices and software. Human factors engineering expertise also helps in root cause analyses to understand the contribution of HFE factors to adverse events.

Cooper, J. B., R. S. Newbower, et al. (1984). “An analysis of major errors and equipment failures in anesthesia management: Considerations for prevention and detection.” Anesthesiology **60**(34-42).

Adaptations of the critical-incident technique were used to gather reports of anesthesia-related human error and equipment failure. A total of 139 anesthesiologists, residents, and nurse-anesthetists from four hospitals participated as subjects in directed or open-ended interviews, and 48 of them functioned as "trained observers." A total of 1,089 descriptions of preventable "critical incidents" were collected. Of these, 70 represented errors or failures that had contributed in some way to a "substantive negative outcome." From these incidents, ten potential strategies were developed for prevention or detection of incidents. The incidents most frequently reported included breathing circuit disconnections, drug-syringe swaps, gas-flow control errors

and losses of gas supply. Only 4% of the incidents with substantive negative outcomes involved equipment failure, confirming the previous impression that human error is the dominant issue in anesthesia mishaps. Among the broad categories of key strategies for mishap prevention were additional technical training, improved supervision, improved organization, equipment human-factors improvements, and use of additional monitoring instrumentation. The data also suggest that less healthy patients are more likely to be affected adversely by errors. It is suggested that, in future studies of anesthesia mortality and morbidity, untoward events should be classified according to preventive strategy rather than outcome alone as an aid to those who wish to apply the experience of others to lessen the risk in their individual practice.

Bogner, M. S. (1999). "Designing medical devices to reduce the liklihood of error." Biomedical Instrumentation & Technology **33**(108-113).

Bogner discusses the importance of the systems approach to ensure design from the perspective of the user in the context of its use. The systems approach can assist in identifying factors that need to be accommodated in device design and contribute to the reduction of error in healthcare.

Brown, S. L., M. S. Bogner, et al. (1997). "Human error and patient-controlled analgesia pumps." Journal of Intravenous Nursing **20**(6): 311-6.

Contrary to the prevailing attitude that error is a source of blame and punishment, errors can be an opportunity to discover a problem and institute activities to correct the problem to reduce the likelihood of recurrence. Often the source of error may be the system in which it occurred, not the person associated with it. Error in any domain, including healthcare, is difficult to identify and address because persons are reluctant to report errors for fear of self-incrimination. The discipline of human factors addresses issues related to human performance including use error. Human factors analysis provides insight into the etiology of use errors and how they can be reduced. Patient-controlled analgesia (PCA) pumps were developed to allow the patient or care-giver more control over pain relief. The PCA pumps can be programmed to deliver pain medication on a continuous basis, intermittently, or as a bolus. Selected adverse incidents involving PCA pumps that were due to use error and reported to the U.S. Food and Drug Administration are described. Finally, implications of those findings and the potential for reducing use error by applying considerations of the discipline of human factors are discussed.

Gosbee, J. (1999). Human Factors Engineering is the Basis for a Practical Error-in-Medicine Curriculum, First Workshop on Human Error in Clinical Systems. http://www.dcs.gla.ac.uk/~johnson/papers/HECS_99/Gosbee.html

Finley, G. A. and A. J. Cohen (1991). “Perceived urgency and the anaesthetist: responses to common operating room monitor alarms.” Canadian Journal of Anaesthesia **38**(8): 958-64.

Increasing numbers and varieties of electronic monitors are used in hospital operating rooms. Many of these are equipped with auditory alarms, which are loud, insistent, or irritating, and thus are frequently disabled by the anaesthetist. This study was planned to evaluate two components of auditory alarm design, which may influence the usefulness of the alarm: the perceived urgency of the auditory signal and its correlation with the urgency of the corresponding clinical situation. We also assessed the ability of practicing anaesthetists to identify the monitor or condition responsible for the alarm. Sixty-four anaesthetists attending a national conference assessed ten common operating room alarm sounds for perceived urgency. Results were compared with the urgency of the corresponding clinical situation as determined by 12 senior anaesthetists. Discrepancies between the clinical and perceived urgencies of several monitor alarms were found, and there was no correlation between the two measures. The subjects were also tested for their ability to identify the alarm sounds correctly. The overall correct identification rate was 33%, and only two monitors were correctly identified by more than 50% of the subjects. The results of this study have implications for design and use of auditory alarms in hospitals and suggest the need for further research.

Hyman, W. (1994). Errors in the Use of Medical Equipment. Human Error in Medicine. M. S. Bogner. Hillsdale, NJ, Lawrence Erlbaum**:** 327-347.

The author reviews technical and human factors related errors in the use of medical equipment. User error has been identified as a significant factor in medical device-related incidents, many of which, appear to have been preventable. User errors can be substantially prevented with proper attention to the user, the environment in which equipment is used, and the design of the device. The design issues include the need to incorporate features in a medical device that will facilitate its use and prevent foreseeable errors and misue under common user and environmental conditions. Product design should be based on a hierarchy focused on hazard elimination, provision of protective measures, provision of automated warnings, and lastly, training the user.

Decision Making and Cognitive Factors Influencing Safety

Lambert, B. L. (1997). “Predicting look-alike and sound-alike medication errors.” American Journal of Health-System Pharmacy **54**(10): 1161-1171.

Many mediation errors are caused by look alike and sound alike medication names, yet few procedures exist to ensure the safety of new drug nomenclature or to identify confusingly similar names from within existing databases. In this study, three automated measures of orthographic similarity were identified and the likelihood of a medication error was examined. These methods might be useful in the name approval process for medications.

Schull, M. J., L. E. Ferris, et al. (2001). “Problems for clinical judgement: 3. Thinking clearly in an emergency.” Canadian Medical Association Journal **164**(8): 1170-5.

The resuscitation of a patient in extremis is frequently characterized by chaos and disorganization, and is one of the most stressful situations in medicine. The authors reviewed selected studies from the fields of anesthesia, emergency medicine and critical care that address the process of responding to a critically ill patient. Individual clinicians can improve their performance by increased exposure to emergencies during training and by the incorporation of teamwork, communication and crisis resource management principles into existing critical care courses. Team performance may be enhanced by assessing personality factors when selecting personnel for high-stress areas, explicit assignment of roles, ensuring a common "culture" in the team and routine debriefings. Over-reliance on technology and instinct at the expense of systematic responses should be avoided. Better training and teamwork may allow for clearer thinking in emergencies, so that knowledge can be translated into effective action and better patient outcomes.

Redelmeier, D. A., L. E. Ferris, et al. (2001). “Problems for clinical judgement: Introducing cognitive psychology as one more basic science.” Canadian Medical Association Journal **164**(3): 358-360.

This article introduces a series on clinical judgement in medicine. Clinical judgement can be defined as the exercise of reasoning under uncertainty when caring for patients. The authors argue that physicians do not act solely on an evidenced basis or on an arbitrary basis. Instead, clinical judgement combines scientific theory, personal experience, patient perspectives and other insights. Examples of clinical judgement range from the monumental (such as whether to discontinue life-support for a patient on dialysis) to the banal (such as whether to discontinue a telephone call when on hold with nephrology). Common elements in this process include missing data, conflicting information, limited time and long-term trade-offs. They relate several problems with clinical judgement including the tendency for people to form opinions on the basis of early information and, once these opinions are formed, their reluctance to change their opinions even when given important new information. Research in nonmedical settings suggests that experts are particularly prone to persevere with their initial ideas and to change their minds less frequently than would be ideal. Because medicine is a highly collaborative effort clinical judgement can be seriously faulty if based on erroneous charting of vital signs, reports of radiology studies, messages about biopsy specimens or other misinformation. Each of us has the weighty problem of deciding how much time to spend trusting others and how much time to spend personally double-checking. Finally, they note that clinical judgment is not a substitute for knowledge. However, physicians can benefit from tools and approaches that enhance clinical judgment. Physicians need more effective ways to get patients to say what matters when recounting their medical history. Physicians need tools for interpreting numerical data and avoiding big mistakes. Physicians can additionally benefit from strategies designed for thinking clearly in an emergency. Some safeguards also seem worthwhile for interacting with administrators and others who may question clinical judgement by collecting crude statistics

Croskerry, P. (2000). “The cognitive imperative: thinking about how we think.” Academic Emergency Medicine **7**(11): 1223-31.

There are three domains of expertise required for consistently effective performance in emergency medicine (EM): procedural, affective, and cognitive. Most of the activity is performed in the cognitive domain. Studies in the cognitive sciences have focused on a number of common and predictable biases in the thinking process, many of which are relevant to the practice of EM. It is important to understand these biases and how they might influence clinical decision-making behavior. Among the specialties, EM provides a unique clinical milieu of inconstancy, uncertainty, variety, and complexity. Injury and illness are seen within narrow time windows, often under pressured ambient conditions.

These operating characteristics force practitioners to adopt a distinctive blend of thinking strategies. Principal among them is the use of heuristics, a form of abbreviated thinking that often leads to successful outcomes but that occasionally may result in error. A number of opportunities exist to overcome interdisciplinary, linguistic, and other historical obstacles to develop a sound approach to understanding how we think in EM. This will lead to a better awareness of our cognitive processes, an improved capacity to teach effectively about cognitive strategies, and, ultimately, the minimization or avoidance of clinical error.

Information Transfer

Failure to convey information about patients can compromise quality of care and lead to patient injuries due to failures to follow-up on positive diagnostic results, or to transfer information to other providers about needed services. Information about patients, their clinical condition and prescribed therapies needs to be transmitted quickly, completely and clearly between clinicians. Electronic patient records, better communication skills among clinicians and better communication technologies are needed to reduce the incidence of incomplete or inaccurate communication resulting in poor coordination of care and adverse events.

Kuehl, A. K., E. A. Chrischilles, et al. (1998). "System for exchanging information among pharmacists in different practice environments." American Journal of Health-System Pharmacy **55**(10): 1017-24.

A system for exchanging patient information among hospital, long-term-care (LTC), and ambulatory care pharmacies is described, and the influence of that system on pharmacist interventions is reported. Study sites consisted of three ambulatory care pharmacies, one LTC pharmacy, and one hospital in a small Midwestern city. Meetings were held by clinicians, the investigators, and hospital administrators to plan the information-exchange system. From January through June 1996, patients admitted to the hospital were checked to see if they came from a participating (source) pharmacy; if so, they were randomly assigned to experimental and control groups. The hospital requested preadmission information from the source pharmacy for experimental group patients and did not do so for control patients. After the information arrived, the hospital pharmacists could use it to identify and document drug therapy problems. When an experimental group patient was discharged, the hospital sent information to the appropriate source pharmacy. A total of 156 patients were enrolled in the study. Complete information transfer occurred for 75% of experimental group patients. Significantly more experimental group patients than control patients had at least one in-hospital pharmacist intervention recorded. Similarly, in the ambulatory care pharmacies (but not the LTC pharmacy) significantly more interventions per patient were documented for the experimental group. Hospital and ambulatory care pharmacists documented

more interventions for patients about whom information had been supplied than for patients for whom that information had not been supplied. No difference in intervention rates was observed for LTC pharmacists, who were already being supplied information by the LTC facilities about patients discharged from the hospital.

Cameron, B. (1994). “The impact of pharmacy discharge planning on continuity of care.” Canadian Journal of Hospital Pharmacy **47**(3): 101-9.

Historically, pharmacist participation in discharge planning has been minimal and has been frequently limited to last minute patient counseling. Hospital pharmacists can contribute to the continuity of patient care by summarizing changes made to a patient's therapy, their rationale, and future considerations in a discharge report to the family physician and/or community pharmacist. In this study, pharmacy discharge summaries were prepared for inclusion in the discharge report to the family physician. Summaries were also forwarded to the community pharmacist, where appropriate. Two types of pharmacy summaries completed were "Rationale for Inpatient Changes" (RIC) and "Recommendations for Future Changes" (RFC) summaries. Evaluation forms accompanying the summaries elicited very favourable responses. An independent review group of two physicians and two pharmacists rated the potential for reduction of patient mortality/morbidity as either marked, modest, minor or negligible; most of the summaries were evaluated as having a "modest" impact. Workload associated with preparation of pharmacy summaries would require additional pharmacy staff. Direct and indirect cost savings, including decreased drug costs and avoidance of drug complications and hospital readmissions, are associated with this service.

Rupp, M. T., M. DeYoung, et al. (1992). “Prescribing problems and pharmacist interventions in community practice.” Medical Care **30**(10): 926-40.

Interventions performed by 89 community pharmacists in 5 states to correct the prescribing problems they identified on new prescription orders were documented by trained observers. Pharmacists intervened to resolve a prescribing-related problem in 623 (1.9%) of 33,011 new prescription orders that were screened and dispensed during the study period. A panel of three expert evaluators concluded that 28.3% of the prescribing problems identified during the study could have caused patient harm if the pharmacist had not intervened to correct the problem. The rate at which pharmacists identified prescribing problems was negatively related to the number of prescriptions they dispensed per hour, suggesting that in pursuing distributive efficiency, some pharmacists may be exceeding their safe dispensing threshold. The authors recommend that the interprofessional system of oversight and verification (i.e., "checks and balances") in the delivery of pharmaceutical care in the community setting should be maintained and strengthened.

van Walraven, C. and E. Rokosh (1999). “What is necessary for high-quality discharge summaries?” American Journal of Medical Quality **14**(4): 160-9.

The objective of this study was to determine what physicians perceive to be necessary for high-quality discharge summaries. One-on-one surveys of 100 hospital-based physicians-in-training and community family physicians were conducted. Participants indicated the amount that 56 items contributed to discharge summary quality on a 15-category ordinal scale. Results were transformed to a continuous scale, extending from -6.6 ("item makes summary useless") through 0 ("item has no effect on discharge summary quality") to 10 ("item is so essential that summary is useless without it"). Quality decreased significantly when summary length exceeded 2 pages and when the delay from patient discharge to summary delivery increased. Summary content that increased quality most included admission diagnosis, pertinent physical examination findings and laboratory results, procedures and complications in hospital, discharge diagnosis, discharge medications, active medical problems at discharge, and follow up. With minor exceptions, hospital and family physicians agreed on contributors to summary quality. For this sample of physicians, summaries were of high quality when they were short, delivered quickly, and contained pertinent data that concentrated upon discharge information.

Del Mar, C. B. and R. G. Wright (1995). “Notifying women of the results of their cervical smear tests by mail: does it result in a decreased loss to follow-up of abnormal smears?.” Australian Journal of Public Health **19**(2): 211-3.

The authors undertook a prospective randomized intervention study of the proportions of women with abnormal cytology results who were lost to follow-up in 42 general practices in urban and rural Queensland, Australia over 26 weeks. Practices in the intervention group were provided with a redesigned cervical smear request form that allowed patients to provide an address for direct notification from the laboratory by mail. Satisfaction questionnaires sent to the general practitioners in the intervention group showed that most made at least some use of direct notification, and most felt it was worthwhile. For women with an initial result of cervical intraepithelial neoplasia (CIN), there was a loss to follow-up of 23 per cent (95 per cent confidence interval (CI) 11 to 39) among the control group compared to none in the intervention group (upper CI 7 per cent), a highly significant difference ($P < 0.001$). Mailing cervical screening results to women may reduce the loss to follow-up of those with CIN findings.

Communication, Coordination and Teamwork

Hackman, J. R. (1993). Teams, leaders and organizations: New directions for crew-oriented flight training. Cockpit Resource Management. E. L. Weiner, B. G. Kanki and R. L. Helmreich. San Francisco, Academic Press**:** 47-70.

Hackman reports results from several years of research on cockpit crews in different airlines. He reviews the development of crew resource management (CRM) training and its impact. The current challenge is to bring CRM and related organizational training and policies into better alignment with knowledge on what is required for team effectiveness. This will require training that enables practice and reinforcement of team skills, as well as a re-examination of the criteria used to select pilots and the ways that airlines schedule pilots and form them into teams. Additional training for captains in crew leadership is also necessary to enhance the abilities of crews to handle demanding, time-critical episodes. The next stage in the evolution of crew resource management must also deal with how organizations are supporting their crews, and in examining the impact of culture on the development of team-oriented pilot selection, training and management.

Helmreich, R. L. and Schaefer (1994). Team performance in the operating room. Human Error in Medicine. M. S. Bogner. Hillsdale, NJ, Lawrence Erlbaum**:** 225-253.

Human errors in operating rooms can result in patient injury or death. This chapter discusses several factors that influence the performance of operating room teams in a European teaching hospital. The authors also present results from a survey of OR personnel in the hospitals and observations on team performance. Organizational factors influencing performance include culture and structure, departmental efficiency, training, evaluation and quality control, work norms, role strain and conflict, and interdepartmental conflict. Environmental factors include operating room design, equipment, and patient characteristics. Team factors include team composition, group climate, norms and intergroup norms. Individual factors include attitudes, aptitude/intelligence, personality/motivation, knowledge/training, physical condition/fatigue and emotional state. The authors adapted questionnaires previously used with flight crews to assess the impact of attitudes on OR performance. Among the results was the finding that operating room personnel do not have a consensus view on how team activities should be led and coordinated. Respondents also varied in their preferred work styles. Anaesthesiologists, surgeons and anesthesia nurses most often preferred consultative leadership styles whereas surgical nurses preferred democratic styles. Many surgeons also endorsed the mild autocratic style. All groups reported a great discrepancy between the style they prefer and the one they encounter in the OR. The authors suggest that these finding suggest that the team concept may be impaired in this setting because many participants do not experience the type of leadership they consider optimal.

Risser, D., M. M. Rice, et al. (1999). “The potential for improved teamwork to reduce medical errors in the emergency department.” Annals of Emergency Medicine **34**: 373-384.

This article describes emergency department care work teams designed to improve team communication and coordination and reduce error. The core of this teamwork system is the teaching of teamwork behaviors and skills, development of teamwork habits, and creation of small work teams, all of which are key teamwork concepts largely drawn from successful aviation programs. Arguments for enculturating teamwork into ED practice are drawn from a retrospective study of ED malpractice incidents. Fifty-four incidents (1985-1996), a sample of convenience drawn from 8 hospitals, were identified and judged mitigable or preventable by better teamwork. An average of 8.8 teamwork failures occurred per case. More than half of the deaths and permanent disabilities that occurred were judged avoidable. Better teamwork could save nearly $3.50 per ED patient visit. Caregivers must improve teamwork skills to reduce errors, improve care quality, and reduce litigation risks

Gaba, D. M. (1994). Human Error in Dynamic Medical Domains. Human Error in Medicine. M. S. Bogner. Hillsdale, NJ, Lawrence Erlbaum Associates**:** 197-224.

Gaba's chapter focuses on sources of error for anaesthesia personnel. He examines how skilled anaesthetists conduct their work and the complex cognitive processes required for optimal performance. Key sources of problems in anaesthesia care include the nature of patient disease and condition, the impact of surgery on the patient, equipment failure, and the commission of surgical or anaesthesia error. Several strategies for preventing error are outlined including planning and precase evaluation of the patient. However since errors cannot be eliminated, "a substantial part of the anaesthetist's task, and a critical arena for optimal versus suboptimal performance, is the reactive detection and correction of the problems that will inevitably occur." Gaba outlines a problem solving model and strategies for managing workload to improve error detection and response.

Croskerry, P. (2000). "The feedback sanction." Academic Emergency Medicine **7**(11): 1232-8.

The emergency department (ED) is a complex environment. Its equilibrium, or homeostasis, is critically dependent on the continuous action of feedback processes. For any system to function efficiently, it needs to know the outcomes of specific actions in a consistent, reliable, and expeditious way. Historical attitudes and the unique operating characteristics of the ED have combined to impose sanctions on the proper provision of feedback. The following features have been identified as obstructive to optimal feedback operation: incomplete awareness of the significance of the problem, excessive time and work pressures, case infrequency, deficiencies in specialty follow-up, communication failures, deficient reporting systems for near-misses, error, and adverse events, biases in case review processes, shift changeover times, and shift work. The result is that clinicians, nurses, and trainees are working in conditions that are

suboptimal for the provision of safe care, as well as for learning and job fulfillment. Good feedback is a necessary condition for well-calibrated performance by individuals, and is integral to effective team function. More needs to be known about outcomes for feedback to work efficiently. The critical role of feedback in other aspects of ED function, such as education and human factors engineering, should be emphasized. The current interest in medical error and evolving attitudes toward a new culture of patient safety provide a unique opportunity to examine feedback and the critical role it plays in ED function. [References: 30]

Schenkel, S. (2000). “Promoting patient safety and preventing medical error in emergency departments.” Academic Emergency Medicine **7**(11): 1204-1222.

An estimated 108,000 people die each year from potentially preventable iatrogenic injury. One in 50 hospitalized patients experiences a preventable adverse event. Up to 3% of these injuries and events take place in emergency departments. With long and detailed training, morbidity and mortality conferences, and an emphasis on practitioner responsibility, medicine has traditionally faced the challenges of medical error and patient safety through an approach focused almost exclusively on individual practitioners. Yet no matter how well trained and how careful health care providers are, individuals will make mistakes because they are human. In general medicine, the study of adverse drug events has led the way to new methods of error detection and error prevention. A combination of chart reviews, incident logs, observation, and peer solicitation has provided a quantitative tool to demonstrate the effectiveness of interventions such as computer order entry and pharmacist order review. In emergency medicine (EM), error detection has focused on subjects of high liability: missed myocardial infarctions, missed appendicitis, and misreading of radiographs. Some system-level efforts in error prevention have focused on teamwork, on strengthening communication between pharmacists and emergency physicians, on automating drug dosing and distribution, and on rationalizing shifts. This article reviews the definitions, detection, and presentation of error in medicine and EM. Based on review of the current literature, recommendations are offered to enhance the likelihood of reduction of error in EM practice.

Sexton, J. B., E. J. Thomas, et al. (2000). “Error, stress, and teamwork in medicine and aviation: cross sectional surveys.” Bmj **320**(7237): 745-9.

The researchers surveyed operating theatre and intensive care unit staff about attitudes concerning error, stress, and teamwork and compared these attitudes with those of airline cockpit crew. Surveys were administered to staff in urban teaching and non-teaching hospitals in the United States, Israel, Germany, Switzerland, and Italy and major airlines around the world. A total of 1033 doctors, nurses, fellows, and residents working in operating theatres and intensive care units and over 30 000 cockpit crew members (captains, first

officers, and second officers) were surveyed. The researchers found that pilots were least likely to deny the effects of fatigue on performance (26% v 70% of consultant surgeons and 47% of consultant anaesthetists). Most pilots (97%) and intensive care staff (94%) rejected steep hierarchies (in which senior team members are not open to input from junior members), but only 55% of consultant surgeons rejected such hierarchies. High levels of teamwork with consultant surgeons were reported by 73% of surgical residents, 64% of consultant surgeons, 39% of anaesthesia consultants, 28% of surgical nurses, 25% of anaesthetic nurses, and 10% of anaesthetic residents. Only a third of staff reported that errors are handled appropriately at their hospital. A third of intensive care staff did not acknowledge that they make errors. Over half of intensive care staff reported that they find it difficult to discuss mistakes. The authors point out that medical staff reported that error is important but difficult to discuss and not handled well in their hospital. Barriers to discussing error are more important since medical staff seem to deny the effect of stress and fatigue on performance. Further problems include differing perceptions of teamwork among team members and reluctance of senior theatre staff to accept input from junior members.

Small, S. D., R. C. Wuerz, et al. (1999). “Demonstration of high-fidelity simulation team training for emergency medicine.” Academic Emergency Medicine **6**(4): 312-23.

Emergency medicine (EM) presents many cognitive, social, and systems challenges to practitioners. Coordination and communication under stress between and among individuals and teams representing a number of disciplines are critical for optimal care of the patient. The specialty is characterized by uncertainty, complexity, rapidly shifting priorities, a dependence on teamwork, and elements common to other risky domains such as perioperative medicine and aviation. High-fidelity simulators have had a long tradition in aviation, and in the past few years have begun to have a significant impact in anesthesiology. A national, multicenter research program to document the costs of teamwork failures in EM and provide a remedy in the form of an Emergency Team Coordination Course has developed to the point that high-fidelity medical simulators will be added to the hands-on training portion of the course. This paper describes an evolving collaborative effort by members of the Center for Medical Simulation, the Harvard Emergency Medicine Division, and the MedTeams program to design, demonstrate, and refine a high-fidelity EM simulation course to improve EM clinician performance, increase patient safety, and decrease liability. The main objectives of the paper are: 1) to present detailed specifications of tools and techniques for high-fidelity medical simulation; 2) to share the results of a proof-of-concept EM simulation workshop introducing multiple mannequin/ three-patient scenarios; and 3) to focus on teamwork applications. The authors hope to engage the EM community in a wide-ranging discussion and hands-on exploration of these methods.

Weiner, E. L., B. G. Kanki, et al. (eds.) (1993). Cockpit Resource Management. San Diego, Academic Press.

A detailed review of the history and development of Cockpit (now Crew) Resource Management Training and the history of human factors knowledge in aviation. The authors include several key individuals involved in this development, including Robert Helmreich, Earl Weiner, Richard Hackman and others.

Risk Management

Taylor-Adams, S. E., C. Vincent, et al. (1999). “Applying human factors methods to the investigation and analysis of clinical adverse events.” Safety Science **31**: 143-159.

Safety in medicine is a rapidly developing field. However, until recently it had been unclear how the skills and tools developed by human factors practitioners in other industries could be applied to medicine. This paper initially outlines the quality and safety programs healthcare systems have traditionally used to improve quality of care, before turning our attention to the epidemiology of medical adverse events. The development of clinical risk management is explained, with a focus on how human factors methods could be used to assist safety management in healthcare. A formal and systematic method to investigate and analyze clinical adverse events and near misses is described, which is based on traditional human factors methodologies. The investigation of clinical adverse events utilizes a semi-structured interview and performance influencing factor questionnaire, whilst Reason's organizational accident causation model is used to analyze adverse events (Reason, J.T., 1993. The human factor in medical accidents. In: Vincent, C. (Ed.), Medical Accidents. Oxford Medical Publications, Oxford). An obstetrics case, concerning a postpartum hemorrhage is used to show how the investigative methods can be used by a clinical risk manager to build up an accurate and detailed description of what happened and the organizational accident causation model can be used to systematically identify why errors occurred. Finally, the applicability and necessary modifications of human factors methods for use in medicine are discussed.

Vincent, C., S. E. Taylor-Adams, et al. (2000). “How to investigate and analyze clinical incidents: Clinical risk unit and association of litigation and risk management protocol.” BMJ **320**(18 March): 777-781.

Analyses of clinical incidents should focus less on individuals and more on organizational factors. Use of a formal protocol ensures a systematic, comprehensive and efficient investigation. The protocol reduces the chance of simplistic explanations and routine assignment of blame. Experience with the protocol suggests that training is needed for it to be used effectively. Analysis of incidents is a powerful method of learning about healthcare organizations. Organizational analyses lead directly to strategies for enhancing patient safety.

Quality Improvement Strategies

Leape, L., A. I. Kabcenell, et al. (2000). "Reducing Adverse Drug Events: Lessons from a Breakthrough Series Collaborative." Joint Commission Journal on Quality Improvement **26**(6): 321-331.

The authors report on the work of a group of healthcare organizations who worked collaboratively to implement strategies to reduce adverse drug events in their organizations using rapid cycle quality improvement methods. Some of the changes made included the specification of protocols for high risk medications such as heparin and coumadin, and the improved reporting of adverse medication events.

National Coalition on Health Care and Institute for Healthcare Improvement (2000). Reducing Medical Errors and Improving Patient Safety: Success Stories from the Front Lines of Medicine. Washington, DC, National Coalition on Health Care**.** 31 pp. http://www.nchc.org/releases/medical_errors.pdf

A series of profiles of institutions and organizations that have improved patient safety and reduced adverse events. The stories include brief descriptions of the work at Dana Farber Cancer Institute following the death of Betsy Lehman, the initiatives at the VH Health System to identify and reduce adverse events and the implementation of computerized order entry systems at Brigham and Women's Hospital in Boston.

Berwick, D. M. (1998). Taking Action to Improve Safety: How to Increase the Odds of Success. Keynote address at Annenberg Center for Health Sciences Conference on Enhancing Patient Safety and Reducing Errors in Health Care, Rancho Mirage, CA., November 1998. http://www.annenberg.net/mederrors/html/keynote.html

Berwick outlines the quality improvement and systems approach to reducing adverse events. Based on the work of the Institute for Healthcare Improvement on reducing adverse drug events and medical errors, Berwick identifies three key principles: preventing errors by reducing system complexity and other sources of error that have been identified by human factor experts and others; making errors more visible when they do occur through better communication and thoughtful automation; and error mitigation, reversing or recovering from errors that occur. Among the strategies for error mitigation are stocking of antidotes near patients at risk, better training through simulation and ensuring that equipment defaults to least harmful modes when it fails.

Spath, P. L. (2000). Reducing errors through work system improvements. Error Reduction in Health Care: A Systems Approach to Improving Patient Safety. P. L. Spath. San Francisco, Jossey-Bass**:** 199-234.

Spath outlines several general work system improvement strategies that reduce or mitigate the effects of human error. She argues that health care organizations need to first examine their systems and processes to identify where errors are likely to occur, and then match "expected error-causing situations with appropriate redesign solutions." These redesigns may eliminate error, reduce error occurrence, or minimize the consequences of error. Building on the work of Berwick, Leape and others, Spath identifies several general work system principles for reducing error, including simplification of work processes, reducing reliance on memory, improving access to information, using constraints and forcing functions, improving communication and decreasing reliance on vigilance. Spath also identifies important considerations in implementing automation as a strategy for reducing error and she cautions that while technology will make important contributions to safety, automation may also increase the opportunity for errors that have not been possible in the past.

Root Cause Analysis

Wald, H. and K. G. Shojania (2001). Chapter 5. Root Cause Analysis. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. K. G. Shojania, B. W. Duncan, K. M. McDonald and R. M. Wachter. Rockville, MD, Agency for Healthcare Research and Quality**:** 51-56.

The authors review the literature on root cause analysis (RCA). They note that while there is insufficient evidence in the medical literature to support RCA as a proven patient safety practice, it may represent an important qualitative tool that is complementary to other techniques employed in error reduction. When applied appropriately, RCA may illuminate targets for change, and, in certain health care contexts may generate testable hypotheses.

Williams, P. M. (2001). "Techniques for root cause analysis." Baylor University Medical Center Proceedings **14**(2): 154-157.

This article outlines several different techniques for root cause analysis as applied to an employee safety event in a Department of Pathology. The techniques include "Ask Why 5 Times, causal tree, and decision table.

Rex, J. H., J. E. Turnbull, et al. (2000). “Systematic root cause analysis of adverse drug events in a tertiary referral hospital.” Joint Commission Journal on Quality Improvement **26**: 563-575.

The authors discuss how root cause analysis techniques may be used to determine the underlying causes of adverse events. They discuss the use of these techniques to investigate a sentinel event in which a child died after receiving an overdose of digoxin.

In addition to the use of cause and effect diagrams, successful root cause analyses require creating a cultural change within the organization to permit staff to participate in investigating such incidents in a non-punitive environment. Over 29 months, 23 serious adverse drug events occurred in the hospital; root cause analyses were carried out on 18 of these events. Work environment and personnel-related root causes were the most important contributors to these events. Identification of these causes led to changes in daily operations, including changes in policy, development of forcing functions or constraints, and additional leadership.

Runciman, W. B., A. Sellen, et al. (1993). “The Australian Incident Monitoring Study. Errors, incidents and accidents in anaesthetic practice.” Anaesthesia & Intensive Care **21**(5): 506-19.

Human error is a pervasive and normal part of everyday life and is of interest to the anaesthetist because errors may lead to accidents. Definitions of, and the relationships between, errors, incidents and accidents are provided as the basis to this introduction to the psychology of human error in the context of the work of the anaesthetist. Examples are drawn from the Australian Incident Monitoring Study (AIMS). An argument is put forward for the use of contemporaneous incident reporting (eliciting relevant contextual information as well as details of use to cognitive psychologists), rather than the use of accident investigation after the event (with the inherent problems of scant information, altered perception and outcome bias). A classification of errors is provided. "Active" errors may be classified into knowledge-based, rule-based, skill-based and technical errors. Different strategies are required for the prevention of each type and it may now be useful to place more emphasis in anaesthetic practice on categories to which little attention has been directed in the past. "Latent" errors make an enormous contribution to problems in anaesthesia and several categories are discussed (e.g. environment, physiological state, equipment, work practices, personnel training, social and cultural factors). An approach is provided for the prevention and management of errors, incidents and accidents which allows clinical problems to be categorized, the relative importance of various contributing factors to be established, and appropriate preventative strategies to be devised and implemented on the basis of priorities determined from the AIMS data. Accidents cannot be abolished; however, an understanding

of the factors underlying them can lead to the rational direction of resources and effort to prevent them and minimise their effects.

Fernandes, C. M., R. Walker, et al. (1997). “Root cause analysis of laboratory delays to an emergency department.” Journal of Emergency Medicine **15**: 735-739.

The researchers’ objectives in this study were to measure the emergency department (ED)/laboratory TAT and other relevant laboratory processing and reporting times, and to identify root causes of laboratory delay. A flow chart was developed for the ordering, collecting, analyzing, and reporting of laboratory results. Time intervals were prospectively recorded for complete blood count (CBC) and K+ in a cross-sectional study, using the flow chart, and defined as follows: TAT was the interval from blood draw (BD) to ED report; BD time was the interval from order processing to BD; and order processing time was the interval from physician ordering to the unit coordinator processing the orders. Median times with interquartile ranges are reported. CBC TAT was 38 min (29-51.5), and K+ TAT 58 min (45-76.5). Order processing time was 7 min (4-15). The laboratory assistant BD time was 17 min (8-30) for CBC and 15 min (7.75-32.25) for K+ as compared to 0 min for a nurse, yet the venipuncture method (laboratory assistant technique) had a recollection rate of 1% (1/93) due to hemolysis vs. 20% (19/95) via the I.V. catheter (nurse technique). Of stat ED blood work, 24% was for admitted patients held in the ED. Laboratory reporting times are delayed with these root causes: laboratory assistant availability; recollection rate; volume of tests for ED admitted patients; and order processing time.

Latino, R. J. (2000). Automating Root Cause Analysis. Error Reduction in Health Care. P. L. Spath. San Francisco, Jossey-Bass**:** 155-178.

This chapter discusses the benefits of automating root cause analysis in healthcare organizations and identifies key attributes that need to be considered in evaluating software packages that perform this task. Automation of root cause analysis in other industries has improved the consistency of accident investigations and helped to ensure follow-up to prevent recurrence of similar incidents. The desirable features of root cause analysis software include both the review of past events and the assessment of potential events using methods such as Failure Modes, Effects, and Criticality Analysis (FMECA). The software should be simple to follow and use. It should guide the RCA team through the investigative process to select causes objectively. The software should be comprehensive, allowing users to integrate information from data collection, validation of hypotheses, and tracking improvements. In addition, software should support the RCA methods selected by the organization, should be flexible, have adequate reporting capabilities, be accompanied by

appropriate training and represent value to the organizations that need to carry out RCA activities.

3.1.5 Disclosure of Error

Hebert, P. C., A. V. Levin, et al. (2001). “Bioethics for clinicians: 23. Disclosure of medical error.” CMAJ **164**(4): 509-13.

In this article the authors review the literature on adverse events and medical errors and discuss the ethical, legal and practical aspects of whether and how they should be disclosed to patients. Ethics, professional policy and the law, as well as the relevant empirical literature, suggest that timely and candid disclosure should be standard practice. Candor about error may lessen, rather than increase, the medico-legal liability of the health care professionals and may help to alleviate the patient's concerns. Guidelines for disclosure to patients, and their families if necessary, are proposed.

Kraman, S. S. and G. Hamm (1999). “Risk Management: Extreme Honesty May be the Best Policy.” Annals of Internal Medicine **131**(12): 963-967.

This paper reviews a humanistic risk management policy that includes early injury reviews, steadfast maintenance of the relationship between the hospital and the patient, proactive full disclosure to patients who have been injured because of accidents or medical negligence and fair compensation for injuries. The financial consequences of this type of policy are not yet known; however, one Veterans Affairs medical center, which has been using this humanistic risk management policy since 1987 has had encouragingly moderate liability payments. The Department of Veterans Affairs now requires such a policy for all its facilities: therefore, comprehensive experience may be only a few years away.

Wu, A. W., T. A. Cavanaugh, et al. (1997). “To tell the truth: ethical and practical issues in disclosing medical stakes to patients.” Journal of General Internal Medicine **12**(12): 770-5.

Physicians have an ethical duty to disclose significant medical mistakes to their patients. The authors offer some practical suggestions for disclosing errors and adverse events, including who should decide whether to disclose, timing, what should be said, and facilitating disclosure of mistakes made by other physicians.

Wu, A. W., S. Folkman, et al. (1991). “Do house officers learn from their mistakes?” JAMA **265**(16): 2089-94.

Mistakes are inevitable in medicine. To learn how medical mistakes relate to subsequent changes in practice, we surveyed 254 internal medicine house officers and asked them to describe their most significant mistake and their response to it. Mistakes included errors in diagnosis (33%), prescribing (29%), evaluation (21%), and communication (5%) and procedural complications (11%). Patients had serious adverse outcomes in 90% of the cases, including death in 31% of cases. Only 54% of house officers discussed the mistake with their attending physicians, and only 24% told the patients or families. House officers who accepted responsibility for the mistake and discussed it were more likely to report constructive changes in practice. Residents were less likely to make constructive changes if they attributed the mistake to job overload. They were more likely to report defensive changes if they felt the institution was judgmental. Decreasing the workload and closer supervision may help prevent mistakes. To promote learning, faculty should encourage house officers to accept responsibility and to discuss their mistakes.

3.1.6 Legal and Ethical Issues

Organizational Culture and Safety

Carthey, J., M. de Leval, et al. (2001). “Institutional resilience in healthcare systems.” Quality Health Care **10**(1): 29-32.

Patient safety relies on developing more resilient cultures in healthcare organizations. The authors provide a useful checklist for assessing the resilience of such organizations.

Perrow, C. B. (1999[1984]). Normal Accidents: Living with High Risk Technologies. New York, Basic Books. Second edition.

Normal Accidents analyzes the social side of technological risk. Charles Perrow argues that the conventional engineering approach to ensuring safety--building in more warnings and safeguards--fails because systems complexity makes failures inevitable. He asserts that typical precautions, by adding to complexity, may help create new categories of accidents. (At Chernobyl, tests of a new safety system helped produce the meltdown and subsequent fire.) By recognizing two dimensions of risk--complex versus linear interactions, and tight versus loose coupling--this book provides a powerful framework for analyzing risks and the organizations that insist we run them.

Reason, J. (1997). Engineering a Safety Culture. Managing the Risks of Organizational Accidents. Aldershot, England, Ashgate Publishing: 191-222.

Reason outlines the components of a safety culture and discusses the steps necessary to create such a culture. He notes that a safety culture will also be a "just culture" where members share the understanding that there will be an appropriate balance between providing immunity to those who report actions that result from system failures, and identifying individuals in those infrequent situations who engage in unreasonably reckless, negligent or malevolent behaviors.

Helmreich, R. L. and A. C. Merritt. (1998). Culture at Work in Aviation and Medicine: National, Organizational and Professional Influences. Aldershot, UK: Ashgate.

The authors identify how culture influences safety, and report on studies of pilots and physicians attitudes toward safety and teamwork. They report on how Crew Resource Management (CRM) training has addressed professional cultural issues. They stress the parallels between the cockpit and the operating room, but note that aviation is considerably further ahead in addressing these issues.

Vaughn, D. (1996). The Challenger Launch Decision: Risky Technology, Culture and Deviance at NASA. Chicago, University of Chicago Press.

Vaughn analyzes the Challenger launch disaster, contradicting conventional interpretations of managerial wrong-doing. She presents an historical account focused on two questions: why did NASA continue launching with a design known to be flawed? And why did NASA launch the Challenger against the objections of engineers on the eve of the launch? Vaughn argues that the Challenger events demonstrate a "normalization of deviance" where social and environmental forces made it acceptable to make risky decisions. More broadly, Vaughn argues that mistakes, mishaps and disasters are influenced by social norms and structures. The "causes" of the disaster were located in the routinized nature of organizational life and the patterns of decision-making and culture that developed in NASA. The problem is not managerial mistakes, but a more complex set of structures and actions that are related to the sources of power and culture in this organization.

Weick, K. E. (2001). Organizational culture as a source of high reliability.. In K. E. Weick (eds.). Making Sense of the Organization Malden, MA, Blackwell Publishers**:** 330-344.

The author describes how the culture of an organization contributes to its ability to be safe and reliable. Traditional sources of high reliability such as training, structure, and redundancy need to be augmented by other practices such as storytelling and nurturing trust to assist in improving reliability.

Westrum, R. (1993). Cultures with Requisite Imagination. Pp. 401-416 in J. A. Wise, V. D. Hokin and P. Stager (eds.) Verification and Validation of Complex Systems: Human Factors Issues. Berlin: Springer-Verlag.

Westrum compares three types of cultures: pathological cultures, bureaucratic cultures, and generative cultures. Generative cultures encourage people to make their thoughts known, bureaucratic cultures ignore new ideas, and pathological cultures crush them. He relates examples of where pathological and bureaucratic cultures lead to major disasters, including the Hubble Space Telescope and the Bjork-Shiley heart value. Members of organizations with effective cultures are given a license to think and use it to probe into things that might go wrong. Such organizations often rely on many measures and possess technology “maestros”, a leader with high standards and a broad attention span.

Reason, J. (1998). “Achieving a safe culture: theory and practice.” Work and Stress **12**(3): 293-306.

This paper discusses four topics relating to safety culture, three theoretical and one practical. The first considers why it is that an unsafe culture is more likely to be involved in the causation of organizational rather than individual accidents. It is the pervasive nature of culture that makes it uniquely suitable for creating and sustaining the co-linear gaps in defenses-in-depth through which an accident trajectory has to pass. The second topic relates to pathological adaptations, and discusses two examples: the Royal Navy of the mid-nineteenth century and the Chernobyl reactor complex. The third issue deals with recurrent accident patterns and considers the role of cultural drivers in creating typical accidents. The final topic is concerned with the practical question of whether a safety culture can be engineered. It is argued that a safe culture is an informed culture and this, in turn, depends upon creating an effective reporting culture that is underpinned by a just culture in which the line between acceptable and unacceptable behaviour is clearly drawn and understood.

Leadership Roles

Berwick, D. M. and L. L. Leape (1999). “Reducing errors in medicine - It's time to take this more seriously.” British Medical Journal **319**(7203): 136-137.

A brief editorial that challenges healthcare leaders to match the achievements in safety in other industries such as aviation.

Reinertsen, J. L. (2000). “Let's talk about error: Leaders should take responsibility for mistakes.” British Medical Journal **320**(18 March): 730.

Reinertson calls for greater attention to healthcare errors, noting that all leaders have a responsibility to direct the attention of healthcare professionals and the community to this problem and to focus on its solution.

Ohlhauser, L. and D. P. Schurman (2001). “National Agenda: Local Leadership.” Healthcare Papers **2**(1): 77-78.

The authors argue that culture change is the key barrier to addressing error in health care. They believe that change must happen provincially, and that professional licensing bodies need to play a key role in these changes.

Conway, J. B. (2000). Strategies for Leadership: Hospital Executives and Their Role in Patient Safety. Chicago, IL, American Hospital Association**:** 12.

An assessment tool that list key activities for hospital leaders and others who wish to engage themselves and their organizations in improving patient safety

Weingart, S. (2000). “Making medication safety a strategic organizational priority.” Joint Commission Journal on Quality Improvement **26**(6): 341-348.

The author outlines the strategy of one organization in addressing medication safety and uses this experience to examine the changes and leadership necessary to achieve this goal.

Organizational Strategies

Knox, G. E., M. Kelley, et al. (1999). “Downsizing, reengineering and patient safety: numbers, newness and resultant risk.” Journal of Healthcare Risk Management **19**(4): 18-25.

Downsizing and reengineering may have harmful effects on patient care. These changes are undertaken in attempt to increase productivity or cut operational costs with results measured in these terms. Less often considered are potential detrimental effects on patient safety or strategies, which might be used to minimize these risks.

Reason, J. T. (1997). Managing the Risks of Organizational Accidents. Aldershot, England, Ashgate Publishing.

A seminal work that identifies the nature and sources of organizational accidents, the defenses against those accidents and strategies for creating safer organizations. Reason presents important ideas and approaches for identifying vulnerabilities, creating more effective defenses, and developing an organizational culture that enables safer operations.

Grabowski, M. and K. Roberts (1997). “Risk Mitigation in Large-Scale Systems: Lessons from High Reliability Organizations.” California Management Review **39**(4): 152-162.

A paper argues that attention should be turned away from single organizations to systems of organizations if they are to be managed in a way that reduces the potential for catastrophic outcomes in organizations. Risk mitigation measures for large-scale systems are derived from research on high reliability organizations (HRO). The paper focuses on characteristics similar to both types of systems - which include simultaneous autonomy and interdependence, intended and unintended consequences of behavior, long incubation periods during which problems can arise, and risk migration - and shows how risk mitigation principles that evolved from HRO research can be applied to large-scale systems.

Weick, K. and K. Roberts (1993). “Collective mind in organizations: Heedful interrelating on flight decks.” Administrative Science Quarterly **38**: 357-381.

High reliability depends on the development of what the authors term a “collective mind”. Based on research on naval carrier flight decks, the authors argue that safety is linked to team performance where vigilance is high and where individuals know and anticipate the actions of others. The team on the flight deck must understand the actions of all in order to work effectively.

Birkmeyer JD, Finlayson EV, et al. (2001). "Volume standards for high-risk surgical procedures: potential benefits of the Leapfrog initiative." Surgery **130**(3): 415-22.

The authors outline the rationale and method for the development of patient volume standards for 5 high risk surgical procedures. These standards are part of a broader effort by a large coalition of employers, the Leapfrog Group, aimed at improving hospital safety. This article outlines the sources of the standards using data from a US patient sample to estimate the total number of each of the 5 procedures - coronary-artery bypass graft, abdominal aortic aneurysm repair, coronary angioplasty, esophagectomy, and carotid endarterectomy - performed each year in hospitals in US metropolitan areas. They then projected the effectiveness of volume standards (in terms of relative risks of mortality) for each procedure using data from a published structured literature review. The analysis indicates that full implementation of the Leapfrog volume standards would save 2581 lives per year. Of the procedures, volume standards would save the most lives with coronary-artery bypass graft (1486), followed by abdominal aortic-aneurysm repair (464), coronary angioplasty (345), esophagectomy (168), and carotid endarterectomy (118).

3.1.7 Major Policy Papers and Reports on Healthcare Error and Patient Safety

A listing of key policy documents in Canada, the U.S., Australia and the United Kingdom that have influence patient safety initiatives. These documents have had a major impact in the development of patient safety and healthcare error initiatives in their respective countries.

Canadian Reports

Sinclair, C. M. (2000). Report of the Manitoba Pediatric Cardiac Surgery Inquest: An Inquiry into Twelve Deaths at the Winnipeg Health Science Centre in 1994. Winnipeg, Manitoba Provincial Court. Accessible at www.pediatriccardiacinquest.mb.ca (checked January 22, 2002)

A detailed and highly readable investigation into the deaths of 12 pediatric cardiac surgery patients at the Winnipeg Health Science Centre. Judge Sinclair's report details the organizational and system failures that led to the deaths. The Minister of Health for Manitoba created a Review and Implementation Committee which developed a detailed response to the report. (The response can be accessed at http://www.gov.mb.ca/health/cardiac.)

Commission of Inquiry on the Blood System in Canada (Krever Commission). (1997). Final Report. Ottawa: Public Works and Government Services.

The Krever Report offers a detailed overview of the events surrounding the tainted blood scandal of the 1980s, as well as an account of his findings from the testimonies of over 400 witnesses who appeared before the Commission. In his report, Justice Krever provides a series of fifty recommendations formed after hearing evidence from various provincial and national authorities and health officials, as well as from individuals who had been infected, or whose lives had been affected, by the contamination of the blood system. The report offers a notable comparison of the Canadian blood system with other international blood systems.

Reports from other jurisdictions

Kohn, L. T., J. M. Corrigan, et al., Eds. (1999). To Err is Human: Building a Safer Health System. Washington, DC, National Academy Press.

National Expert Advisory Group on Safety and Quality in Australian Health Care (1999). Implementing safety and quality enhancement in health care. Canberra, Australia, Commonwealth of Australia Department of Health and Aged Care**:** 49.

National Health Service [U.K.] (2000). An organisation with a memory: Report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer. Norwich, UK, Department of Health**:** 91.

National Patient Safety Foundation [US] (1999). Agenda for Research and Development in Patient Safety.

US. Quality Interagency Coordination Task Force (QuIC) (2000). Doing what counts for patient safety: Federal actions to reduce medical errors and their impact. Washington, DC: Quality Interagency Task Force. Available at www.quic.gov/report/toc.htm

President Clinton established a Task Force representing US federal department with responsibilities for healthcare. The Task Force report identifies was that these agencies can respond to the issues raised in the IOM report, *To Err is Human.*

United States General Accounting Office (GAO) (2000). Adverse Drug Events: The Magnitude of Health Risk is Uncertain Because of Limited Incidence Data. Washington, DC, GAO**:** 47.

3.1.8 Professional Education

Council on Graduate Medical Education (COGME) and National Advisory Council on Nurse Education and Practice (NACNEC) (2000). Collaborative Education to Ensure Patient Safety. Washington, DC, Bureau of Health Professions, Health Resources and Services Administration, US Department of Health and Human Services**:** 150. Available from http://www.bhpr.hrsa.gov/dn/nacnep/patientsafety.htm.

This volume presents papers developed by national advisory councils for medicine and nursing in the U.S. as part of an effort to enhance patient safety. The meeting resulted in five major findings: (1) Patient safety cannot be accomplished without interdisciplinary practice approaches. (2) Patient safety gains are unlikely to be achieved at a satisfactory pace in the absence of revolutionary changes. (3) Current system discontinuities need to be confronted towards the aim of building a true, safety-oriented system of care. (4) A significant cultural change in medicine and nursing is required to achieve the needed gains in patient safety. And, (5) Patient safety requires that patients become acculturated in the need to participate actively in their own health care. Several of the key readings are outlined below.

Headrick, LA. (2000). Learning To Improve Complex Systems of Care. pp. 75-88 in Collaborative Education to Ensure Patient Safety. Report to Secretary of US Department of Health and Human Services and Congress. Washington, DC: Health Resource and Services Administration, DHHS.

Kaplan, HS and JB Battles. Managing Error for System Improvement. pp. 34-46 in Collaborative Education to Ensure Patient Safety. Report to Secretary of US Department of Health and Human Services and Congress. Washington, DC: HRSA.

Wakefield M and ET O'Grady. (2000). Putting Patients First: Improving Patient Safety Through Collaborative Education. pp. 20-32 in Collaborative Education to Ensure Patient Safety. Report to Secretary of US Department of Health and Human Services and Congress. Washington, DC: Health Resource and Services Administration, DHHS.

Croskerry, P., R. L. Wears, et al. (2000). "Setting the educational agenda and curriculum for error prevention in emergency medicine." Academic Emergency Medicine **7**(11): 1194-200.

Graduate and postgraduate medical education currently teaches safety in patient care by instilling a deep sense of personal responsibility in student practitioners. To increase safety, medical education will have to begin to introduce new concepts from the "safety sciences," without losing the advantages that the values of commitment and responsibility have gained. There are two related educational goals for emergency medicine (EM). First to develop a group of safety-educated practitioners who can understand and implement safe practice innovations in their clinical settings, and will be instrumental in changing our professional culture. Second, EM must develop a group of teachers and researchers who can begin to deeply understand how safety is maintained in emergency care, develop solutions that will work in emergency department settings, and pass on those insights and innovations. The specifics of what should be taught are outlined briefly. Finally, careful attention will have to be paid to the way in which these principles are taught. It seems unlikely that a series of readings and didactic lectures alone will be effective. The analysis of meaningful cases, perhaps supplemented by high-fidelity simulation, seems to hold promise for more successful education in patient safety.

Barach, P. (2000). “Patient safety curriculum.” Academic Medicine **75**(5): 551-2.

The author outlines a three-part patient safety curriculum in the anesthesia residency programs affiliated with Harvard Medical School. The five major clinical challenges addressed were human error, error-reporting systems, systems assessment, human factors engineering, and realistic medical simulation. Part 1 of the curriculum consisted of putting over 600 residents through real-life simulated crisis scenarios enacted (since 1994) in a mock operating room, with debriefings and with didactics on critical incident management. Part 2 consisted of a confidential survey, approved by an Institutional Review Board, of house officers on the value of the simulator experience. Results from this survey demonstrated that the residents found the simulation and the safety curriculum to be integral to enhancing their education and improving their clinical skills and patient care. Part 3 consisted of creating an accredited one-month elective for residents focusing on the five clinical challenges we identified. The elective, using adult-learning principles, has two components: learning how to create simulated scenarios, how to work the simulator, and how to do debriefing of critical incidents; and the rest of the time is spent in independent study with guided reading material from the Simulation Center. Each resident is expected to create an original clinical scenario to be used for future clinical simulations.

Devitt, J., M. Kurrek , et al. (1997). “Testing the raters: inter-rater reliability of standardized anaesthesia.” Canadian Journal of Anaesthesia **44**(9): 924-8.

The authors assess the use of an anaesthesia simulator to provide a more structured and standardized evaluation of physician performance. The reliability of using the simulator for this purpose is not known. Two one-hour clinical scenarios were developed, each containing five anaesthetic problems. For each problem, a rating scale defined the appropriate score (no response to the situation: score = 0; compensating intervention defined as physiological correction: score = 1; corrective treatment: defined as definitive therapy score = 2). Video tape recordings, for assessment of inter-rater reliability, were generated through role-playing with recording of the two scenarios three times each resulting in a total of 30 events to be evaluated. Two clinical anesthetists, uninvolved in the development of the study and the clinical scenarios, reviewed and scored each of the 30 problems independently. The scores produced by the two observers were compared using the kappa statistic of agreement. The authors found that the raters were in complete agreement on 29 of the 30 items. There was excellent inter-rater reliability (= 0.96, $P < 0.001$). They conclude that the rating of video recordings of anaesthetist performance in a simulation setting can be used for scoring of performance. However, the validity of the scenarios and the scoring system for assessing clinician performance have yet to be determined.

3.1.9 Lessons From Other Industries

Amalberti, R. (2001). “The paradoxes of almost totally safe transportation systems.” Safety Science **37**(2-3): 109-126.

Safety remains driven by a simple principle: complete elimination of technical breakdowns and human errors. This article tries to put this common sense approach back into perspective in the case of ultra-safe systems where the safety record reaches the mythical barrier of one disastrous accident per 10 million events (10(-7)). Three messages are delivered: (1) the solutions aimed at improving safety depend on the global safety level of the system. When safety improves, the solutions used to improve the safety record should not be further optimized, they must continue to be implemented at present level (to maintain the safety health obtained), and supplemented further by new solutions (addition rather than optimization rationale); (2) the maintenance and linear optimization of solutions having dwindling effectiveness can result in a series of paradoxes eventually replacing the system at risk and jeopardizing the safety record obtained in the first place; and (3) after quickly reviewing ambiguities in the definition of human error and the development of research in this area, this article shows, through recent industrial examples and surveys, that errors play an essential role in the acquisition and effectiveness of safety, at individual as well as collective levels

Battles, J. B. (2001). “Disaster prevention: Lessons learned from the Titanic.” Baylor University Medical Center Proceedings **14**: 150-153.

Battles analyzes errors in the sinking of the Titanic and then compares these errors to those that occur in healthcare. He identifies organizational culture, the focus on individual blame and the failure to identify potential weaknesses in the system as key parallels. Latent errors make the greatest contribution to errors, and technological solutions are uncertain answers to averting the unexpected.

Maurino, D. E., J. Reason, et al. (1995). Beyond Aviation Human Factors: Safety in High Technology Systems. Aldershot, UK, Ashgate.

The authors discuss the contribution of human factors to aviation safety and discuss ways to manage these errors to minimize their incidence and impact. They outline the progress made in aviation safety from the pursuit of organizational strategies to improve flight crew coordination and communication.

Helmreich, R. L. and J. M. Davies (1997). "Anaesthetic simulation and lessons to be learned from aviation." Canadian Journal of Anaesthesia **44**(9): 907-12.

The authors review the use of simulators in anaesthesia training and compare this to the development and use of simulation in aviation. Simulation in anaesthesia is more suited to evaluating the skills of individuals, while aviation simulation tests both individual skills and team performance

Helmreich, R. L. (1997). "Managing human error in aviation." Scientific American **276**(5): 62-7.

Mistakes by flight crews contribute to more than two-thirds of aviation accidents. Training to enhance team performance may reduce potentially fatal errors. The FAA has moved to make crew resource management (CRM) training mandatory for flight crews at all major and regional airlines. Airlines have placed increased emphasis on selecting pilots who are not only technically competent but also show themselves able to function as members of a team. The lessons learned from aviation CRM and the data on the performance of flight crews under stress is being applied to other high risk professions, including medicine.

3.2 Mail Survey

3.2.1 Response Rates

The questionnaires were distributed through the mail to appropriate personnel and departments of 170 organizations across Canada (69 professional colleges and associations and 101 healthcare facilities). Overall, 48 completed questionnaires were returned by mail or fax (23 from colleges and associations and 25 from healthcare facilities). Table 1 outlines the responses of the survey. Overall, the response rate for the survey was 33%, the refusal rate for the survey was 4% and the estimated non-response was 63%.

Table 3. Response Rate

Questionnaire Status	Healthcare Facilities	Colleges and Associations	Overall
A. Initial Mailing	101	70*	171
B. Total Number of Completed Questionnaires	25	23*	48
C. Number of Incomplete Questionnaires	76	47	123
Reasons for Incomplete Questionnaires			
D. Questionnaire sent to incorrect person	4	2	6
E. Questionnaire sent to same person twice for two different organizations	2	0	2
F. Refusal – Completed Telephone Survey	0	3	3
G. Refusal – Received too late, too busy	4	2	6
H. Refusal – Felt not appropriate for organization or was not working long enough to complete	5	7	12
I. Unknown reason – no response	61	33	94
Response Rate = B/A-(D+E+F+H)	28%	39%	32%
Refusal Rate = G/A-(D+E+F+H)	4%	3%	4%
Estimated non-response = I/A-(D+E+F+H)	68%	57%	64%

*One organization was originally classified as a healthcare facility but asked to be sent a Colleges and Associations questionnaire as they thought the questions were more appropriate. As a result, they completed and returned a Colleges and Associations questionnaire instead of a Healthcare Facilities questionnaire. This is reflected in the totals for initial mailing.

Tables 3a and 3b outline the distribution of types of organizations providing responses to the mail survey. Respondents from all types of organizations responded to the mail survey.

Table 3a. Organization Type of Mail Survey Respondents

Characteristic	Healthcare Facilities – Respondents (N)	Colleges and Associations – Respondents (N)	Overall – Respondents N (Row %)	Total Valid N
Community Healthcare Centre (CHC)	3		3 (21%)	11
Community Hospital	5		5 (16%)	26
Homecare Organization	5	1*	6 (38%)	10
Large Teaching Hospital	5		5 (31%)	11
Long Term Care Facility	2		2 (17%)	10
Small Hospital	5		5 (21%)	19
Government Organization		1	1 (17%)	5
National Organization		7	7 (32%)	15
Professional Organization		6	6 (23%)	20
Professional College		8	8 (30%)	19
TOTAL	25	23	48 (33%)	146

*One organization was originally classified as a healthcare facility asked to be sent a Colleges and Associations questionnaire as they thought the questions were more appropriate. As a result, they completed and returned a Colleges and Associations questionnaire instead of a Healthcare Facilities questionnaire.

The range of response rates for each type of organization is lowest for community healthcare centres (16%), and long term care facilities and government organizations (17%), and highest for homecare organizations (38%). The distribution of individuals who indicated they were too busy to complete the survey was not linked to any one type of organization. Other reasons for non-response are not known.

All regions of Canada were represented by survey respondents; however, there was a higher representation from Ontario, Saskatchewan and Manitoba compared to other regions. For the purposes of this analysis government organizations were included with professional associations and colleges since they are not primarily healthcare delivery organizations.

Table 3b. Region of Mail Survey Respondents

Characteristic	Healthcare Facilities – Respondents (N)	Colleges and Associations – Respondents (N)	Overall – Respondents N(Row %)	**Total Valid N**
Atlantic	3	2	5 (23%)	22
Quebec	5	3	8 (27%)	30
Ontario	11	3	14 (45%)	31
Sask., Manitoba	2	3	5 (45%)	11
Alberta	2	4	6 (43%)	14
BC	2	1	3 (14%)	21
National		7	7 (41%)	17
TOTAL	25	23	48	146

3.2.1.1. Description of Non-Respondents: Results from the Follow-up Calls

The week of October 8th, participants who had not yet responded received a follow-up phone-call to encourage participation, and also to inquire about reasons for non-response. Those who received a questionnaire were given the option of mailing the questionnaire and additional materials to SWC in the pre-stamped, self-addressed envelope or faxing their response. Appendix G presents a response rate tree to show the response rate diagrammatically. The results from the follow-up phone-calls were as follows:

- Out of fifty-eight non-respondents who were left messages asking them to: a) complete the survey and fax or mail it to SWC, b) call or e-mail the project leader if they had lost the survey, and c) call or e-mail the project leader with reasons why they would or would not be completing the survey:
  - Fifty-four gave no response (6 CHCs, 16 Community Hospitals, 2 Government Organizations, 2 Homecare Organizations, 5 Large Teaching Hospitals, 4 LTC Facilities, 5 National Organizations, 4 Professional Organizations, 1 Professional College, 9 Small Hospitals), and
  - Four organizations returned a survey after the phone-calls - two were added for data analysis (2 Community Hospitals), and two were too late to be included in data analysis (1 Homecare Organization, 1 unknown - ID# was removed)
- Out of twenty-one non-respondents who were sent an e-mail message with the same requests as the telephone calls (see above - e-mails were sent to these organizations due to the success of contacting individuals in the telephone surveys by e-mail to set-up appointments):
  - There was no response from 20 organizations (3 Community Hospitals, 2 LTC Facilities, 3 National Organizations, 4 Professional Associations, 7 Professional Colleges, 1 Small Hospital).
  - One professional association replied to the e-mail but did not forward a questionnaire.
- Out of thirty-seven non-respondents who were contacted:

- Four non-respondents claimed they forwarded the survey to the appropriate person because they felt they were not the appropriate person (1 CHC, 1 Professional Association, 2 Small Hospitals). A follow-up phone-call was made to this person as well, but they did not respond to the message.
- Three non-respondents had already completed the telephone interview and did not feel it was necessary to complete the mail survey (2 National Organizations and 1 Professional College).
- Two non-respondents were identified as being a "duplicate" person - they worked for multiple organizations and did not feel they needed to complete the survey twice (1 Large Teaching Hospital and 1 Community Hospital).
- Eighteen non-respondents refused to complete the survey. The reasons given were:
  a) Hasn't worked there long enough to fill out survey (1 non-respondent - 1 Small Hospital).
  b) Not appropriate to the organization (11 non-respondents - 2 CHCs, 1 Government Organization, 2 Homecare Organizations, 2 National Organizations, 3 Professional Associations, 1 Professional College).
  c) Five non-respondents said they were too busy to complete the survey (1 Community Hospital, 1 Government Organization, 1 Homecare Organization, 1 Professional Association, 1 Large Teaching Hospital).
- Ten non-respondents requested another survey by fax. Out of these ten non-respondents:
  - Nine organizations did not complete a survey (1 Homecare Organization, 1 LTC Facility, 2 National Organizations, 2 Professional Colleges, 2 Small Hospitals, 1 CHC).
  - One organization completed a survey (1 Homecare Organization).

- Six non-respondents said the survey was sent to the incorrect person. There was an attempt to contact the correct person, but it was not successful (2 Small Hospitals, 1 Community Hospital, 1 LTC Facility, 1 Government Organization, 1 Large Teaching Hospital). The large teaching hospital said they may have been able to complete the survey but since it was sent to the incorrect person initially, they did not have the time.
- Five respondents were not able to be contacted (1 Professional Association, 1 Government, 1 Small Hospital, 1 LTC Facility, and 1 Homecare Organization).

3.2.2 Results of the Mail Questionnaire

What follows is a presentation of the results of the mail questionnaire. An analysis of the open-ended comments can be found in Appendix C.

3.2.2.1 Main Patient Safety Issues

Healthcare facilities and colleges and associations were asked what the main patient safety or healthcare errors issues they (or their organizations members) are facing today. The top themes by healthcare facilities and colleges / associations are shown in Table 4 followed by more detailed descriptions of these themes.

Table 4. Patient Safety or Healthcare Errors Identified by Survey Respondents

Theme	Healthcare Facilities	Colleges and Associations
Medication Errors	100% (N=25)	91% (N=21)
Falls and/or Injuries Due to Restraints	88% (N=22)	9% (N=2)
Other Accidental Injuries	32% (N=8)	-
Communication and Documentation Errors	24% (N=6)	87% (N=20)
Errors Related to Access/ Waiting	40% (N=10)	39% (N=9)
Abuse	24% (N=6)	9% (N=2)
Diagnostic Errors	4% (N=1)	39% (N=9)
Human Factors	12% (N=3)	39% (N=9)
Procedural Errors	36% (N=9)	13% (N=3)
Infections/Wounds	16% (N=4)	17% (N=4)
Competency Training/ Competency of Staff	20% (N=5)	9% (N=2)
Errors Due to Equipment Failure	16% (N=4)	4% (N=1)

- **Medication errors**: This theme includes all types of medication errors. Some of the respondents gave specific medication errors such as dose-related errors (incorrect dose, dose too late, dose missed), giving medication to the wrong patient, giving the incorrect medication to the patient, problem with handwriting recognition or label recognition.

- **Falls and/or injuries due to use of restraints:** This theme refers to falls and/or other injuries that may occur as a result of using restraint.
- **Other accidental injuries:** This theme refers to injuries that are caused by self-harm, nursing function and/or equipment failure.

- **Communication and documentation errors:** This theme included missing physician orders, miscommunication following organ donation, identification errors, and inappropriate care due to miscommunication, a miscommunication or lack of communication between physicians and clients, nurses and/or homecare providers and patients, physicians and nurses, physicians and physicians.

- **Errors related to access / waiting:** These responses refer to the inability to get treatment/services in a timely manner. Respondents consider this is a patient safety concern because of the danger of delays in treatment and deterioration of patients' status on waiting lists.

- **Abuse:** Abuse includes both verbal and physical abuse, and also abuse from both healthcare workers and other patients.

- **Diagnostic and lab errors:** Errors that occur during the patient's initial assessment or errors in lab results from inaccurate tests or loss of results.

- **Human factors**: This theme includes errors in medical judgment, errors due to lack of use of evidence and best practice, and errors due to stress/workload.

- **Procedural errors:** These errors include errors made in the care and treatment process, for example, IV systems are not double-checked.

- **Competency training**: Respondents are concerned that errors are being made because of deficiencies in staff education and training.

- **Equipment errors**: Patients are at risk due to malfunctioning equipment, or wrong equipment used.

- **Infections/Wounds:** These are "patient safety" concerns because they have to do with wounds or infections that may result in adverse outcomes for patients. Respondents listed both primary and secondary wounds and infections under this theme.

Other patient safety concerns include:

- Unexpected surgical events
- Unsafe / unhygienic environments in community
- Wandering patients – patients leaving the inpatient chronic care unit unattended
- Confidentiality of patient information
- Improper nutrition
- Mental health issues
- Hazards in the home

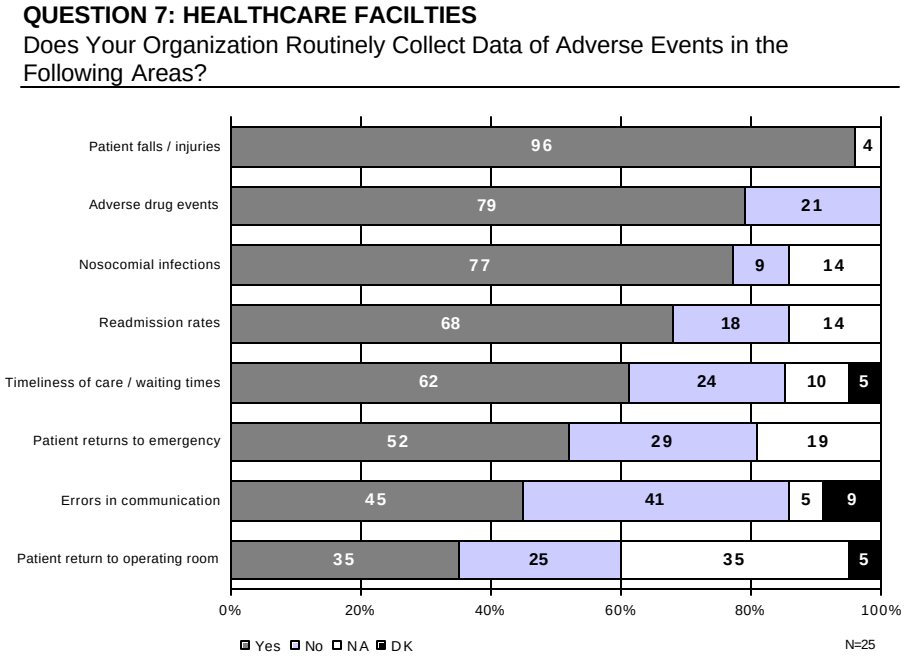
- Readmission rates

3.2.2.2. Data Collection and Use of Patient Safety and Healthcare Error Data

In the mail survey, healthcare facilities were asked whether they routinely collect data on adverse events in eight areas (see Figure 1 below). The main points are:

- Over 75% of respondents collect information in traditional areas of incident reporting including patient falls (96%), adverse drug events (79%) and nosocomial infections (77%).
- Less than 50% of respondents collect information on errors in communication (45%) and patients returning to the operating room (35%).

Figure 1.



*It should be noted that the sample size is 25; the percentages reflect the number in the sample.

3.2.2.3 How Data are Collected and Used

Respondents were also asked to describe how healthcare error data are collected and used. These results were analyzed for each type of data collected. The full list of data collection methods can be found in Appendix D.

The most common data collection methods include:

- Incident reports
- Audits/review of health records
- Rounds
- Tracking/surveillance systems (infections, OR)
- Admission Discharge and Transfer System (ADT)
- Utilization data
- Statements of discharges and re-admissions
- Client database reports
- CIHI database/reports
- Regular QA activity
- Patient complaints
- Documented in charts
- Wait lists/times
- Identification and monitoring of internal indicators
- Data collected from lab results

Data are most often collected using paper forms, documented in patient charts, or through special reports. Some organizations have automated data collection but this does not appear to be the norm. There was mention of using existing sources of data like the CIHI database, lab results and utilization data from administrative records and external reports, for example, the Western Canadian Wait List Project.

Most organizations indicated that the data collected are reviewed, but who reviews the data varies between organizations and depends on the type of data. In some cases data are aggregated and shared with management, QA committees, or practitioners. Results were unclear about whether front line staff regularly received aggregated data and how often the data were reviewed (quarterly, yearly, etc.).

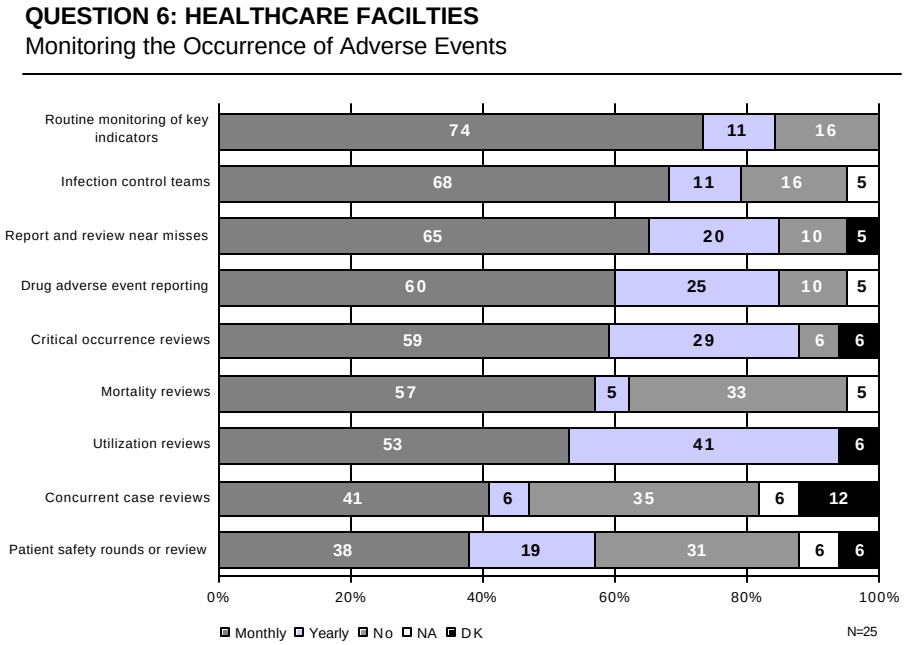
Many open-ended comments discussed the ‘reporting’ of data. Results were unclear regarding how the data were used to prevent future incidences or to do quality improvement projects.

3.2.2.4 Monitoring

Healthcare facilities monitor the occurrence of adverse events through a variety of mechanisms. The following chart shows if and how often healthcare facilities monitor the occurrence of adverse events. The main points are:

- Over 60% of respondents monitor adverse events monthly through monitoring of key indicators, infection control teams, reporting and reviewing of near misses, and drug adverse event reporting.
- Fifty-three percent (53%) of respondents monitor adverse events yearly through utilization reviews.
- Fewer organizations monitor adverse events through monthly utilization reviews (53%), mortality reviews (57%), concurrent case reviews (41%), and patient safety rounds (38%).

Figure 2.

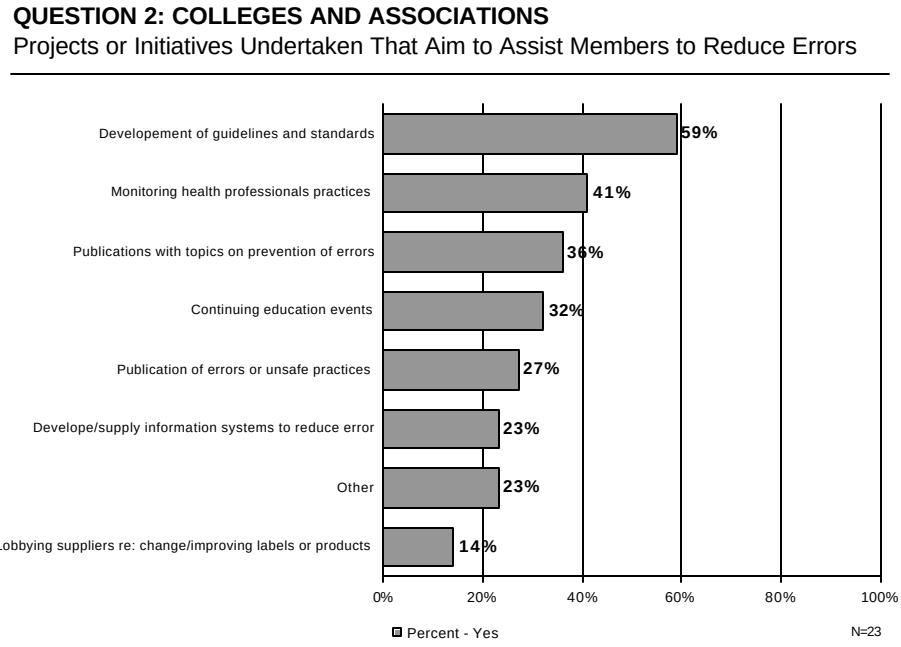


*It should be noted that the sample size is 25; the percentages reflect the number in the sample.

3.2.2.5 Current projects and initiatives

Respondents were asked to choose from a list of projects or initiatives that have been undertaken in their facilities to reduce errors or have aimed to help members of colleges and associations to reduce errors. These results are reported separately for the two types of organizations: colleges and associations and healthcare facilities.

Figure 3.



*It should be noted that the sample size is 23; the percentages reflect the number in the sample.

The main points are:

- The majority of Colleges and Associations have developed guidelines and standards to assist members to reduce errors. Second to this initiative are monitoring health professionals and publications with topics on the prevention of error.
- Few (14%) of respondents have lobbied suppliers regarding the change or improvement of labels or products.

"Other" projects or initiatives that have been undertaken to help members of colleges and associations to reduce errors are:

- Participating in the Canadian Coalition on Medication Incident Reporting and Prevention (CCMIRP)
- Catalyst to develop policy

- Nurse substance misuse: rehabilitative focus and support for members
- A booklet on Preventing and Managing Errors relative to medications in pharmacy
- Facilitation of the development/enhancement of structures to support health districts in improving patient safety
- Facilitation of educational opportunities and resources
- Annual reports on the number & type of client concerns
- Projects to address root causes
- Development of a national collaborative framework.

Colleges and associations were also asked how items mentioned above are contributing to improved patient safety and the reduction of healthcare errors. The following main themes emerged from their responses:

- **Standards and guidelines:** 62% (N=15) are contributing to improved patient safety by giving a framework of reference for healthcare professionals, providing guidance and outlining important policies and procedures, how to question unsafe practice, how to identify adverse events, and what are the expectations for safe and ethical care.

- **Education:** 57% (N=13) are contributing to patient safety by addressing issues about patient safety at conferences and meetings, providing feedback to physicians on prevention, raising awareness in the public and among healthcare workers, and keeping healthcare workers up-to-date regarding professional responsibilities.

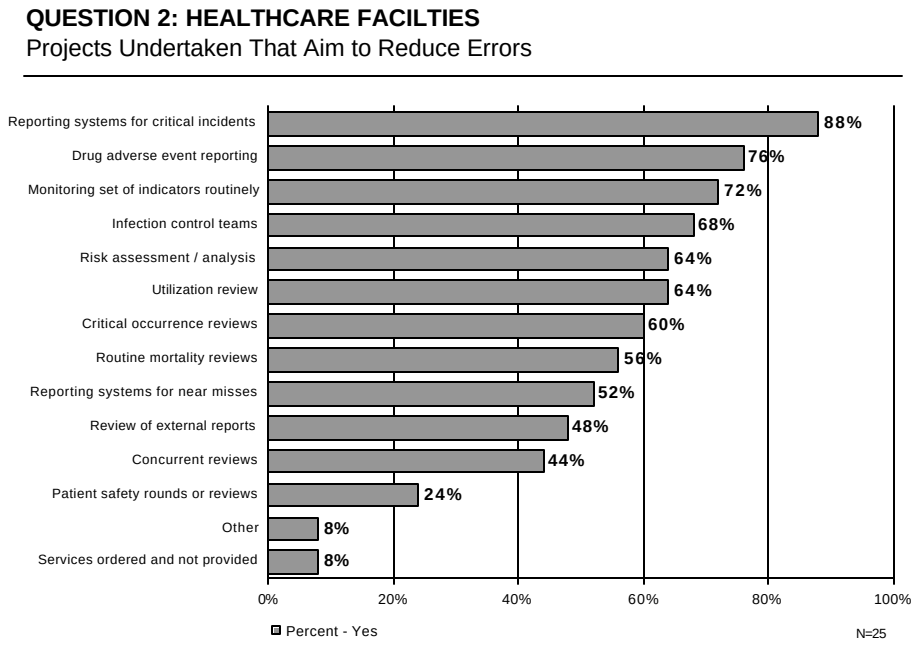
- **Policy Development:** 48% (N=11) are contributing to patient safety by providing rules for healthcare professionals to follow.

Professional associations and colleges indicated that these efforts were contributing to patient safety through:

- Increased accountability
- Collaborations with other organizations
- Credentialing (determining what credentials are needed for specific roles)
- Increased funding opportunities
- Quality improvement
- Improved technology
- Monitoring drug utilization patterns
- Understanding the problem

In a similar vein, healthcare facilities were asked to choose from a list of projects that have been undertaken in their organization that aim to reduce errors. The results are in the following chart.

Figure 4.



*It should be noted that the sample size is 25; the percentages reflect the number in the sample.

The main points are:

- The top types of projects that healthcare facilities have undertaken are reporting systems for critical incidents (88%), drug adverse event reporting (76%), and routine monitoring of set indicators (72%).
- Less than 10% of healthcare facilities have undertaken projects that look at services that are ordered but not provided, and only 24% of facilities do patient safety rounds or reviews.

Other projects that were undertaken by facilities include:

- Reviewing any equipment malfunction and other issues involved in a code error or incident
- Falls alert protocol
- Reviewing incident reports to resolve and prevent occurrence of medication incidents
- Provision / expansion of IV drug administration system
- Introduction of Pyxis automated drug distribution system
- Introduction of MAR (medication administration record)
- Review of policy and procedure and changes to policy and procedure

- Site inspections (Occupational Health and Safety Committee)

When asked whether these projects led to reduction in the number of errors and adverse events, 60% of healthcare facilities said “Yes”, 8% said “No”, and 32% said they “Didn’t Know.”

When asked how errors were reduced, the following themes emerged:

- **Policy / protocol / procedure** (28%, N=7)**:** This theme includes the development of policies and procedures through guidelines, case reviews, protocols, and standardization of systems processes.

- **Education, Information and Dissemination** (12%, N=3)**:** Education has helped to reduce errors by promoting compliance in reporting errors, and training staff in how to use new equipment.

- **Communication** (8%, N=2): One of the respondents suggested that their monthly newsletter has contributed to a reduction in error and adverse events.

- **Quality improvement / root cause analysis / process change** (24%, N=6)

- **Increased reporting** (12%, N=3)

Other items mentioned included:

- Improved supervision from senior team members
- Medication assistance programs
- Polypharmacy reviews

3.2.2.6 Documentation

Thirteen respondents said they had some policy or other documentation concerning their work in the area of patient safety and healthcare error. Five respondents said they were willing to share this documentation. For a list of documents that were forwarded through the mail and telephone surveys, please see Appendix B.

3.2.2.7 Future Projects and Initiatives

Both colleges and associations and healthcare facilities were asked whether they have other plans to initiate new efforts or extend current activities to reduce errors and adverse events or to assist members/profession in reducing errors and adverse events.

The top themes listed in descending order of frequency by healthcare facilities and colleges and associations are shown in the following table (Table 5).

Table 5. Future Projects and Initiatives for Healthcare Facilities and Colleges/Associations

Healthcare Facilities	Colleges and Associations
• Work on reporting systems (33%, N=8) • Quality improvement activities (29%, N=7) • Comprehensive organization / Started planning (25%, N=6) • Review teams for specific issues (25%, N=6) • Client survey / involvement (13%, N=3) • Training (8%, N=2) • Credentialing (8%, N=2) • Culture shift (4%, N=1)	• Education (30%, N=7) • Standards and guidelines (30%, N=7) • Policy development (26%, N=6) • Risk Management (13%, N=3) • Technological solutions (13%, N=3) • Publication (8%, N=2) • Other: Workshops, discussions about funding, committee participation

- **Work on reporting systems:** Examples include chart reviews, audits, and developing a common reporting system for all facilities within a district, electronic systems.

- **Quality improvement activities:** This theme includes best practice teams, improving utilization management, doing indicator analysis, improving work with the risk management departments, and tracking.

- **Comprehensive organization / start planning**: This theme includes development of comprehensive patient safety plans, development of an ethics committee, integration with the Achieving Improved Measurement (AIM) standards of CCHSA, and plans for long term approaches to patient safety.

- **Client survey involvement:** Respondents plan on using newsletters to involve clients, and study the clients' experience with patient safety issues.

- **Standards and guidelines:** These colleges and associations are planning to refine and up-date guidelines and to share information related to guidelines.

- **Policy development:** Three of the colleges and associations are working with the Royal College of Physicians and Surgeons of Canada regarding policy development for a national strategy for patient safety.

- **Risk Management:** This theme includes audits and the development of a quality council.

- **Technological solutions:** Some respondents are planning to work on systems improvements**.**

3.2.2.8 Strategy in Patient Safety

Healthcare facilities were asked what strategies they use to encourage error reporting. The top themes listed in descending order of frequency are:

- Policy (48%, N=12)
- Education (48%, N=12)
- Non-punitive reporting (40%, N=10)
- Follow-up action (16%, N=4)
- Improving reporting process (16%, N=4)

Other answers included:
- Accreditation self assessment
- Confidentiality
- Language change
- No bureaucracy
- Open communication, personal relationships
- Risk management as a resource to support staff
- Supervision by senior staff
- Quality improvement efforts

3.2.2.9 Other Ways to help to Identify Errors

Both colleges and associations and healthcare facilities were also asked what other aspects of the way an organization operates would help to identify errors and improve patient safety. The top themes that emerged from this question are shown below in Table 6:

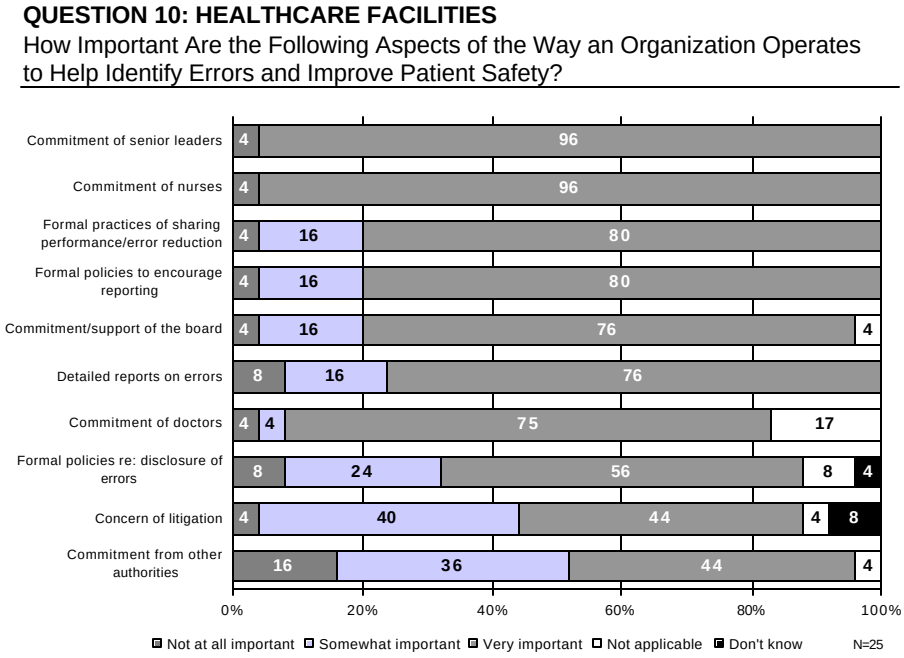
Table 6. Aspects of the Way an Organization Operates that Would Help to Identify Errors and Improve Patient Safety

Healthcare Facilities	Colleges and Associations
• Culture change (32%, N=8)	• Culture change (26%, N=6)
• Improve system / Process design (24%, N=6)	• Improve system / Process design (48%, N=11)
• Teamwork / Involving staff (32%, N=8)	• Teamwork / Involving staff in process (17%, N=4)
• Communicating with patients (24%, N=6)	• Improve communication (17%, N=4)
• Information technology (16%, N=4)	
• Education (16%, N=4)	• Policy development and education (22%, N=5)
• Improve resources and staffing (12%, N=3)	
• Improve reporting structure (8% N=2)	• Improve reporting structure (26%, N=6)
• Other : adherence to core values, accountability, professional protection (16%, N=4)	• Other : (improve legislation, improve overall organization (8%, N=2)

3.2.2.10 Important Aspects in Identifying Errors and Improving Patient Safety

Colleges and associations and healthcare facilities were asked how important certain aspects of organization operations are to help identify errors and improve patient safety. The following charts show the results for healthcare facilities and colleges and associations separately.

Figure 5.



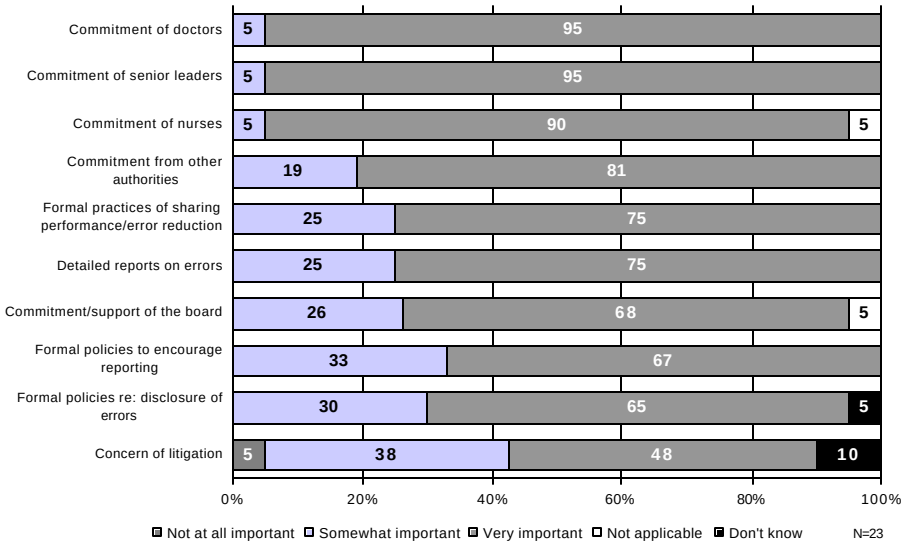
*It should be noted that the sample size is 25; the percentages in the chart reflect the number in the sample.

The main points for healthcare facilities are:

- The most important aspects of the way an organization operates to help identify errors and improve patient safety are commitment of Senior Leaders and commitment of nurses (both were rated 96% “very important”).
- Most of the aspects on the list were give high ratings of importance.
- The less important aspects were concerns about litigation and formal policies to encourage reporting.

Figure 6.

QUESTION 10: COLLEGES AND ASSOCIATIONS
How Important Are the Following Aspects of the Way an Organization Operates to Help Identify Errors and Improve Patient Safety?



*It should be noted that the sample size is 23; the percentages in the chart reflect the number in the sample.

The main points for colleges and associations are:

- The most important aspects of the way an organization operates to help identify errors and improve patient safety are commitment of doctors, commitment of senior leaders and commitment of nurses (all were rated 90% or more “very important”).
- Most of the aspects on the list were give high ratings of importance.
- The lesser important aspects were concerns about litigation and formal policies regarding the disclosure of error.

3.2.2.11 Barriers/Challenges

All respondents were asked what barriers or challenges exist in their organization or their members'/professions' organizations that make identifying or reporting errors and promoting safety difficult. Themes that emerged from the responses are shown in Table 7 below:

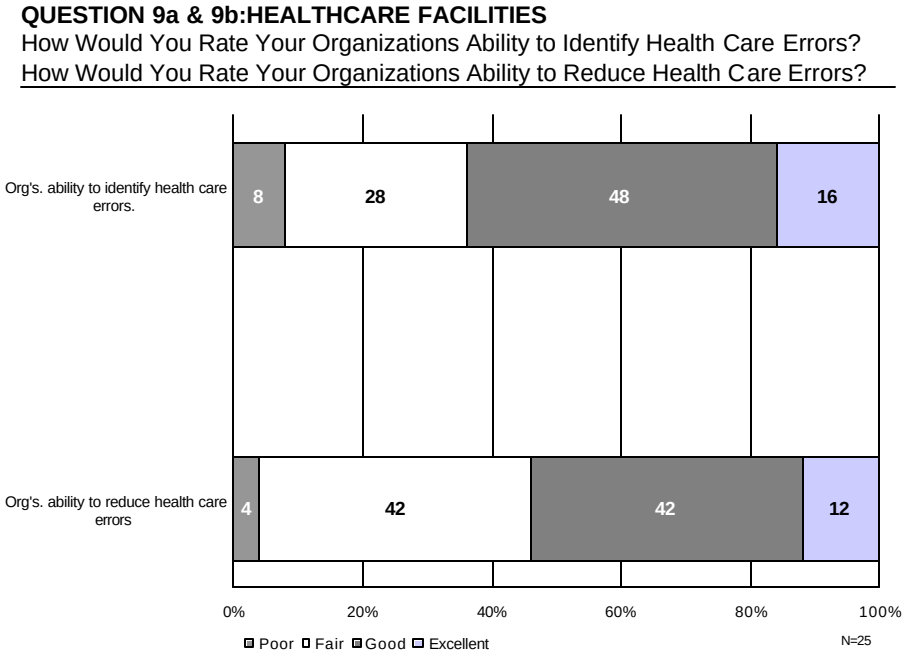
Table 7. Barriers and Challenges that exist to make Identifying or Reporting Errors and Promoting Safety Difficult

Healthcare Facilities	Colleges and Associations
• Culture (including fear of reprisal, blame culture and culture of "doctor-god") (72%, N=18)	• Culture (including fear of reprisal, blame culture and culture of "doctor-god") (48%, N=11)
	• Legislation / regulation / jurisdiction (63%, N=15)
• Resources and staffing (28%, N=7)	• Resources and staffing (35%, N=8)
• Teamwork / Communication (28%, N=7)	• Communication / understanding the issue (22%, N=5)
• Lack of Time (20%, N=5)	
• Competing priorities (12%, N=3)	• Leadership at all levels (17%, N=4)
• Reporting structure (4%, N=1)	• Reporting structure (13%, N=3)
• Technology (12%, N=3)	
• Accountability (4%, N=1)	• Accountability (4%, N=1)
• Other: System / Process (4%, N=1) Confidentiality (4%, N=1)	

3.2.2.12 Quality of patient safety

Healthcare facilities were asked to rate their organization's ability to identify and reduce healthcare errors. The following chart shows these results.

Figure 7.



*It should be noted that the sample size is 25; the percentages in the chart reflect the number in the sample.

The main points are:

- Overall, healthcare facilities are positive about their patient safety efforts, but feel there is room for improvement (32% rated their ability to identify errors as Fair or Poor; 44% rated their ability to reduce error as Fair or Poor).
- Sixteen percent (16%) of healthcare facilities rated their ability to identify healthcare errors as "Excellent" and 48% rated their ability as "Good".
- Twelve percent (12%) of healthcare facilities rated their ability to reduce healthcare errors as "Excellent" and 44% rated their ability as "Good".

3.3 Telephone Interviews

3.3.1 Description of Respondents

Initially, 46 leaders in patient safety and healthcare error were identified by key informants across Canada. After the interviewing process began another 36 individuals were nominated for interviews. Overall, 49 interviews were completed.

- Several individuals were excluded from the sample because:
    - they refused an interview because they had already completed a mail questionnaire or the organization had already responded (n=7)
    - they had left the organization or could not be found (n=1)
    - they referred the interviewer to different individuals to interview (n=5)
- Reasons for non-response included:
    - Messages left with no response (n=11)
    - No response (n=2)
    - Cancelled telephone interview for reasons including lack of time, personal reasons, lack of organizational support to respond (n=3)
- Reasons for refusals included:
    - Time commitment (n=2)
    - No reasons given (n=2)

Table 8 outlines the responses of the telephone survey. Overall, the response rate for the survey was 71%, the refusal rate for the survey was 16% and the estimated non-response was 23%.

Tables 9 and 10 identify the roles of the nominees and the number of individuals interviewed from each region and organization type. When people were interviewed they may have recommended that we talk to another individual from an organization that was previously interviewed or to another individual within their organization. A decision was made to interview individuals from different organizations rather than additional ones from those organizations where individuals had already been interviewed.

Table 8: Response Rate

Interview Status	Overall
A. First Level of Interviews Based on Initial Nomination	46
B. Additional Nominated Individuals for Interviews	36
C. Total Number of Completed Interviews	**49**
D. Person left organization or does not exist	1
E. Number of Non-responders	16
Reasons for Non-response	
F. Messages Left with no response	11
G. No response	2
H. Cancelled telephone interview	3
I. Referred to another individual	5
Reasons for Refusals	
J. Refusal: Completed Mail Questionnaire	5
K. Refusal: Already spoke to organization	2
L. Refusal: Time commitment	2
M. Refusal: No reasons given	2
Response Rate = C/(A+B)-(D+J +K+I)	**71%**
Refusal Rate = J+L+K+M /(A+B)-(D+J+K+I)	16%
Estimated non-response = E/(A+B)-(D+J+K+I)	23%

All regions of Canada were represented by participants, however, there was a higher representation from Ontario and Saskatchewan/Manitoba compared to other regions. There was also a higher representation from National organizations compared to the other regions.

Table 9: Regions of Nominees and Respondents

Regions	**Nominees**	**Respondents**	**Proportion of Sample**
Alberta	7	2	4%
Atlantic	7	4	8%
British Columbia	6	4	8%
Saskatchewan, Manitoba	15	11	22%
Whitehorse	1	1	2%
Yellowknife	1	1	2%
National Organizations	11	10	20%
Ontario	26	13	27%
Quebec	8	3	6%
Overall	82	49	*99.00%

*did not add to 100% due to rounding

A number of different types of organizations were represented in the interviews. The largest group was from large teaching hospitals (41%), followed by small hospitals (14%), and government (10%).

Table 10: Organization Type of Nominees and Respondents

Regions	Nominees	Respondents	Proportion of Sample
Consulting Companies	2	0	0%
Government	6	5	10%
Health District	6	3	6%
Homecare	1	1	2%
Independent Practitioner	2	1	2%
Insurance	2	2	4%
Large Teaching Hospital	37	20	41%
Not-for-profit	1	1	2%
Professional Association	4	3	6%
Professional College	11	4	8%
Research	1	0	0%
Small Hospital	7	7	14%
University	2	2	4%
Overall	82	49	*99.00%

*did not add to 100% due to rounding

3.3.2 Telephone Interview Findings

The findings reported in this section are based on analysis of the recorded interviews. Findings are presented in the same order as questions were asked. Selected quotes (in italics) from participants are provided for illustration. The main points for each question will be described under the following headings:

- Types of information collected on healthcare errors and adverse events
- How information about healthcare errors is used
- An accurate picture of the number and type of healthcare errors in your organization
- Projects or initiatives undertaken to reduce healthcare errors and improve patient safety
- Whether projects or initiatives lead to an increase in the reporting of healthcare errors
- Whether projects or initiatives lead to a decrease in healthcare errors and adverse events
- Limitations of the success of these projects or initiatives
- Other plans to initiate new efforts or extend current activities to reduce healthcare errors and adverse events

- Culture of your organization that may help in identifying healthcare errors and improving patient safety
- Values, culture and approach conducive to minimizing risk of healthcare error
- Barriers and challenges that make identifying healthcare errors and promoting safety difficult
- Suggestions for sharing information related to healthcare error and patient safety in a timely manner
- Formation of a committee to work on common issues related to healthcare error and patient safety
- Actions that need to be taken in your organization to improve patient safety and reduce healthcare error
- Actions that need to be taken in the Canadian Healthcare System to improve patient safety and reduce healthcare error

3.3.2.1 Types of Information Collected on Healthcare Errors and Adverse Events

Respondents discussed the type of data that are collected. All types of data mentioned by respondents can be found in Appendix E. Many individuals reported that they collect information using an incident report. These reports were completed using different forms, and in different ways by different organizations. For example,

> "*I would say at this time, our information tends to be fairly traditional, in the use of incident reports, in the use of people flagging issues that may have occurred. Sometimes the really big incidents don't have an incident report*."

> "*Everybody does incident reporting …to …varying degrees of success. A lot of the data we collect you can abstract it and people tabulate it, but the difficulty is that a lot of people get this information and then I don't think a lot happens because of it.*

People indicated that although reporting incidents may be mandatory, there is no way to know how many incident reports are missing.

> "*It's mandatory in the sense that if it's recognized, it's supposed to be reported... there's no way to know how many we're missing though, because there's no way to monitor it. So, in a sense it's up to the nursing units and the nurses to record those events*."

Two respondents commented that the incident reports are in print format, although they wanted to move to electronic format.

> *"So any kind of adverse event that happens to patients or visitors is collected and - right now, it's in print format. I'm trying to get a software program that will enable us to do it electronically, but most of the really good ones are prohibitively expensive. So right now, it is in print format."*

Two individuals indicated that they collect information about potential errors. The interviewee below reported that the information that is used by their organization is collected across the country.

> " *We don't really call it errors, ... it is basically a system for us to reconcile something that we've done wrong prior to giving [medication] to the patients. Say, for example, the system that we have right now that nurses send us memo to correct our computer entry for what we call "The Medication Administration Record". So we would make an error in the Medication Administration Record, and they would send us a memo that said, "Form C you entered this thing incorrectly. Please change." And then we go on and change it. So this is a standard method, probably across the nation that everybody does. You know, you made an error in the record and you'd go change it. But if you look at the system itself as a whole for error reporting, those would be potential errors, right? So I wanted to look at it as potential errors rather than as a reconciliation record*."

One individual indicated that as a result of participation in a collaborative project of the Institute for Healthcare Improvement (a U.S. non-profit agency), they now collect information about medication errors and potential errors rather than using a general incident report.

> "*As far as I know until we were participants in the IHI collaborative, it [data] was collected in the general context of the incident reports, as opposed to a specific documentation for healthcare errors...any incident, whether it was considered an error or not. …And since we have joined the IHI collaborative, we now do a scan of 10 random charts per month looking for specific adverse drug events, and also triggers for those events, which may be helpful to find out indicators of potential error, and get potential error or potential adverse events. They are reviewed manually, …specific adverse events are looked for and specific triggers. Triggers being scenarios where there might be an error or an adverse event. For example, a person who is on anti-coagulants whose clotting time is higher than the therapeutic range, there is potential there that there may have been an error, or an adverse event, but they have not necessarily occurred. That is like a flag, that there might be an error or an adverse event*."

Three people interviewed indicated that they do not collect data on adverse errors and do not have plans to do so in the future.

Six individuals reported using a standard form, four reported the use of a database, one reported documenting the information in a private file, one reported receiving the information through mail, phone, e-mail or letter assuring confidentiality, and three reported using print format only. Respondents indicated they would like to purchase a software program for tracking incidents and adverse events, but they find the prices a deterrent.

> "*I enter them into my own databases right now. I have them on an Excel program myself. But what I really want is a good computer program. So right now, I'm investigating - you know, I would really like to get a good computer program. But some of the best ones are $50,000.00 wh ich we just don't have*."

Several respondents indicated that there is an underreporting of medical errors and others felt that there should be a more systematic method of collecting data.

> *"Well whatever you hear about error and adverse outcomes, rest assured that they are underestimated because nobody, to my knowledge, ever reported an error when there was not one, or an adverse outcome when there was not one, or a medical death or injury when there was not one."*

There remains considerable disagreement about terminology. For example, one individual did not agree with the definition of medical error. He said,

> *"Well, before we go another millisecond forward, I have to say the definition of healthcare error is grossly defective. And I cannot answer anything related to that because it's a meaningless definition. What it purports to be is a method of separating preventable adverse outcomes from unpreventable adverse outcomes. …Everybody makes errors, some of these errors end up being translated in a sense some way into an adverse outcome, but most of them do not. So we have to be intelligent about this and not assume that an error always is…to quote what you have said, "a preventable adverse outcome." Most adverse outcomes are preventable, some of them are not, but whether they are preventable or not has nothing whatsoever to do with error…People historically have collected instances of adverse outcomes. It's like collecting automobile accidents. Errors, on the other hand, are things that people do which are unintended, and most of which have no adverse outcome or even any outcome at all. Many of them are caught immediately by the person who, to whom this error happened. Some of them are caught by other people. Some of them are prevented by the*

> *design of the system. For example, trying ... to use one kind of injection device, which doesn't fit the needs of the system, which immediately tells you that you have made an error. It's like picking up the wrong key to get into your car. You made an error. You picked up the wrong key and tried to open the door of the car, but the lock doesn't accept the key, so you are immediately notified of your error. There's been no adverse outcome at all. So an error is a behavioral event. And nobody collects errors. If they did collect errors, in my view it would be more efficient and beneficial to collect all the errors that are done wrong or attempted to be done wrong, and not even bother to collect the adverse outcomes, which were a very small fraction. Every error, whether leading to an outcome or not, is predictive of opportunity for patient injury. So, if I pick up the wrong hypodermic, if I pick up the wrong medication, even if I do not injure a patient, nonetheless it demonstrates that there is an opportunity for a patient to be injured at some other less happy time.*

3.3.2.2. How Information about Healthcare Errors is Used

Respondents discussed how information about adverse events and healthcare errors is used (Appendix E for a complete list). Eight indicated that the information is compiled into a report either quarterly, annually or in individual case reports. Fifteen respondents reported examining the data to determine trends. These trends and/or reports are reviewed by an internal group within the organization (mentioned by 14 respondents). In addition, four respondents described a multidisciplinary process in reviewing the trends and other information regarding adverse events and healthcare errors. For example, one said,

> "*We bring a large multidisciplinary group together for a very formal, very structured, two to three hour meeting around the event. We go over the facts of the occurrence, which are compiled, from the health record and from interviews with staff done before the review. We ensure that they are accurate by presenting them in a draft sequence of events and then we ensure that they are accurate by asking participants to review them and make sure that they are accurate. At that point…we would discuss potential contributing factors … We look at processes or circumstances that could potentially have led to the error. Number of overtime shifts, or poor labeling, any number of things…bad communication, that would have potentially contributed to the adverse outcome. And then the final phase of it is the development of recommendations. Probably the most unique part of this is…the multidisciplinary format. What happens is that the people who actually participated in the adverse outcome have the opportunity to change the system, and we get really good responses*."

Many respondents reported looking at specific cases to better understand systemic issues at the organization.

> *"We discuss the issues involved. These are closed door [discussions]. We discuss what contributed to the morbidity or mortality, it may be something systemic, beyond our control. It may be individual practice, it may be none of the above; it's been bad luck or sick patients. We try to focus on things that are systemic issues, that we can discuss and try and improve, so [it's] kind of a quality assurance type of work. We are trying to highlight, address issues and have discussion about what we can do to change our practice, to change our approach to not have it happen again."*

British Columbia has legislation that protects practitioners who discuss events from legal action to discover the nature of this discussion. This legislation permits healthcare workers to review an adverse event, and protects such discussion from the courts.

> "*In British Columbia we have what we call Section 51. …Section 51 [allows us] as healthcare workers to review and investigate the adverse event, and the process of investigation and documentation of that process is protected from the court. So that [discussion] would not be used as evidence for prosecution. …And we do fill out a Section 51 [form] for some of the incident reporting*."

One individual indicated that although data are collected to identify systems changes, the collection of the data needs to be more systematic. For example,

> "*We are recognizing it [data collection] needs to be more systematic. At this time, in a random way, it identifies where we need to do systems change… [but] it's not done in a systematic fashion, as one would anticipate it should be*."

One way of looking at trends is to create a physician profile on the errors that individuals have made. For example in one organization,

> "*Every month we collect all of these adverse patient occurrences including deaths, and they go cumulatively into a computer in a program that we have on Access. At the end of the year we count all these up, and it allows us to build a profile of a particular surgeon or anesthetist. So, we have the stats on individual physicians in this hospital. We've been doing this for about... oh, fifteen years*."

Five respondents reported that the incidents are reviewed first at a departmental level and if applicable to others will be reviewed at a regional level. Over one-third of respondents review the information in order to make recommendations to improve patient safety.

> "*We would want to trend those numbers and monitor those numbers…what we're interested in is the kind of changes that can be made following a good investigation into an adverse event and whether that could be applicable to more than one facility. If one facility had…one issue that occurred…after investigation - we're interested in seeing if we can gather some general implications from that, that we could use in a broader sense*."

One respondent noted he may enlist help from the media or publish data in journals in order to disseminate the information if it may make a big impact on the healthcare system or reduce errors.

> *"If something [from the report of errors] is very, very interesting and might have a big impact on…[other] healthcare practitioners or hospitals or patients specifically, …we would try to do a follow up with a reporter. And we compare the data with …the U.S. database and find out whether a similar error has occurred, and how often it occurred, then analyze it and see how we could make the system better. If the problem is an urgent one, we actually send out an alert to as many practitioners in the hospitals in Canada as possible. If something is urgent, we need to flag them and not to have some accident happen. Other than that we publish the information …in one of our journals – XXXXXX XXXX. We have various ongoing columns each month. So [there are] different ways [to] disseminate the information depending on the urgency, and depending on the line of severity."*

A number of respondents gave us specific examples of how they used data to improve patient safety. Three specific examples follow:

> *"One of the more frequent circumstances in which real tragedies occurred where a patient clearly needed access to tertiary level care and a physician contacted a colleague at one particular site in a tertiary-level centre, and was told there was no room in the critical care unit, and the patient was held back at the home base, while there were two other hospitals in that district and there was no systemic strategy to actually make sure that none of the resources in the district were available. It was still sort of one-on-one communication between the individual doctors, and not an actual systematic engagement to make sure that this patient got access to all of the tertiary care services that were in the larger district. This was the springboard for the realization that doctors weren't necessarily thinking and acting in a systematic way. They were still, in many instances, communicating only with one colleague in a centre where there might have been twenty people providing the care. …that led to the situations where people were significantly delayed in getting care, and in fact often died at the home base when they could*

have been transferred to another location earlier and attended by another physician."

Another respondent reported an incident in a hospital.

"One most recent example is… that we've had a number of patients who were brought down from their…units to a diagnostic area, for tests, who were receiving high flow oxygen. The oxygen tanks that went with them became empty in the course of their wait or the actual test. In a few of those incidents, the patient actually went into respiratory arrest. So [this was] obviously a very, very serious event. And although none of them actually died, they did have prolonged hospital stays and more complications. When this came to my attention, we reviewed the whole policy around transportation of patients to diagnostic imaging areas and off the unit, for patients that were running high-flow oxygen. We made some recommendations to do that differently. Those recommendations were then passed to our Nursing Council and also were passed as a regional policy."

A third respondent noted that,

"[Better reporting systems could]…be used to potentially make recommendations for labeling changes, or information to healthcare professionals about how the product would be used…. For example on drug names…If you have a series of issues around one product and its similarity to another product name then you might make recommendations for name changes or at least warnings could go out to healthcare professionals and to the public with regards to how those products are used. Generally if it is a regulatory initiative then it would be an actual requirement to make a change. If it is just a warning to healthcare professionals there would be follow-up if there were continued reports of similar problems."

One example of an organization that uses the data as a tool for learning and improving follows:

> *"What we are trying to use it [reports of an error] as a learning tool. …We are trying to create a culture where is not bad to report where error happened, and how could we learn to do things differently. So is it a problem with process? Is it a problem with staff education? [For] each one of the incidents the managers are supposed to follow up themselves and used it as a learning tool for their staff and the person who did the error. Or, if it's the process issue then have to gather the staff, can we look at things differently. So it's used as a tool that way as well."*

One organization described a specific protocol that is adopted from the Association of Litigation and Risk Management in England:

> "*The process involves defining what the care management problem is [and] putting together a clinical summary of the events. In the course of interviews, the A.L.A.R.M. protocol suggests that you actually take each interviewee through a structured interview, looking at the contributory factors from the point of view of task factors, the specific task that was the problem. Individual factors such as [whether] the person concerned was ill on that day, or something related to the individual, some variation in their practice. Then the team factors, how was the rest of the team functioning? Were there factors that led to this incident that involved, for example, poor relations between staff, communication issues? And, finally, work environment factors. An issue, for example, would be two widely separated units, people being called from one to the other. Staff spread too thin. Poor staffing, etc. Then having done all of that, there is a post-interview checklist…. What I've been doing is interviewing each person, looking for all these factors…then when I've completed the interviews, I just make my own notes, and try to put this into a format that summarizes the experiences of everybody, so you get a picture of what these contributory factors are. Then, I try to look at the organizational management and institutional context factors, and the implications and action points… For example, in one case I found that we had the protocols, but people weren't following them. [At] the end, of course, [we identify] the implications and action points. I tried to make it very specific. For example, there was a problem with the paging system. Action: I will discuss this with such and such and make a recommendation that... and will evaluate it in X number of weeks*."

3.3.2.3. An Accurate Picture of the Number and Type of Healthcare Errors in your Organization

Of those interviewed,

- Thirty-nine (39) respondents felt that the information collected does not give an accurate picture of the number and type of healthcare errors in the organization
- three respondents felt that it does
- four respondents felt that it does to some extent
- one respondent did not feel the question was relevant for their organization
- two did not know

Respondents described why they felt that the number and type of healthcare errors reported were either accurate or were not accurate (see Appendix E for complete list). Five respondents indicated that there are problems with voluntary reporting.

Several respondents talked about the underestimate of errors using current data collection methods. Two representative quotes follow:

> "*Well, I think that it's generally accepted that there's a trend--it's under-reporting. I think people have seen it as failure or that they may be chastised, or there may be some punitive action taken. …So I think there is whole lot happened out there that doesn't get reported unfortunately. We are trying to create a culture that accepts [the possibility of] error. There's a long way to g*o."
>
> "*I suspect that it is an underestimate so far...when we are scanning charts we are looking for adverse events, and we are also looking for some objective data that have been defined as triggers...OK these triggers…are potential adverse events. But I would suspect that there are other errors that have occurred that are not documented…I suspect that what we are recording by chart review is an underestimate of actual errors that occur, simply because they are not being documented or that it is difficult to determine them from the documentation in the chart, and so they are not identifiable to us in a retrospective review.*"
>
> "*We don't have [a system similar to the one] that they developed in Australia. We don't have an incident monitoring system …we would never pick up near misses or latent errors in the field. We just wouldn't pick any of that stuff up. And it's being estimated that the reporting mechanism that currently exists in the North American Health Care system probably misses 95% of the errors that actually occurred*."

Other respondents were more positive about the impact of current reporting systems. While existing systems do not capture all errors, several respondents talked about many errors being clinically uneventful:

> " *The vast majority of these medication errors are clinically uneventful...or the wrong medication given at a wrong time but did not result in any patient morbidity or mortality, therefore, those would not really be collected. "Oops shouldn't have done that, you know, if we delay medication by 20 minutes, well, the drug will wear off or something." But we probably do collect the serious adverse events*."

The fear of blame and the punitive system were mentioned by many respondents as a reason for the underestimate of reporting adverse events. A representative quote follows:

> "*I think that there's still a bias within our system…that the person who is completing the incident report may, in some way, be…brought under some kind of disciplinary action*."

One individual indicated that although that individual has never seen anyone disciplined for a medical error, the culture within the organization is that there may be repercussions for an individual who is at fault.

> "*In the two years I've been here…I've never seen any staff member disciplined for any type of medical error… -- not formally disciplined. But I still think there's that attitude with the staff that by reporting it, that somehow they're being blamed, or there's some repercussions, that kind of thing… And generally, there isn't, although the reality… is, too, that if you do have one nurse that's made six medication errors in a month, then maybe you have a competency issue in terms of medication… And you can't ignore that aspect. But that we shouldn't be blaming, because by blaming people and making them feel that they should be… disciplined, then I think you're just encouraging them not to report.*"

A number of respondents also indicated that people might be too busy, not know how or not think about reporting errors. Others also indicated that educating people about how to report and the importance of reporting might be a good way to increase reporting of errors.

> "*I think it's because we're all very busy. We often recognize an adverse event, deal with it entirely locally. It may be an adverse event related to something that I did or something that I recognized that a nurse or a colleague did. I deal with it at that level and I forget to make into a formal adverse event that gets recorded in the database*."

One individual indicated that reports about medical errors are more commonly published in the literature now than they were which may indicate that the culture of healthcare is changing.

> "*If you look at the actual publications on medical error, (I did a summary of the last 60 years)… if you go back to 1940, …the average each year was about one report talking about error. By the time you get to 1998 I think it was up to about 200 [per year] and if you look at 2001, it would be in the 1,000s. There's been a huge increase in publications about medical error which suggests, in fact, strongly one of two things: either medical errors are increasing or people are more willing to talk about it. And I think it's obviously the last. Some people have argued that increasing technology in medicine has contributed to further error, and I'm certain that it has. But that explosion of literature of error is mostly due to the unmasking of the phenomenon that people have become more willing to talk about it. …The culture of silence is being replaced by the culture of patient safety. …I never imagined that I would witness such a transformation [such] has occurred in the last couple of years. It's phenomenal*."

3.3.2.4 Projects or Initiatives Undertaken to Reduce Healthcare Errors and Improve Patient Safety

A number of projects or initiatives have been undertaken across the country to reduce healthcare errors and improve patient safety (see Appendix E for complete list mentioned by respondents). Many initiatives are related to raising awareness of the importance of healthcare errors and patient safety within each organization and across the country through educational seminars and presentations. For example,

> "…*there's been sessions in grand rounds about the book To Err Is Human. There's been a lot of people attending a lot of conferences on medical error. There's been discussion in places that wouldn't previously have had that discussion about what that means*."

As well, in response to incident reports that have been reviewed there have been changes to policies, products (medication labeling) and standards of practice identified by many respondents. For example this respondent spoke about a change as a result of an error in using heparin.

> "*One of the big things has been heparin errors in cardiology... using the improper heparin for both flush lines and drips. We put in a major change in where we stocked the heparin; how we had heparin labeled, and practices were looked at on all my nursing units. That is one of the biggest things I have done related to errors*."

Quality improvement was another initiative mentioned by several respondents. Here is an example,

> "*We seem today to participate in a huge variety of interdisciplinary, inter-sectoral activities which are focused on quality improvement, and our organization believes very strongly that to advance the agenda of patient safety and quality improvement we need to have professionals work together more effectively as teams. So we certainly do a fair bit in the public policy sector to try and change the way doctors, not [only] doctors, but the way health professionals are educated, work as team members, and try to foster team approaches*."

Four researchers were conducting studies. Here is an example of the type of research being conducted.

> " *Working with colleagues there we tried to identify potential risky possibilities. You see the ideal situation is to be proactive, to look at existing practice and if a hazard can be identified. In other words, let's imagine if somebody does A instead of B, could a patient be injured? If the answer is yes, then unless there is an overriding, absolute necessity for A to be available, you make it unavailable in order to forestall the possibility that particular injury or death. So, we try to do as much of that as possible, but usually of course unless things of that sort are called to our attention, we have a difficult time. However, there are areas where I am doing some work with both Canadian and American colleagues, on the confusing similarity of pharmaceutical names. This very often leads to errors in prescribing, dispensing and administering… [for] drugs such as Cerebrex and Celebrex. The minute the latter came on the market, there was confusion between the former and the latter. We're [also] working on a variety of ways to do computer estimation of the probability of error by people based merely on the spelling and pronunciation of the name chosen for pharmaceuticals."*

Other respondents spoke about the formation of internal as well as inter-organizational and national committees to address healthcare errors and patient safety. These committees have both general patient safety and specific agendas related to certain topics such as medication incident reporting. One example is a steering committee that was formed by the Royal College of Physicians and Surgeons of Canada.

> "*The steering committee will include representatives from specialty medicine, family medicine, nursing, and pharmacy. It will include people who are experts in informatics, people who have a background in health policy, and will include representation from the public. The Five Working Groups [under this steering committee] include: 1) Measurement and*

Evaluation; 2) Systems Issues; 3) Regulatory Issues; 4) Education and Professional Development; 5) Information and Communication."

Another committee related to medication incident reporting was described:

> "*We are actually working with a coalition of healthcare organizations on a system for medication system incident reporting and prevention...it really had its genesis a year ago. …We now have a contractor working on a business plan for our medication incident reporting prevention system, … with a final report due late February 2002. …The underlying intent is finding a way to collect information on medication incidents, assess that information, disseminate the results…back out to the various practitioner areas where it is required, as well as…to having some sort of oversight group that would be able to make recommendations to appropriate bodies for a change in the system. Those appropriate bodies either being the federal government if it's a product related issue, the professional practice bodies if it's a professional practice issue, as well as professional voluntary groups if it happens to be a sort of standards of practice related initiative or issue*."

Another respondent spoke of an internal committee to deal with safe medication practices.

> "[we have formed a] *safe medication practices subcommittee and our first initiative there is to remove concentrated potassium chloride from wards, and we're about 80% there*"

Another specific example is a mentoring program mentioned by one respondent as a result of the Sinclair Report in Manitoba.

> "*This [mentoring program] is based on the consequences of the Sinclair Report... And the issue was new physicians and their credentials, and their capacity to do operations, particularly for surgeons, but it's applied to every new physician coming on board. So, apart from the credentialing process being revamped and the references being checked rather more thoroughly, there's also a requirement for new physicians to have a mentor attached who doesn't necessarily observe or supervise, but is aware of and can track the first two or three months of the performance of the individual to make sure they match up to what their credentials suggest. That's new. It's not across the board yet. It's being definitely applied in surgery, because that's where the issue was. And that was the result of both internal and external departments*."

Another example is a patient safety advisory group that is formed to produce and coordinate the response to healthcare errors across disciplines.

> "*the biggest district here has just set up a patient safety advisory group. And they are actually going to be charged with producing and coordinating the response across all disciplines—it will be interdisciplinary dissemination of information*."

3.3.2.5 Projects or Initiatives to Increase in the Reporting of Healthcare Errors

Nine respondents reported that these initiatives had led to an increase in the reporting of healthcare errors, three indicated that it may have increased the reporting to some extent, eleven felt that they had not, two indicated that it was too early to tell, seven hoped that it had (but were not entirely sure), and four indicated that they did not know. One individual indicated that as the culture changes people would be more likely to report errors.

> "*I think as we discuss it more openly, the culture changes. And I know certainly having participated in the review process …we see a much higher level of comfort in our culture with errors, and a much higher…or much more…people working in healthcare …I believe are more tolerant of error because they can see the process piece. So where as couple of years ago we are all pointing fingers at one another, now people understand that there is a process in place to deal with an error. And that is a blame-free process that it is designed to support not indict them. And I think that's why we are going to get more reporting. As we get more reporting, we're going to be able to start looking at information and we'll be able to make changes that we need to make to reduce healthcare errors*."

3.3.2.6 Reduction in the Number of Healthcare Errors and Adverse Events

Many respondents felt that they were just getting started with their projects so they were unlikely to have reduced the number of errors yet. Three respondents felt that they did lead to a reduction in the numbers of healthcare errors, nine respondents reported that they didn't feel that the initiatives had led to a reduction in the numbers of healthcare errors and adverse events, one hoped that it did, eleven indicated that they did not know, and five felt that it had not yet led to a reduction.

One respondent indicated that they do not measure outcomes well enough to know whether the number of healthcare errors is reduced.

> "*Part of the problem is that we don't measure outcomes well enough. We don't measure stuff up front well enough and we don't measure stuff at the end well enough. How much are we going to be able to do? The main thing right now is budgetary restriction that everyone is going to go through. So the patient safety stuff is very important but it tends to be done after other operational stuff is dealt with.*"

Another respondent described the application of human factors to medical errors:

> *"It hasn't changed the reporting, but …[our efforts have] reduced the number of errors…we took one design then took a mock-up of the existing commercial device. And then we analyzed the job and so on from a human factor engineering perspective. …We redesigned the human computer interface for this device. And we showed that when people used the human factors interface, errors go down."*

3.3.2.7 Limitations of the Success of these Projects or Initiatives

Limitations to the success of these projects that were identified by respondents include:

- Punitive system
- Too early to tell
- Voluntary reporting
- Culture
- Lack of resources

Specifically with regard to culture one respondent stated the following:

> "*Culturally it has been a difficult issue to get people willing to bring preventable adverse events forward. Partly from just professional habits, partly because of loss of respect of colleagues, partly because of fear of litigation. And partly because of realizing that unless something good comes of it, there's not much value in reporting. Unless you know there is a responsive system for evaluation and improvement, it's not worth the heartache sometimes*."

This respondent also indicated that lack of resources might prevent follow-up.

> "*Then there are the resources which [are needed] even if you go to the trouble of reporting, you need people who have time to actually follow-up, strategize on reasonable changes that could be made, and then see if the changes actually lead to improvement in care, reduction of errors. That would cause a significant commitment of resources."*

3.3.2.8 Other Plans to Initiate New Efforts or Extend Current Activities to Reduce Healthcare Errors and Adverse Events

There were a number of ways mentioned by respondent to initiate new efforts or extend current activities to reduce healthcare errors and adverse events (see Appendix E for a complete list). Seven respondents reported collaborating with individuals, other organizations or provinces. Two examples follows:

> "*We're doing collaborative things like working with the nursing community across the country to try to institute some indicators on work life safety*"

> "*We intend to get a 'best practice medication group' going and a risk management error team"*

> "*I'm on the patient safety task force in the U.S. It's a committee that is directed by [a professional society], and we have charged with trying to come up with initiatives to reduce error. One of them is to invite people to submit cases to us and we'll do the analysis of the case, and label the particular error that was involved in the case and provide the …root cause analysis of the clinical case and publish our commentary in [a professional] journal. Now that feature has just been initiated and I'm working on the first case now and it's going to press probably in a week or two*."

Several respondents spoke about the culture of safety and about teaching people to embrace their errors. One example follows:

> *"I guess a lot of residents and fellows go through my division and I'm teaching them to embrace their errors. So that by spreading the word locally I'm creating a generation, I'm trying to create a generation of [specialists]…that will maybe be inclined to report their errors. I've also tried to involve [specialists] in the city by presenting a grand round of [medical] error, and many of them have expressed interest. ... I'm hoping to teach about error, the concept of reporting error and spread the word that way...But it has to be much broader than that. It really has to be a bottom-up approach. You have to get the janitors, and the nurses and the doctors in the trenches, but everybody interested, not just the head of the division….*"

Several respondents spoke about teaching medical students and clinicians about medical errors. One example follows:

> "*We identified the cases and they're presented in a book format for the students so that they can read about the case. And then they read an analysis of all the errors that occurred in the case. And they're also provided with a glossary at the end of the manual, which…gives them all the definitions. So we try to make an effort to introduce them to the language of medical error. And we also take real clinical case material and show them how the errors work in practice.*"

Other respondents indicated that they would either introduce or continue with a quality improvement approach that would hopefully improve patient safety.

> *"I am very involved in quality improvement, and indirectly, obviously, efforts towards quality improvement will improve safety. In the "[specific] Program" I anticipate that I would have an opportunity to…influence which indicators are chosen as targets. And I would like to think that we will follow the AIM [Achieving Improved Measurement] indicators in the CCHSA recommendations, which involve systems competency, work-life, community-planned focus and responsiveness, and of course, system competency does involve safety."*

Another example of an initiative was a patient fall assessment. This initiative focused on developing a risk assessment for falls and determining nursing care needs based on the risk assessment.

Finally several respondents indicated that they would like to educate patients and develop a disclosure policy on medical errors.

> "*We had been looking at developing a Patient's Bill of Rights here. We haven't got it off the ground, we're just looking at it. …The other thing I want to do is to develop a policy. We don't currently have a policy within the hospital on disclosure of medical errors, particularly the serious ones, the ones that can create either an extended length of stay or some kind of harm to the patient. Right now it's just totally up to the physician. …I think, as a facility, we need to develop a policy on that*."

Several researchers described future topics of interest related to medical errors. These topics include:

- A survey across Canada on the use of infusion devices to find out more about the frequency of adverse events
- Research on tracking and improving patient safety with colleagues at a U.S. university
- Research on use of e-health innovation
- Examining the safety practices at a call centre for the emergency medical services in an urban

3.3.2.9 Culture of Your Organization that May Help in Identifying Healthcare Errors and Improving Patient Safety

A number of aspects of the culture of the respondents' organizations were identified that may help in identifying healthcare errors and improving patient safety (see Appendix E for a complete list). The most commonly identified dimension of the culture of the organization that may help in identifying healthcare errors is a non-punitive culture. Some comments about this aspect of culture included the following:

- *"when [the staff] know that we are not into blaming, but looking into how to improve outcomes they are very supportive of it"*
- *"try to emphasize the necessity of reporting…try to make it a very non-punitive approach"*
- *"find an effective process for root cause analysis and an effective process for building a culture within their district"*
- *"valuing front-line staff, getting them involved …and giving them a lot of recognition--rightly deserved recognition for what they're doing"*
- *"we've been slowly moving away from convenient, formal disciplinary hearings, which are very adversarial processes"*
- *"we're trying to reduce the level of discomfort at identifying deficiencies, recognizing that they will happen"*

- *"you need a culture which does not seek to punish people…the law has no function in patient safety…we live in a culture where the law tends to override the underlying goals of the medical side of things."*

A non-punitive culture is essential for open, transparent disclosure of medical errors, and for encouraging a systems approach to looking at errors.

Several respondents commented on the ways in which a non-punitive approach would create organizational environment where safety was valued.

- *"a non-punitive approach to error, an educational approach to error, a quality improvement approach to error [are all necessary] for the protection of information."*
- *"the main thing is to get rid of the concept of blame…they are used to looking at the system and focusing extensively on a scapegoat"*
- *"the most important thing is to not blame people…just because you make a mistake doesn't mean you are incompetent"*
- *"a non-punitive approach will help you get the investigation going, to get the facts straight"*
- *"a non-punitive reporting system where physicians, nurses and others can be comfortable in reporting problems that occur either in the system or individual problems"*

A respondent indicated that we need to educate people to understand that it is okay to make a mistake.

> *"Well I think [it is important] to allow people…to develop a kind of culture [where] it is acceptable to take a risk, to err, that we are human, it's going to happen. We'll try our best to put in place a process [and] system to alleviate that, but there may be situations where [errors] happen. …. What we are trying to do is find out what made those errors happen, so that we can put [changes] in place and prevent it from happening in the future. So [we need] people [to] tell us what the errors are, so that we can educate everybody to prevent those in the future so that others don't repeat them."*

Several respondents made comments about the need for a systems approach to examining medical errors:

- *"a systems approach rather than blame and a commitment to correct systems problems that contribute to error [are needed]"*
- *"the idea that systemic problems will be addressed"*
- *"changing the culture from one that has been focused on who caused the error and doing something about an individual to actually looking at what the underlying causes of error are, the systems issues related to error"*

Several respondents suggested that commitment from leadership from healthcare organizations and government is important to create this kind of environment.

> "…*little can be done [with regard to patient safety], or little is done if the higher up administration and the CEO don't believe it. …We need someone right from the top, [it] doesn't matter at what level, right from the Ministry or from the Health Canada or from the CEO of organization, from managers, they have to believe in that and to make it [happen]. Just to talk about it and not doing anything [means it] is not going to go anywhere. And I think this is one of the areas that I think we really need to make sure that patient safety really truly in the agenda of priority. It's not easy. I think the other challenge is so many healthcare challenges that facing healthcare people right now. Patient safety may be falling through the crack somewhere*."

As well, five respondents indicated that additional resources are needed to address medical errors including reducing current workloads of staff, providing money and staff to be able to address medical errors . Three respondents indicated that appropriate infrastructure and computer technology is necessary in order to track errors. Two other respondents felt that systematic methods of data collection are needed in order to track medical errors more accurately.

3.3.2.10 Barriers and Challenges that Make Identifying Healthcare Errors and Promoting Safety Difficult

Many barriers and challenges to identifying healthcare errors and promoting safety were identified by respondents. (A complete list is found in Appendix E) The most commonly identified barrier was the punitive or adversarial system of reporting errors.

Some specific examples of a punitive approach are:

- "*Certainly I think if you have punitive system in place [it discourages reporting]. I worked in a hospital once, and I think there was a policy if you had three medical errors, you were fired. So, you know, and this policy went on for a number of years. Everyone--nurse, staff, it's a huge hospital knew about this policy. No one was ever fired, but it was very punitive. People feared it. Especially I guess when you have two medical errors, you knew that if you had a third one, you lose your job. I think those kind of system are very punitive*."
- "*there is still…at least a perceived punitive approach to error and I think that makes people nervous about raising those issues*"
- "*people being disciplined for the errors that they make*"
- "*should change the culture, I think there's a culture that has been based on blame and the diligence of the practitioner being held to account*"
- "*one of the big barriers is the fear of being identified as the prob*lem"

One individual discussed the balance between openness in reporting and disclosure and liability issues:

> "*We have to…find the right balance between getting people to talk and be open and - and doing some of those things that legally are quite risky - and that's talk about possibilities without really knowing, at this point, what all occurred. Doing all of that with a balance, as I said, for protecting the liability and balancing that with the openness and disclosure. And that's what we're struggling with, because we can't wait for any changes in the legal system - it's too slow - and so we have to take some risks…I think one of the obstacles is to get people to understand how their communication, both verbal and written, is extremely important, that we don't want people, as they have in the past, to summarize in one statement something rather audacious about somebody's provision of care when they really know very little about it. And that it should be done in an organized, sort of objective way….people [must] really encourage good communication and good documentation…. So, as I said, the obstacles for me are making sure that people understand how they should be communicating about this and how they should be handling the situation, as well as balancing the liability issue*."

Seven respondents indicated that the lack of time and human, monetary and technological resources are another barrier to reporting errors. Comments about the lack of resources follow:

- "*We have real challenges in human resources….Our resources are stretched very thin, let's say for respiratory therapists, and now we're going to be without respiratory therapists for high-risk deliveries. I think that is going to reflect on patient care. It's sometimes difficult to be pushing this whole idea of quality improvement and safety when on the other hand, we don't have the resources in terms of personnel and skills to do as much as we did last week*."
- "[one problem is a] *shortage of pharmacists; another is heavy workload*"
- "we *do not have necessarily good information systems…you need to have good equipment, good staff…it's very difficult to get nurses, physicians…if you're running "lean and mean" …it doesn't enhance your ability to create a safer environment for sur*e"

With regard to organizational size, two respondents indicated that the complexity of large organizations was a barrier for identifying healthcare errors and promoting safety.

> " *In smaller organization [when] something happened it's pretty[much] common knowledge; it's easier. In large organizations to come with those kind of things …we are extremely short staffed, our resources are limited. We know our error rates are going up even if they are not reported they are going up. We know that ... people are tired. So there are a lot of factors that I think are contributing to the error rate.*"

Respondents also spoke about legal obstacles including the fear of litigation as being a barrier to reporting errors. For example,

> "*I think…a fear of litigation is always out there…It's not well defined and it's not overly prevalent in Canadian society, but it's there, it's always kind of hanging over practitioners' head. Legislation like I've talked about makes it difficult for us to share information… just recently we had similar errors occur two or three hours from us in the same province of less than a million people. That's a huge barrier when you're talking about legislation that prevents us from being able to exchange information…with others.*"

Two respondents indicated that people do not know or think about identifying healthcare errors. One respondent said that there is a lot of "*ignorance*" and that most staff "*don't have a good understanding of the nature of error*".

Two respondents also indicated that physician commitment was often difficult to get, but important in order to be able to report healthcare errors.

3.3.2.11 Suggestions for Sharing Information Related to Healthcare Error and Patient Safety in a Timely Manner

Nineteen respondents indicated that it would be helpful to get information about healthcare error and patient safety through the Internet via a website, e-mail, listserv, chat group or electronic bulletin. Respondents had comments like the following:

- "*e-mail format for group setting, like discussion groups, chat groups*"
- *"Net-based system…central resource, some threaded discussions and chat rooms*"
- "*e-mail…electronic newsletter…it's got to be …web-based or something fast*"
- "*internet is a great vehicle for doing these things, and even having a network can help you to have people to ask questions of* "
- "*advocate putting up a web page…at the site of [specialty group], where physicians can then see the identified cases and discuss them. You know so that errors can be shared. Shared information going across disciplines because of the generic nature there, but also each specialty has its own particular type of what we called " phenotypic " error. You can talk about generic error because the principle of errors are the same, the foundation principle of errors are the same, but within the specialties phenotypic errors …[are] peculiar for that specialty. The things that I do in [my specialty] an obstetrician doesn't do.*"

Six people indicated that in order to share information, there would need to be anonymous reporting or a non-punitive approach.

Six people also indicated that an information repository located centrally would be handy for sharing information in a timely fashion.

- *"Creating a repository for learning would be one good thing"*
- *"electronic database [would be useful so] that we can share things with each other"*

Others indicated that a national incident reporting system would be helpful for sharing data. One individual had a caution about a national database,

> "*I know that in the States, they have a national database and that has been a not so great success story. And it's certainly…left a lot of practitioners with bad taste in their mouth. Because then it becomes reportable to their professional associations, and practitioners end up in discipline and that's really a bad circle we're talking about. A national organization around patient safety would be fabulous. Reporting would be great too, but the difficult part is being able to do that and still provide the cultural blame free shift we want to do, that's the tricky one*."

Several also mentioned that data and methodological standards should be required in order to make comparisons of data. Also mentioned were the importance of standardized definitions of healthcare error and adverse events. A number of people suggested sharing information in print format such as through a newsletter or letter. One individual indicated that we need to determine what needs to be shared prior to suggesting the process for sharing information. Another person believed that we need to collect the information prior to determining what and how to deal with the information.

3.3.2.12. Formation of a Committee to Work on Common Issues Related to Healthcare Error and Patient Safety

Thirty-three respondents felt that a committee dealing with patient safety at the national level should be formed; one respondent felt that it should not be formed; five respondents were apprehensive about a committee being formed; four indicated that there were committees already formed. One individual felt that there should be a provincial committee.

In terms of forming a committee respondents commented:

- "*we can always learn from each other*"
- "*the benefit of the committee is often related to who's on the committee and their commitment to sharing things and their ability when they get that stuff home to actually influence change*"
- "*any kind of really effective initiative would…have many layers to it…certainly a national voice….but then…it would have to filter down… right to the micro level of the patient care environment to be really effective*."
- "*I am not sure that we need to form new committees. I think that there are probably some existing structures that would be perfectly viable and perfectly functional*"
- "*with membership from each of the provinces or territories*"
- "*healthcare is organized provincially…if you want to have legislative power you might have to go provincially…a national committee could be useful, but I think to be most useful it would have to have provincial branches*"
- "*can always benefit from one another's ideas and experiences…governments and the healthcare system's stewards have to take an interest in quality and make that part of the indicators of the reporting that is in this report card for healthcare…need some leadership from our governments*"
- "*equivalent or comparable to the National Patient Safety Foundation that exists in the States, and exists in Australia*"

With regard to intersectoral collaboration, one respondent said,

> *"Well ,yes, I think probably at every level there needs to be a lot of inter-sectoral communication and collaboration. Looking to the south of us, there is some envy of the fact that in the U.S. this is, you know, after the IOM report it's got attention at the level of the President of the U.S. and there were certain steps... And so, I think at every level, including the national level, there needs to be committees or working groups that cut across traditional barriers between different organizations."*

This respondent also highlighted the importance of having champions at the local level.

> "*One of the things though I really hasten to point out is that … the end of the day healthcare is delivered at the provincial and local level, and unless you can get people, unless you can get champions involved at a fairly local level, a lot of lofty things very national won't necessarily make a difference.*"

One respondent spoke about adding a section about medical errors to the maintenance and competence of physicians.

> "*We currently in Ontario actually, [have] something called MOCOMP, maintenance of competence. At the end of the year, every doctor has to submit to the governing body of his or her province or state a list of continuing medical education activities. So, how come there isn't a line item there on error, examining your errors? Maybe this should just be part of the maintenance of competence. How many hours did you spend in the last year examining the errors that you made in your practice and sharing with colleagues. These are, that doesn't appear on the MOCOMP form right now, but it should."*

3.3.2.13 Actions that Need to be Taken in Your Organization to Improve Patient Safety and Reduce Healthcare Error

Individuals identified a number of different actions underway at their organizations to improve patient safety and reduce healthcare error (see Appendix E for the complete list). The most commonly mentioned action was education. Comments regarding education follow:

- "*constant continuous education…people having ownership of ensuring that it gets out there somehow, repeating it over and over and over again*"
- "*increase awareness of the problem*"
- *"for sure we have to do the education. I think that's a big piece…what are some of the recommendations that may be made"*

Automated systems and technology were also mentioned by three respondents.

- "[we need to] *have automated systems that support those activities…I've been impressed by the automated system that the Latter Day Saints[Hospital] in Salt Lake City has published on*"
- "*use as much automation as we can in terms of computerized order entry, bar coding, automated dispensing*"

Systematic data collection on errors was mentioned by three respondents as well.

- "*improved reporting, not just higher sensitivity to error, but clear classification of the error and the reason for the error*"

Three individuals also indicated that more effective and proactive interventions would increase patient safety.

- "*focus all of our programs and initiatives, our resources and so on, on the quality issue*"
- "*do a root cause analysis*"

Several respondents indicated that there needs to be a non-punitive approach in order to increase the willingness to report information.

One respondent indicated that it would be desirable to focus on patient outcomes in addition to medical errors.

> *"The other thing, I guess something that bothers me a little bit is the whole focus on medical error. It's just a piece of outcome …I think we are measuring the wrong thing. I think we should be measuring patient outcome. If patient outcomes are undesirable then we need to swim up stream, find out why, was it medical error?"*

One respondent indicated that improving the health and environment of workers is likely to improve patient safety.

> *"I think the health for our workers. I think that's probably #1--work environment. We have a unsuitable work environment.....we don't have enough staff, we don't have enough beds, we work people too hard, they're tired, they are working overtime, interact with people in disaster. So that's one thing we are trying to address in our organization, reducing our volume of ... people overtime*."

3.3.2.14 Actions that need to be taken in the Canadian Healthcare System to Improve Patient Safety and Reduce Healthcare Error

A number of actions were identified that need to be taken in the Canadian healthcare system to improve patient safety and reduce healthcare error were identified (see Appendix E for a complete list). The most commonly identified action for the Canadian healthcare system is a universal database for tracking and monitoring. One comment regarding this database follows:

- "a *national monitoring system and national standards for what's acceptable in terms of safe practice [are needed]*"

Intersectoral collaboration was discussed by several respondents as well.

- "…it should be intersectoral, interprofessional…needs to be an eclectic membership"

Several respondents identified national leadership as important.

- "*Well I really cannot talk very much about what is happening in the rest of Canada. But I think that the leadership must come from the top. The top of the government, the top of organizations, and so on and so forth."*
- *"some national leadership on this would be really great"*

One individual spoke about changing the punitive culture so that error reporting increases using cost savings as the rationale.

> *"As long as that (punitive) culture exists, it's going to be an uphill battle to do error reporting. I don't think that many people will pick up the baton and start reporting their errors unless they are mandated to by their hospital or by their local governing body. …Maybe a financial argument has to be made. Last year X errors were made in the [hospital], which translated into Y error of complications, which resulted into Z dollars being paid to lawyers and patients.*"

3.3.3 Summary of Main Themes from Telephone Interviews

Several common themes were identified across this analysis of responses. These themes emerged from examining generalized statements across the data by respondents about beliefs, attitudes, values or sentiments that were of over-riding importance to respondents (Luborsky, 1994). The specific themes from this analysis were:

Encouragement of a Non-punitive Approach
It was felt that healthcare errors were not well reported because of the potential for disciplinary action and blame for those who caused the error. A non-punitive approach was viewed as important in order to increase reporting and for sharing information across the country.

Education Needed for Healthcare Workers about Healthcare Error
It was felt that by educating healthcare workers about the importance of healthcare errors and their systematic documentation, they would be more likely to report errors. In addition, if people felt that reporting would result in improvements to patient care they would be more likely to report the errors. Individuals need to be aware that it is acceptable to make a mistake and that we need to find out what caused the error in order to prevent it from happening in the future.

Quality Improvement Approach
Many organizations utilize a quality improvement approach in order to improve the care that resulted in healthcare errors. This approach will help to focus on systems issues rather than focusing solely on the individual involved in the healthcare error.

Culture Needs to Change
The culture within organizations and within healthcare generally needs to change from one of blame and a focus on individual contributions to error to one of learning, and a focus on root causes and systems issues.

National Leadership and a Coordinated Approach
Leadership is required nationally to determine standard definitions for healthcare errors, and set standards for collecting data and reporting healthcare errors. Respondents believed that resources should be spent to coordinate a national strategy on healthcare errors by disseminating and sharing information (electronically or otherwise), providing organizations with the ability to track healthcare errors. Other issues like a national research agenda and funding to study healthcare errors, developing an information repository, a national database and providing additional resources to healthcare in order to be able to concentrate on healthcare errors within their organizations were also mentioned.

Champions are Needed at the Local Level
Respondents noted that in order to stimulate attention to healthcare errors within organizations, champions and internal leaders are required. These leaders may include both senior management and front-line managers and clinicians. These individuals would help to ensure that the organizational strategy is working and would be able to troubleshoot difficulties encountered.

Non-Systematic Collection of Healthcare Error Data and Lack of Technology to Support It
In general, the data on healthcare errors in organizations are not collected systematically. Many organizations use different definitions for what they collect (e.g., incidents, critical incidents, deaths, etc.) and use different reporting forms. Even within organizations there are differences in what is being collected and how the data are examined. Many organizations currently collect their data in paper format only which may limit their analysis and use.

Legal and Insurance Issues
Reports of healthcare errors are discouraged because healthcare professionals can be held liable and sued. The fear of legal action and disciplinary procedures means that organizations do not get full information about adverse events and errors. The reluctance of insurance companies who may not want errors to be discussed prior to claims being assessed also creates a barrier to reporting healthcare errors.

Lack of Resources Including Human, Monetary and Time
Inadequate resources, including time, money and personnel are commonly seen as a deterrent to collecting data in a systematic way, investigating healthcare errors and adverse events, and following-up to improve the system of care. Financial investment is needed to purchase systems for tracking errors. Additional staff are required to track, investigate and follow-up healthcare errors and adverse events. Staff within each department should also be trained to identify errors and improve care.

3.4 Legal Issues Review

The legal review focused on key materials identified by Canadian experts on health law and on materials located in our literature search. This review begins with a short section on definitions. We then review the two sources documents and several other pertinent items.

3.4.1 Medical Law – definitions and principles

Under Canadian law a physician may be subject to criminal as well as civil liability when causing death or bodily harm to another person.

Everyone who undertakes to administer surgical or medical treatment to another person or to do any other lawful act that may endanger the life of another person is, except in cases of necessity, under a legal duty to have and use reasonable knowledge, skill and care in so doing. Everyone who undertakes to do an act is under a legal duty to do it if an omission of the act is or may be dangerous to life (Canadian Encyclopedic Digest, 1994, Ref.106).

The law of negligence governs the majority of actions brought against hospitals, doctors and healthcare professionals. The term malpractice is often used to describe this type of action (Picard and Robertson, 1996).

In order to be successful a negligence action must meet four requirements (Canadian Encyclopedic Digest, 1994, Sec.109, Picard and Robertson, 1996):

- The defendant must owe the plaintiff a legal duty of care
- The defendant must breach the standard of care established by law
- The plaintiff must suffer injury or loss
- The defendant's conduct must have been the actual and legal cause of the plaintiff's injury.

Doctors will not be held responsible for unforeseeable accidents that occur in the normal course of medical treatment. This "reasonable foreseeability test" is used for determining proximate cause in malpractice suits. The court will consider whether a reasonable person should have anticipated that the consequences might be a natural result of that act or omission to act (Canadian Encyclopedic Digest, 1994, Sec.112).

A physician in his or her practice does not guarantee success or perfect results but only that he or she will use a *reasonable degree of skill and learning and exercise reasonable care and his or her best judgment to achieve a good result* (Canadian Encyclopedic Digest, 1994, Sec.116).

A doctor's conduct will be judged according to standards existing at the time the mishap occurred. The standard tests of foreseeability and avoidability are inapplicable where the medical profession is generally unaware of the risk or the type of injury suffered by the patient at the time the treatment was administered (Canadian Encyclopedic Digest, 1994, Sec.118).

The standard of care required is that of a reasonable medical practitioner. He or she must bring to his or her task a reasonable degree of skill and knowledge and exercise a reasonable degree of care. He or she must use that degree of skill that could reasonably be expected of a normal, prudent practitioner of the same experience and standing (Canadian Encyclopedic Digest, 1994, Sec.122; Picard and Robertson, 1996).

A doctor must warn patients of any dangerous side effects of drugs which he or she prescribes. He or she must determine at the earliest possible time whether adverse side effects are present. Once embarking on a radical course of treatment with potentially dangerous drugs, a doctor must exert the utmost vigilance for the patient's safety (Canadian Encyclopedic Digest, 1994, Sec.127).

A doctor is legally and ethically bound to treat a patient's drug addiction or refer the patient to a drug treatment centre (Canadian Encyclopedic Digest, 1994, Sec.128).

A surgeon must exercise reasonable care in the initial decision to proceed with an operation, in the performance of the operation and in the post-operative treatment. However, he or she has no duty to positively advise for or against elective surgery. Once a surgeon has undertaken to perform elective surgery, he or she has heightened duty to use skill, knowledge and care. He or she must ensure that patients fully appreciate the special risks involved in the proposed procedure and are informed of its gravity, of any material risks involved or of any special or unusual risks attendant upon the performance of the operation, including undetermined risks if the surgical procedure is experimental. Where surgery is capable of being performed under general or local anaesthetic, the anesthetist has a duty to advise the patient and offer a choice (Canadian Encyclopedic Digest, 1994, Sec. 129).

3.4.2 Picard and Robertson Text

The first key resource identified by our expert informants was "Legal Liability of Doctors and Hospitals in Canada" by Picard and Robertson (1996). This text is the standard Canadian text on health care liability. We already have cited several key points from this text above and do not intend to review this text further, but we note that it contains a detailed description of liability issues related to patient safety and health care error and will serve as a resource to those who seek information in this area.

3.4.3 The Prichard Report

The second document identified by our expert informants was a report to the Conference of Ministers of Federal/Provincial/Territorial Health known as "The Prichard Report."

The report was written following a period in the 1980s when the number and cost of legal suits against doctors and hospitals began to increase rapidly. These suits resulted in increased costs for physicians, healthcare organizations, the Canadian Medical Protective Association (which insures most Canadian physicians) and provincial governments. Government became more involved in supporting liability payments for physicians as part of fee negotiations and in helping healthcare organizations pay insurance premiums. During this period, several legal experts began to call for reform in this area of law. These forces led to the appointment of a review committee by the Federal and Provincial Ministers of Health chaired by Robert Prichard who was then the Dean of the Faculty of Law at the University of Toronto. The review lasted two years and culminated in the publication, *Liability and compensation in health care : a report to the Conference of Deputy Ministers of Health of the Federal/Provincial/Territorial Review on Liability and Compensation Issues in Health Care*." (Prichard, University of Toronto Press, 1990).

The Prichard Report contains a comprehensive review of the Canadian legal issues to that time. There were seven principal findings:

1. There had been a substantial increase in liability for health care providers in Canada from 1975 to 1990. In particular orthopedic surgeons, anesthesiologists and obstetricians and gynecologists had suffered from a very substantial increase in the number of claims and the cost of liability insurance for protection from these claims.
2. These increases had occurred despite the fact that there had been no important change in legal doctrine during that fifteen year period.
3. Insurance costs for physicians and health care institutions had grown very rapidly in the 1980s.
4. Medical litigation was expensive, complicated and slow.
5. The threat of civil liability improves quality and safety and health care system.
6. Despite the growth in litigation, less than ten percent of those suffering avoidable injuries in the healthcare system are compensated.
7. The situation was serious in 1990 and should be attended to before it reached crisis proportions.

The report offered 79 recommendations aimed at improving the situation. The three principal recommendations were:

1. The system of tort liability should be maintained but with improvements in the way damages were calculated and to ensure increased access to justice for injured persons.
2. Hospitals and other institutional health care providers should have increased accountability for the quality and safety of health care in their institutions. Prichard later summarized this recommendation this way, "*The vast majority of avoidable medical injuries take place in hospitals and health care institutions. It was our judgment that most of the improvement lay not so much in the behavior of individual physicians in individual cases, but in systemic improvements, in risk management, in quality assurance, in procedural arrangements designed to make health care safer. That comes from focusing on incentives for institutions to improve their performance, to recognize that provision of health care is a multi-disciplinary team effort in which the physician is only one actor. Systemic risks call for systemic changes and a shift in focus from the doctor to the health care institution." (Proceedings of the Tort reform Conference, 1998)*
3. An alternative to tort litigation should be developed to provide a realistic route to compensation for those who suffer serious unavoidable injuries.

3.4.4 CMPA Tort Reform Conference

The Canadian Medical Protective Association (CMPA) hosted the Tort Reform Conference in Toronto on November 5 1998. Robert Prichard spoke at that conference. He reviewed his original report and commented on events during the ensuing eight years. The following are quotes from Prichard's presentation as presented in the conference proceedings.

"What has happened since we reported in 1990? In summary, I would say not much. There has not been an explosion in litigation, indeed we have had a relative plateau. There has been no meaningful reform in the intervening period. Most of what we recommended has not been done. There have been some minor adjustments but fundamentally the situation remains the same in 1998 as it was in 1990."

"There has been one significant change in this field where fundamentally not much has changed. That has happened in response to the problems in the blood supply system, the problems of hepatitis victims. There is a latent sympathy for people who suffer injury in the course of health care. When Mr. Rock and his colleagues tried to compensate those who were injured by fault and not compensate other hepatitis victims, his position was not popular with Canadians. What I see as a real risk to health care providers, a real risk to doctors, a real risk to the CMPA, is if Canadians get up a head of steam about

uncompensated victims of medical mal-occurrence. It could lead to another significant escalation in liability and the number of claims brought."

"… within the debate about tort reform, I think the evidence suggests that well designed tort reform can make a useful difference in reducing the social cost of this system of dealing with health care injuries."

"I think the mistake in the report that I issued was to try to do it all in one big step. It was too ambitious to think we could change the whole system in a federal country in one step. It is a province-by-province challenge and I think the recommendations did not take into account the political anatomy of the era. I think what we need to do is develop experiments. The American evidence suggests that experiments can take place working with types of injuries or types of providers, to try to identify one or two or three workable proposals to see if we Canadians can make improvements. We have been leaders in the development of high quality, accessible health care, and it seems entirely appropriate for Canadians to be leaders in dealing with the unfortunate victims, persons who suffer avoidable health care injuries."

Madam Justice Ellen Picard also spoke at the conference and reviewed the experience abroad. In particular she described the New Zealand no-fault system, the Swedish experience and the recent work on limitations in the area of neurologically impaired newborns in Florida and Virginia. She pointed out that lessons can be learned in Canada from these initiatives and that *"if indeed, moving forward incrementally in the area of social justice is the Canadian way, then perhaps it is time to take another step forward."* (Picard, 1998).

The conference also heard the hospital perspective from Rino Stradiotto who serves as counsel to the Health Insurance Reciprocal of Canada (HIROC). HIROC is the only insurance reciprocal of its kind in Canada and has 85 public hospitals and 77 healthcare related institutions as subscribers. At the time of the conference Mr. Stradiotto's firm (Borden & Elliot) was receiving one new file per day from HIROC. His comments included the following:

"Public hospitals are no longer perceived as caregiving institutions. They are viewed as providers of service and there is no reluctance or hesitation to institute an action whenever there is perceived dissatisfaction with the care provided or with the outcome of the care. Public expectations as to what the healthcare system should provide are often unrealistic and there is a growing tendency to find someone responsible whenever the outcome is not up to the expectations. There is reluctance to recognize that healthcare is not a science of results but of reasonable efforts."

and …

"I can only ever so briefly touch on what I might refer to as the non-financial costs of malpractice litigation. I sense alarming growth in fear, bewilderment, anger, frustration, resentment and animosity of health care professionals toward the current litigation process. It is understandably of serious concern to the health care professional who has dedicated his or her life to caring, to be accused of substandard conduct, are even worse, to be said to have caused or contributed to serious harm to a patient or the death of a patient. The process of resolving such claims should not unduly add to these stresses and concerns." (Stradiotto, 1998).

The 1998 tort reform conference considered tort options and reforms including court ordered structures and the elimination of subrogation. Court ordered structures are settlements that involve non-taxable annuities instead of a single payment. The conference heard evidence that this would substantially reduce total liability costs in Canada while ensuring equitable settlements. The conference also heard arguments that subrogation, the recovery of costs by the insurance plans, should be eliminated. The conference proceedings contain a list of recommendations as follows:

1. It is recommended that a uniform limitation period within which medical malpractice actions can be commenced be developed for Canada.

2. It is recommended that in those cases involving seriously compromised infants where the medical evidence demonstrates that there is little or no cognitive ability, courts should not award general damages at all, or should only award a much reduced amount.

3. It is recommended that the Federal Income Tax Act be amended to eliminate the need for gross-up in lump sum personal injury awards. If the need for gross-up remains, its calculation should be standardized.

4. It is recommended that courts across Canada should be given the power to order periodic payments in appropriate cases and those orders should be subject to periodic review in the event of a significant change of circumstances.

5. It is recommended that courts be urged to make future care awards based on an assessment of what might be of actual benefit to the injured plaintiff. It is recommended that no amount be awarded for future income loss in those cases in which all of the other plaintiff's needs have been adequately addressed. If future income loss is to continue to be awarded, then the calculation should be based on the applicable average industrial wage for entry level earners.

6. It is recommended that the collateral source rule be discontinued such that the defense would only be required to pay for amounts, which the plaintiff actually lost.

7. It is recommended that provincial governments forego any right of subrogation of future health care costs.

8. It is recommended that restrictions be put in place to ensure that only those family members who have incurred actual out-of-pocket expenses, who actually have a meaningful relationship with or are dependent upon the plaintiff in some real way be given the right to claim compensation.

9. It is recommended that all courts provide the opportunity for mediation or some form of alternate dispute resolution as early as possible in the action.

3.4.5 Structured Settlements

There has been progress in the development of structured settlements in some provinces. Manitoba has established legislation where courts are permitted to order damages paid through periodic payments. This legislation allows due consideration of the issues and is permissive. It allows the court, in appropriate cases, to impose a structure. There are other examples of legislation that mandate structures in certain cases (e.g., Ontario Insurance Act for certain motor vehicle cases; California Code of Civil Procedure for all cases where future damages exceed $50,000).

3.4.6 Privileging

Privileging refers to the legal protection from discovery for review activities undertaken by professionals for the purposes of quality assurance and quality improvement. Some health professionals believe that privileging of information allows them to hide the facts of incidents; but this is not correct. Facts of a case are always discoverable. There are also ethical grounds for disclosure of the facts to patients should a medical misadventure occur. Most jurisdictions in Canada now have some legal protection of the privileging type in place. Here are the pertinent items from the relevant legislation in four provinces.

Statutes of Alberta 9(1)

(a) "quality assurance activity" means a planned or systematic activity the purpose of which is to study, assess or evaluate the provision of health services with a view to the continual improvement of
  (i) quality of health care or health services, or
  (ii) the level of skill, knowledge and competence of health service providers;

(b) "quality assurance committee" means a committee, commission, council or other body that has as its primary purpose the carrying out of quality assurance activities and that is
  (i) appointed by
    (A) a regional health authority
    (B) the Alberta Cancer Board
    (C) the Provincial Mental Health Advisory Board
    (D) the board of an hospital under the Hospital Act or
    (E) the operator of a nursing home.
  (ii) established by or under another enactment of Alberta, or
  (iii) designated by an order of the Minister of Health as a quality assurance committee for the purpose of this section.

(c) "quality assurance record" means a record of information in any form that is created or received by or for a quality assurance committee in the course of or for the purpose of its carrying out quality assurance activities, and includes books, documents, maps, drawings, photographs, letters, vouchers and papers but not software or any mechanism that produces records.

9(2) A witness in an action, whether a party to it or not, is not liable to be asked to produce any quality assurance record in that person's or committee's possession or under that person's or committee's possession.

9(5) Neither

(a) the disclosure of any information or of any document or anything contained in a document, or the submission of any report, statement, memorandum or recommendation, to a quality assurance committee for the purpose of its quality assurance activities,

nor

(b) the disclosure of any information, or of any document or anything contained in a document, that arises out of the quality assurance activities of a quality assurance committee, creates any liability on the part of the person making the disclosure or submission.

British Columbia Evidence Act 51 (1) (Chapter 124)

"board of management" means a board of management as defined in the Hospital Act;

"committee" means any of the following:

(a) a medical staff committee within the meaning of section 41 of the Hospital Act:

(b) a committee established or approved by the board of management of a hospital, that includes health professionals employed by or practising in that hospital, and that for the purpose of improving medical or hospital care or practice in the hospital

(i) carries out or is charged with the function of studying, investigating or evaluating the hospital practice of or hospital care provided by health care professionals in the hospital, or

(ii) studies, investigates or carries on medical research or a program;

(c) a group of persons who carry out medical research and are designated by the minister by regulation;

(d) a group of persons who carry out investigations of medical practice in hospitals and who are designated by the minister by regulation; "health care professionals"

51(2) A witness in a legal proceedings, whether a party to it or not,

(c) must not be asked to produce nor be permitted to produce, in the course of the legal proceeding, a record that was used in the course of or arose out of the study, investigation, evaluation or program carried on by a committee.

51(3) Subsection (2) does not apply to original or copies of original medical records or hospital records concerning a patient.

51(4) A person who discloses information or submits a record to a committee for the purpose of the information or record being used in a course of study, an investigation, evaluation or program of that committee is not

liable for the disclosure or submission if the disclosure or submission is made in good faith.

51(5) A committee or any person on a committee must not disclose or publish information or a findings or conclusion of the committee except to
- (a) a board of management,
- (b) in the circumstances the committee considers appropriate, to an organization of health care professions.
- (c) By making a disclosure or publication
  - (i) for the purpose of advancing medical research or medical education, and
  - (ii) in a manner that precludes the identification in any manner of the persons whose condition or treatment has been studied, evaluated or investigated.

Manitoba Evidence Act (Chapter E150)

9(1) A witness in any legal proceeding, whether a party thereto or not, is excused from answering any question as to any proceedings before, or producing any report, statement, memorandum, recommendation, document, or information of, or made by, a committee to which this subsection applies and that is used in the course of, or arising out of, any study, research, or program carried on by a hospital or any such committee for the purpose of medical education or improvement in medical or hospital care or practice.

Protection from liability
A witness is protected from the disclosure of any information or of any document or anything therein, or the submission of any report, statement, memorandum, or recommendation, to any committee to which subsection 9(1) applies, for the purpose of its being used in the course of any study, research, or program carried on by a hospital or any such committee for the purpose of medical education or improvement in medical or hospital care or practice.

New Brunswick Evidence Act 43.3(2)

A witness, whether a party to a legal proceeding or not, is excused from

(a) providing any information as to any proceeding before a committee established by a hospital corporation to conduct any study, research or program for the purpose of medical education or improvement in medical or hospital care or practice.
(b) Producing any document made by or for a hospital corporation or a committee established by the hospital corporation for the purpose of being used in the course of, or arising out of, any study, research or program the dominant purpose of which is medical education or improvement in medical or hospital care or practice.

3.4.7 Selected Other Medical-Legal References

The following additional references offer other information and perspectives on legal issues and the current status of debate on medical-legal reform in Canada and elsewhere.

1, Capen K. (1996). Prevention should be the preferred insurance program for all Physicians. Canadian Medical Association Journal. 154: 1385-87.

Discusses the recent fee increases for the CMPA and provincial rebate programs. The author quotes from a recent CMPA newsletter:

"The volume of work . . . about which members seek assistance has increased significantly, and the cost of providing that help has risen substantially. . . . By its increasingly frequent use of structured settlements the Association seeks to take advantage of sometimes quite significant savings. By its participation in a court-initiated Alternate Dispute Resolution Pilot Project [we hope] that at least some legal actions can be brought to a conclusion well short of trial."

"However, there are elements of court awards and settlements over which the CMPA has no direct control. Items such as the cost of future care over the lifetime of a very seriously disabled patient can account for millions of dollars, especially when a court determines that a patient requires care in a specially constructed and equipped home [from] highly trained personnel employed around the clock."

2. Beckman H, Markakis K, Suchman A, et al. (1994). The doctor-patient relationship and malpractice: lessons from plaintiff depositions. Arch Intern Med 154: 1365-1370

A US study of why patients sue doctors and hospitals. It points out that not all adverse outcomes result in legal action, and threatened lawsuits do not always involve adverse outcomes. Seventy-one percent (71%) of problems involved physician-patient relationship issues.

The four main themes behind the lawsuits were:

- desertion of the patient (physician sent a surrogate or was perceived as unavailable or too important, or patient felt abandoned), 32%;
- devaluation of the views of the patient or family (physician discounted the illness and suffering, attempts to advocate on the patient's behalf and the opinion of the patient or family, or failed to listen), 29%;
- delivering information poorly (physician failed to provide an explanation or to keep the family up to date, blamed the patient or family for a bad outcome and communicated insensitively), 26%; and
- failing to understand the patient or family perspective (physician did not pay attention to patient discomfort, failed to solicit opinion or failed to recognize the psychosocial impact of a medical problem), 13%.

3. Coyte P, Dewees D, Trebilcock LL. (1991). Medical malpractice -- the Canadian experience. New Eng J Med; 321: 89-93.

A study of Canadian physicians' experiences with medical malpractice. Canadian physicians are only 20% as likely as their American counterparts to be sued for malpractice. Possible explanations for this discrepancy include the presence of universal health insurance, more generous social-welfare programs, limited use of contingency fees, limited awards for non-pecuniary damages such as pain and suffering, infrequent use of juries, a less litigious culture and "the effective defence work of the CMPA."

4. Duranceau A. (1998). The Canadian Medical Protective Association. Bull Am Coll Surg. Mar; 83(3): 22-8.

A comprehensive description of the role, structure and function of the CMPA.

5. Dubin CL. (1997). An Independent Review of the Canadian Medical Protective Association. Ottawa, Canada.

In 1996 the CMPA requested that retired chief justice Charles Dubin examine the structure, management, operations, and funding of the organization. The resulting report is an extensive examination of both the CMPA and the justice system as it pertains to legal liability.

6. Hatlie MJ. (2000). Scapegoating Won't Reduce Medical Errors. Medical Economics (May 22) p.97 – 100.

Errors are normal in complex systems like health care. The essence of our safety challenge is to design systems that learn from failure and use that information to protect us from our own innate fallibility. Physicians, nurses, health plan executives and hospital administrators need a "safe harbor" to openly discuss mistakes and how to prevent them without the threat of litigation or drastic punishment hanging over their heads. Patients also need to be brought into the discussion.

3.4.8 Disclosure

We include two references to the issues around disclosure of error by professionals and institutions to patients.

1. Finkelstein D, Wu AW, Holtzman NA, Smith MK. (1997). When a physician harms a patient by a medical error: ethical, legal, and risk-management considerations. Clin Ethics. Winter; 8(4): 330-5.

Errors that harm patients are infrequently brought to the attention of these patients. The full disclosure of such medical errors is in the best interest of patients because it allows them to understand what has occurred, and to gain appropriate compensation for the harm that they have suffered. Physicians have been given little guidance regarding how to conduct a relationship with the patient after such an injury. The authors argue that the physician must continue to respect the patient, and communicate honestly with him or her throughout their relationship, even after the patient has been injured. It is painful to admit our errors, especially to those who have been harmed by them. Nevertheless, offering an apology for harming a patient should be considered to be one of the ethical responsibilities of the profession of medicine. Monetary compensation alone is not to be offered as a charitable gesture; rather, it should be accompanied by an apology to demonstrate the responsibility of the physician to the trusting patient. Full and honest disclosure of errors is most consistent with the mutual respect and trust patients expect from their physicians. Clearly, physicians' ethical responsibilities sometimes differ from their legal and risk-management responsibilities.

2. Hebert PC. Disclosure of Adverse Events and Errors in Healthcare: An Ethical Perspective. Drug Saf 2001; 24(15): 1095-1104

Adverse events and medical errors affecting patient care are recognised internationally as major problems in medicine. The failure of health care professionals and health institutes to address this problem has threatened to undermine public confidence in the health care system as a whole. Less focus has been directed at the ethical issues raised by negative outcomes of care, specifically the issue of disclosure. Efforts to prevent negative outcomes of care must be supplemented by policies of increased honesty and openness with patients and their families about adverse incidents. Disclosure should be made easier, not riskier, for healthcare practitioners so clinicians can learn from mistakes and improve patient care. Ethical guidelines for error disclosure must distinguish between disciplinary action and reporting of adverse incidents. Disclosure of negative outcomes requires tact and good communication skills. Healthcare institutions should provide training for the clinicians in this area, if necessary. As a general rule, patients should be informed of unexpected adverse incidents as soon as possible. Medical staff should be rewarded for adverse event reporting and protected from institutional retaliation on account of errors made in health care.

3.4.9 Ethical Obligations of a Physician

The CMPA for the last 100 years has taken the position that when medical errors occur, it is only fair that patients who are victims of such misfortune should receive compensation. The Canadian Medical Association (CMA) accepts the responsibility for delineating the standard of ethical behaviour expected of Canadian physicians and has developed and approved the Code of Ethics as a guide for physicians (Baylis, Downie and Dewhirst, 1996).

The code applies to physicians; including residents and medical students.

<u>General Responsibility</u>

- Consider first the well-being of the patient.
- Treat all patients with respect; do not exploit them for personal advantage.
- Provide for appropriate care for your patient, including physical comfort and spiritual and psychosocial support, even when cure is no longer possible.
- Practice the art and science of medicine competently and without impairment.
- Engage in lifelong learning to maintain and improve your professional knowledge, skills and attitudes.

- Recognize your limitations and competence of others, and when indicated, recommend that additional opinions and services be sought.

3.4.10 References

Baylis F, Downie J and Dewhirst K. (1996). Code of Ethics. CMAJ. 155(8): 1176 A-B.

Beckman H, Markakis K, Suchman A et al (1994). The doctor-patient relationship and malpractice: lessons from plaintiff depositions. Arch Intern Med. 154: 1365-1370.

Canadian Encyclopedic Digest (Western). Carswell, Toronto, 1994.

Capen K. (1996). Prevention should be the preferred insurance program for all Physicians. Canadian Medical Association Journal. 154: 1385-87.

Coyte P, Dewees D, Trebilcock LL. (1991). Medical malpractice -- the Canadian experience. New Eng J Med. 321: 89-93.

Dubin CL. (1997). An Independent Review of the Canadian Medical Protective Association. Ottawa, Canada.

Duranceau A. (1998). The Canadian Medical Protective Association. Bull Am Coll Surg. 83(3): 22-8.

Finkelstein D, Wu AW, Holtzman NA, Smith MK.J (1997). When a physician harms a patient by a medical error: ethical, legal, and risk-management considerations. Clin Ethics. 8(4): 330-5.

Hatlie MJ. (2000). Scapegoating Won't Reduce Medical Errors. Medical Economics. (May 22), p.97-100.

Hebert PC. (2001). Disclosure of Adverse Events and Errors in Healthcare: An Ethical Perspective. Drug Saf. 24(15): 1095-1104.

Picard E.I. and Robertson G. B. (1996). Legal Liability of Doctors and Hospitals in Canada. Scarborough, Ont. Carswell.

Picard, E.I. (1998). Tort Reform Overview: Experience Abroad. Proceedings of CMPA Tort Reform Conference, p.27-29. Toronto: CMPA.

Prichard JRS. (1990). Liability and compensation in health care: a report to the Conference of Deputy Ministers of Health of the Federal/Provincial/Territorial

Review on Liability and Compensation Issues in Health Care. Toronto, University of Toronto Press.

Stradiotto, Rino (1998). Hospital Viewpoint. Proceeding of CMPA Tort Reform Conference, p.18-19. Toronto: CMPA.

Tort Reform Conference in Toronto on November 5, 1998. The proceedings of that conference can be found on the web at http://www.cmpa.org/cmpaweb/public/english/tort-e.cfm

4. Discussion

4.1 Limitations of the Study

Three sources of data were used for this report: a mail survey of healthcare delivery organizations and professional associations and colleges; a telephone survey of Canadian experts; and a detailed literature review of patient safety materials, with an expanded focus on issues related to disclosure and negligence. The three sources of data are largely independent and offer different types of information. Since the principal investigators agreed that they would not have access to the names and roles of individuals who were interviewed by phone or returned mail questionnaires, there is no way of assessing the overlap between these two surveys. However, several potential telephone survey respondents noted that they had already filled in a questionnaire, and declined to be interviewed. Given the relatively small numbers of telephone interviews and surveys, and the use of random sampling for the mail survey, there is likely to be limited overlap in these samples. At the same time, results from these data can only be compared in terms of overall conclusions. And there is no way of assessing if individuals may have provided information to both surveys.

4.1.1 Mail Survey

Any mail survey has the potential for a self-selection bias. In this study, the refusal rate for the mail survey was 4% and the estimated non-response rate was 63%. It is certainly possible that those individuals who refused to participate in the survey and/or those who did not complete the survey had different opinions than those people who did respond to the survey.

The final respondents were representative of all regions and all organizational types.

We used formal and proven methods to try and maximize the response rates. This included the extra follow-up calls that were made to the non-responders to encourage them to participate and find out why people were not responding. The main reasons given for not responding were that individuals were too busy to fill out the questionnaire or they felt that the survey was not appropriate to their organization.

We have considered the possible reasons for non-response:

- It is possible that some individuals and organizations are anxious about letting the issue of patient safety and healthcare error surface. In such organizations avoidance of the issue might be the norm.
- Some organizations may not yet have begun to deal with the issues of patient safety in a substantial way. This could be because of a lack of resources, human or financial, to address safety concerns.
- Other organizations may not have developed organizational knowledge concerning patient safety and health care error. In such organizations patient safety may not have been given priority.
- In some organizations we found it difficult to identify an individual or department that had accountability for patient safety. This might have been because no person has been assigned accountability for the reasons cited in the two bullets above. However, it is also possible that these organizations may have developed programs and responsibilities in this area but not communicated these developments adequately to the majority of staff. So when we asked who we should talk to, the people we contacted did not know.
- In some cases, organizations may have began to work in this area but only have limited results at this time and did not feel it was important to report them to us.

4.1.2 Telephone Survey

The telephone survey employed a snowball technique and achieved a response rate of 71%. The refusal rate for the survey was 16% and the estimated non-response was 23%.

Although snowball sampling used in the telephone survey does not involve random sampling techniques, the purpose of the survey was to identify individuals and organizations known for their leading edge activities in patient safety and healthcare error. This approach is appropriate because patient safety activities are still in early stages and limited to relatively few organizations in Canada.

During the second round of telephone interviewing, very few new referrals were made indicating the sampling method had achieved saturation of those known to be working in the field. Final interviews were representative of all regions and organization types.

4.1.3 Consistency between the Surveys

In this study two methodologies (in-depth telephone interviews and a mail survey) were used to investigate current Canadian healthcare practices regarding patient safety and healthcare errors. Participants in the mail survey were different from those in the telephone interviews and represented different organizations. Opinions were collected from all regions across Canada and from all different types of healthcare organizations. The results for the different data collection methods were analyzed separately but revealed similar but complementary findings.

This suggests that whatever bias exists for the mailed responses is in the direction suggested above.

4.2 Opportunities and Challenges Identified

The surveys provided a consistent picture concerning activity in patient safety in Canada. From the results we identified several opportunities and challenges that can inform programs and initiatives in this area.

- Many respondents made a plea for leadership at local, regional and national levels.
- It appears that scarce resources – human and financial – are perceived to be a major barrier to progress in this area.
- Fear of litigation is an issue but appears to be less dominant than would have been expected based on anecdotal evidence.
- Punishment, fear and possible professional censure are major barriers at the local level.
- There is a lack of coordinated and systematic processes to collect information on adverse events and errors in Canadian healthcare organizations.
- There is little information available about programs to enhance patient safety in Canadian healthcare organizations.
- Some see improved computerized information services as an important improvement, but costs for such services are viewed as prohibitive.
- Large numbers of organizations reported that even historical surveillance systems – death reviews, incident analysis, etc. – were not functioning well or were not present. It is unclear if these surveillance activities have never occurred in these settings, or have been abandoned.
- Relatively few Canadian organizations are improving existing efforts or adopting new interventions to improve safety in Canadian healthcare organizations.

- Respondents highlighted the need for formal training in specific tools like Root Cause Analysis (RCA) that are specific to improvement work in patient safety.
- Respondents identified the need to develop systems to allow regional and national sharing of changes made to improve safety. It was pointed out that such sharing across organizations and regions may require changes in legislation to ensure protection from litigation (see 3.4.6 above).
- Almost 50% of health care delivery organizations felt that they could not effectively enhance patient safety.
- There was an identified need for education among health care professionals concerning patient safety issues.
- Respondents stated that we need to "go up stream", focusing on systems and the prevention of error.

4.3 Specific Findings

The following discussion summarizes the combined results from the two surveys organized under several headings that reflect the original goals for the surveys.

4.3.1 Specific Issues of Concern about Patient Safety

Participants in both surveys were familiar with the topic of patient safety and healthcare error and recognized the importance of monitoring and reducing healthcare errors. It appears that incident reporting and investigation of adverse events have been taking place in healthcare organizations for many years. However, focusing on improving monitoring systems and prevention of adverse events is relatively new for most organizations contacted. Medication errors, falls and/or injuries due to restraints, communication and documentation errors, errors related to access/waiting, procedural errors and diagnostic errors were the most often mentioned types of errors identified by Canadian healthcare organizations.

There are concerns mentioned by many respondents about how errors are currently being defined, monitored, and acted upon. There is a lack of appropriate tracking systems and protocols to identify adverse events or near misses in many organizations. The punitive culture of many organizations and the lack of resources dedicated to systematic data collection and response to errors hinders the progress of accurately reporting and reducing healthcare errors.

Most organizations feel that healthcare errors are under-reported and will continue to be until the above-mentioned concerns are addressed. Several

participants indicated that many errors are missed because they are uneventful (the patient is not harmed). But knowledge of these events may be useful in redesigning systems to prevent future errors. It is also of concern that current tracking systems focus on capturing adverse events and thus we miss learning from the near misses.

Although many organizations are collecting data and reporting it, there was less indication about how the information is acted upon. Some organizations discussed the use of quality improvement models to create change but most mentioned that data was reviewed at meetings and possible changes discussed without a clearly defined approach to improvement.

4.3.2 Emerging or Potential Safety Issues Identified by Organizations

Respondents expect the types of errors that will be seen in the future will be the same as those seen today. However, there was concern expressed by several respondents that the current workload and stress healthcare professionals are under may increase the risk to patients and limit an organization's ability to make changes. Many are concerned that understaffing and burnout may increase further if healthcare budgets remain constrained.

Improvements in tracking and responding to healthcare errors are new initiatives in most Canadian healthcare organizations. When asked whether their patient safety initiatives are resulting in decreased errors, many participants indicated it was too soon to know.

On a positive note, there are researchers who are investigating how to prevent healthcare errors and working with pharmaceutical and medical equipment companies to change drug labeling and to understand medical device use so that the chances of using or prescribing the wrong medications are reduced. In addition there are private companies developing ways to automate the tracking of healthcare errors.

The in-depth interviews revealed that there are a number of initiatives planned or underway that are attempting to make the reporting of medical errors non-punitive and focused on a learning approach. Few of these efforts are beyond early stages.

4.3.3 Patient Safety Tools, Programs and Surveillance Systems in Use Now

Some professional organizations have put in place professional practice standards, position statements, practice guidelines, and medico-legal handbooks to assist health professionals in identifying adverse events and medical errors and making changes to reduce such events.

Efforts to improve medication practices are being carried out by the Institute for Safe Medication Practices (see documents forwarded to Health Canada with this report). In addition, the Canadian Coalition on Medication Incident Reporting and Prevention is in the process of developing a business plan for a Canadian Medication Incident Reporting and Prevention System.

In 2001 there were a number of conferences and special meetings held to discuss patient safety and healthcare errors. The Royal College of Physicians and Surgeons released a position statement regarding errors in medicine and on creating a national strategy. Information and educational resources have been developed by professional colleges to assist health professionals with the prevention and identification of errors and the legal issues surrounding them.

Some respondents reported automated systems that were in use. These included:

- Admission discharge and transfer systems (ADT) that monitors patients' utilization of services
- The Pyxis automated drug distribution system
- Automated Medication Administration Record (MAR)

It appeared that many organizations have developed their own reporting systems for critical incidents, adverse drug event reporting and monitoring of specific indicators.

4.4 Leading Patient Safety Practices in Canada

When we asked about leading practices the respondents reported a number of initiatives and/or projects that show promise, but, in most cases, they cautioned that it may be too early to clearly label them as leading practices. However, there were common elements involved in the initiatives that they discussed.

- They take a non-punitive approach to error identification and investigation.
- They look for near misses as well as adverse outcomes.
- They involve multi-disciplinary teams to investigate and improve care.
- They focus on identifying aspects of the system that contribute to errors rather than blaming individuals.

- They often involve collaboration with other organizations for a coordinated approach to improving patient safety.
- They use the data collected to identify improvements and make changes in order to reduce errors.

These common elements reflect the ideas in the literature and descriptions of leading practices in other jurisdictions.

The following are examples of the leading edge initiatives that Canadian healthcare organizations are involved in:

1. The Institute for Healthcare Improvement Collaborative on reducing Adverse Drug Events and Medical Errors. IHI is a Boston-based nonprofit organization that works to improve healthcare quality. Participating organizations document healthcare incidents whether they are considered an error or not and make changes to improve care.
2. One organization indicated that they now scan 10 random charts per month looking for specific adverse drug events and triggers for those events.
3. One organization talked about how they review and take action on events. They use a multidisciplinary group that follows a very formal and structured approach that involves going over the facts and interviews that took place around the event, ensuring they are accurate, discussing potential contributing factors, and then developing recommendations. By using this model, the people who were involved in the adverse outcome have the opportunity to change the system.
4. Legislation in British Columbia (see 3.4.6 above) now allows healthcare workers to review and investigate adverse events, and the process of investigation and documentation of that process is protected from the courts.
5. A Medication Incident Reporting and Prevention System is in development for national monitoring of adverse drug events.
6. Research is being done in collaboration with American colleagues around the identification of 'potential' hazards that could lead to errors. One specific project is looking at how similar pharmaceutical names can cause confusion.

Respondents to the surveys suggested that other organizations in Canada may be developing new ways of tracking and preventing healthcare errors. However, since there are no national forums that would facilitate their identification, these practices are difficult to identify.

An over-riding theme of the interviews was the importance of national leadership and a coordinated approach for addressing patient safety and healthcare error. It was felt that leadership is required nationally in terms of determining standard definitions for healthcare errors, setting standards for

collecting data and reporting healthcare errors. In addition, respondents believe that resources should be spent to coordinate a national strategy on healthcare errors by disseminating and sharing information (electronically or otherwise) and providing organizations with the ability to track healthcare errors. Other issues like a national research agenda and funding to study healthcare errors, developing an information repository and a national database, and providing additional resources to the healthcare system in order to be able to focus on healthcare errors within individual organizations were also stressed by respondents.

5. Conclusions/Recommendations/Next Steps

5.1 Method for Developing the Recommendations

Based on the results of the surveys and literature reviews undertaken for this project, we developed a series of recommendations to improve patient safety and reduce healthcare errors in Canada. Our method for this required several steps. First, the principal investigators (Norton and Baker) reviewed the study materials independently. (The materials for the telephone and mail surveys had been anonymized by research staff prior to their review, as stipulated by the ethical requirements of this study.) Following this, they met with three researchers from Smaller World Communications who had been directly involved with the survey work. The first part of this meeting consisted of a detailed review of all the findings. Then the group brainstormed a series of recommendations based on the shared vision of the results that emerged from this review. These were recorded and circulated by email the following day to enable further assessment and review.

5.2 Report Recommendations

The resulting recommendations are presented below categorized in four areas.

5.2.1 Build Awareness and Set Priorities to Improve Patient Safety in Canada

1. Governments and other stakeholders should convene an expert committee representing clinical disciplines and management with knowledge of patient safety systems, tools and other resources. This committee would develop an agenda for addressing patient safety issues in Canadian healthcare, including a list of approaches to and sources for methods and tools for patient safety relevant to Canadian health care organizations. This list would be of interest to provincial ministries of health, regional authorities, healthcare organizations and accrediting agencies.

2. An invitational meeting should be convened for senior leaders in healthcare. The meeting, conducted with input from the Federal/Provincial/Territorial Conference of Ministers of Health and linked with activities of the National Steering Committee on Patient Safety, should build greater awareness and disseminate 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.

5.2.2 Develop Better Reporting Systems

3. New regional and national reporting systems and mechanisms should be pilot tested and evaluated. Key evaluation points must include the linkage of discovered adverse events to improvement efforts. Pilot projects should be undertaken to assess the effectiveness of such efforts. While most work to date has occurred in acute care facilities, new systems to identify adverse events and errors should be tested at all levels of the system – acute, chronic and community.

4. There should be expanded support for the existing and developing national and provincial Adverse Drug Event (ADE) reporting systems.

5.2.3 Build Skills, Disseminate Knowledge and Implement Systems to Improve Safety

5. Healthcare organizations should be strongly encouraged and supported in heightening their focus on errors, adverse events and near misses, and to link this to improvement work and system change.

6. Three to five high priority patient safety issues should be identified. National expert panels should be convened to share ideas and develop national strategies in each area. Examples of priority issues could include falls prevention, data systems and workforce concerns in safety.

7. A series of regional meetings or workshops should be held to disseminate knowledge about these best practices, improvement strategies and ideal designs for making improvements in priority areas to reduce adverse events.

8. Support should be made available to create carefully evaluated demonstration projects in idealized design, system change and patient safety in Canada.

9. Support should be provided to develop curricula and learning experiences in patient safety at all educational levels (undergraduate, post graduate and continuing professional education).

10. A one-year “safety fellowship” program should be developed. Two or three representatives (at least one MD along with one or two other health professionals) from each province and territory should be named and supported as fellows. The purpose of this fellowship would be to develop these individuals’ knowledge and skills in all aspects of patient safety to enhance Canadian capacity in this area.

11. Safety research and system change should become a cross cutting theme at the Canadian Institutes of Health Research, and emphasized in work at the Canadian Foundation for Health Services Research.

5.2.4 Create Organizational and Policy Level Supports for Patient Safety Efforts

12. Canadian professional colleges and organizations should be encouraged to be active in the areas of disclosure policy and legislation, and to lobby for appropriate legislation to enable them to expand their efforts.

13. Patient safety programs and initiatives should be integrated into the Canadian Council on Health Services Accreditation standards and other healthcare accreditation standards.

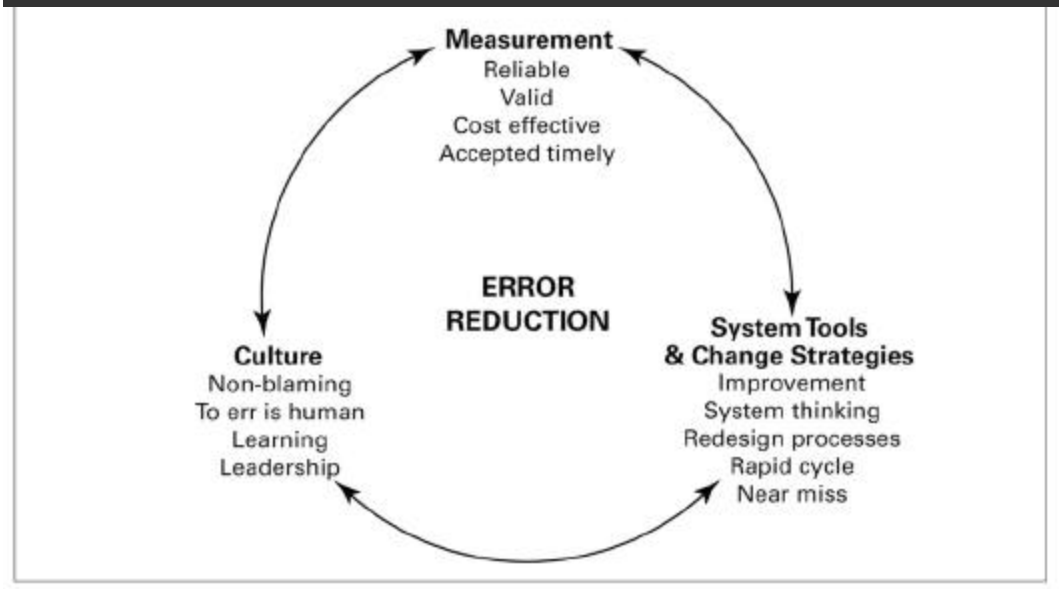
14. Legislation change could enhance reporting of errors and near-misses and should be encouraged and supported.

15. Effective strategies for risk management and risk management programs need to be investigated. Current risk management efforts focus on reducing risk and safeguarding institutional assets. More “proactive” approaches to improving patient safety that are under development elsewhere need to be undertaken in Canada. (e.g., see Vincent, C., S. E. Taylor-Adams, et al., 2000).

5.3 Linking Recommendations to a Conceptual Model

To help the reader clarify the potential impact of these recommendations we have analyzed them in terms of model for improving patient safety developed in earlier work (Baker and Norton, 2001. See 3.1.1 of this report for a summary).

FIGURE 8: A Conceptual Model of Strategies for Making Healthcare Safer



The model, displayed above, illustrates the interdependency of the three major domains involved in patient safety. The three domains are *Culture*, including leadership and learning activities; *System Tools and Change Strategies*, including the methods needed to alter current systems of practice to improve safety; and, *Measurement,* which includes data collection and reporting to identify priority areas and the impact of improvements on adverse events and errors. We analyze the recommendations in the table below using symbols to illustrate where recommendations address each domain. A box with no ? symbol indicates that the recommendation does not, in our opinion, directly contribute to the indicated dimension of the model. If the box contains one ? then we feel there is some contribution to that dimension. Finally if the box contained two ? ? then we believe the recommendation would contribute strongly to the indicated dimension. As the table below illustrates, all three areas of culture, system tools and change strategies and measurement would be strongly supported through these recommendations.

Table 11. Congruence of Recommendation with Baker and Norton Model

Recommendations	Culture and Leadership	System Tools and Change Strategies	Data & Measurement
1. Expert Committee On Patient Safety	? ?	? ?	?
2. Leadership Workshop	? ?	?	?
3. Improve Adverse Event Monitoring & Reporting Systems			? ?
4. Support ADE Reporting			? ?
4. Support Increased Healthcare Organizational Focus On Safety	? ?	? ?	?
6. Set High Priority Areas	? ?	? ?	? ?
7. Regional Workshops to Disseminate Best Practices	?	? ?	?
8. Financial Support For Demonstration Projects	?	? ?	?
9. Financial Support for Patient Safety Education	? ?	?	?
10. Create Patient Safety Fellowships	? ?	? ?	? ?
11. CIHR & CHSRF Support for Patient Safety Research	?	? ?	? ?
12. Professional Colleges Should Encourage Greater Disclosure and Transparency	? ?	?	?
13. Integrate Patient Safety Into Accreditation	? ?	? ?	? ?
14. FTP Ministers Should Encourage Legislation Review and Policy Changes	? ?	?	?
15. Improve Risk Management	? ?	? ?	? ?

5.4 Final Remarks

These recommendations provide an initial set of actions to improve knowledge about patient safety among healthcare professionals in Canada and to create organizational and regional policies and systems that will improve the current efforts. While there are several important patient safety initiatives underway across Canada, these are largely isolated endeavors. These efforts need to be studied carefully and assessed in terms of their costs and their impacts on patient and organizational outcomes. Successful efforts need to be more broadly disseminated. Further, we believe that greater attention is needed to track current activities to develop better data collection and reporting, and to create system changes and educational efforts to improve safety. Patient safety initiatives are underway in Australia, the United States and the United Kingdom. Closer connection to these efforts would help to identify new systems, policies and programs that would be helpful in Canada.

We believe that the proposed initiatives outlined here would begin meet the challenges posed in section 4.2. They will require cooperation and investment from healthcare professionals, healthcare delivery organizations and the federal and provincial governments of Canada. The safety of patients in Canada, and the creation of higher quality of care will only come with sustained attention to and greater investment in the knowledge and systems that are being developed to improve patient safety.

Appendix F: Patient Safety and Healthcare Error Glossary of Terms

Patient Safety and Healthcare Error
Glossary of Terms

These definitions are taken from several sources, but primarily from definitions complied in Appendix 1 in L. Zipperer and S. Cushman (eds.) *Lessons in Patient Safety*. Chicago: National Patient Safety Foundation, 2001. We have included the reference sources for these definitions. Debate still continues remains about the meanings of several of these terms, including "error" and "safety" so these definitions should not be regarded as official or uncontroversial.

Accident

An unplanned, unexpected, and undesired event, usually with adverse consequences.

Senders JW.
Medical devices, medical errors and medical accidents. In Bogner, MS (ed). *Human Error in Medicine*. Hillsdale, NJ: Lawrence Erlbaum Associates, 1994: 166.

Active failures

Errors and violations committed at the "sharp end" of the system – by pilots, air traffic controllers, police officers, insurance brokers, financial traders, ships' crews, control room operators, maintenance personnel, and the like. Such unsafe acts are likely to have a direct impact on the safety of the system and, because of the immediacy of their adverse effects, these acts are termed *active failures*.

Reason J.
Managing the Risks of Organizational Accidents. Aldershot, UK: Ashgate, 1997.

Adverse drug event (ADE)

An injury from a medicine or lack of an intended medicine.

Bates DW, Cullen D., et al.
Incidence of adverse drug events and potential adverse drug prevention. *JAMA* 1995; 274: 29-34.

Adverse event

An injury that was caused by medical management (rather than underlying disease) and that prolonged the hospitalization produced a disability at the time of discharge, or both.

Brennan TA, Leape LL, Laird NM, et al.
Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *New England Journal of Medicine* 1991; 324:370-376.

Adverse drug reaction (ADR)

An unexpected, unintended, undesired, or excessive response to a medicine that

- Requires discontinuing the medicine (therapeutic or diagnostic),
- Requires changing the medication therapy,
- Requires modifying the dose (except for minor dosage adjustments),
- Necessitates admission to a hospital,
- Prolongs stay in a health care facility,
- Necessitates supportive treatment,
- Significantly complicates diagnosis,
- Negatively affects prognosis, or
- Results in temporary or permanent harm, disability or death.

American Society of Hospital Pharmacists. ASHP guidelines on adverse drug reaction monitoring and reporting. *American Journal of Health System Pharmacy* 1995; 52:417-9.

Blunt end

…where regulatory, administrative and organizational factors reside…The blunt end of the system is the source of the resources and constraints that form the environment where practitioners work. The blunt end is also the source of demands for production that sharp end practitioners must meet.

Cook RI, Woods DD, Miller C.
A Tale of Two Stories: Contrasting Views of Patient Safety. Chicago: National Patient Safety Foundation. 1998. Available at: www.npsf.org/exec/report.html.

Critical incident

A human error or equipment failure that could have led (if not discovered or corrected in time) or did lead to an undesirable outcome, ranging from increased length of hospital stay to death.

Cooper JB, Newbower RS, Kitz RJ.
An analysis of major errors and equipment failures in anesthesia management: considerations for prevention and detection.
Anesthesiology 1984; 60: 34-42.

Error

An error is defined as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., an error of planning).

Reason J
Human Error. Cambridge, UK; Cambridge University Press, 1990.

High reliability organization

Hazardous organizations whose design and management allows them to achieve extremely high levels of reliable and safe operations.

Roberts K.

Some characteristics of one type of high reliability organization. *Organization Science* 1990; 1(2): 160.

Hindsight bias

Finding out that an outcome has occurred increases its perceived likelihood. Judges are, however, unaware of the effect that outcome knowledge has on their perceptions. Thus, judges tend to believe that this relative inevitability was largely apparent in foresight, without the benefit of knowing what happened.

Fischhoff B.

Hindsight ? foresight: the effect of outcome knowledge on judgment under uncertainty. *J Exper Psycho Human Percept Perform.* 1975; 1: 288-299.

Incident

Involves damage that is limited to parts of a unit, whether the failure disrupts the system or not.

Perrow C.

Normal Accidents: Living with High-Risk Technologies. Princeton, NJ: Princeton University Press. 1999.

Incident reporting

A process used to document occurrences that are not consistent with routine hospital operation or patient care.

Cullen DJ, Bates DW, Small SD, Cooper JB, Nemeskal AR, Leape LL.

The incident reporting system does not detect adverse drug events: a problem for quality improvement. *Jt Comm J Qual Improv.* 1995; 21(10):541-548.

Lapses

Internal events [that] generally involve failures of memory.

Reason J.

Managing the Risks of Organizational Accidents. Aldershot, UK: Ashgate. 1997.

Latent failures

Delayed-action consequences of decisions taken in the upper echelons of the organization or system. They relate to the design and construction of plant and equipment, the structure of the organization, planning and scheduling, training and selection, forecasting, budgeting, allocating resources, and the like. The adverse safety effects of these decisions may lie dormant for a very long time.

Reason J.

Foreword.

In: Bogner MS, ed.

Human Error in Medicine. Hillsdale, NJ. Lawrence Erlbaum Associates; 1994.

Malpractice

Physicians also ordinarily do a worse job than juries or judges in distinguishing between honest misjudgments (the currently popular term is “mispractice") and negligent errors (i.e., malpractice).

Kapp MB.

Medical error versus malpractice. DePaul J Law. 1997; 1:751-772.

Medication error

Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. [Developed for use by the National Coordinating Council on Medication Error Reporting and Prevention]

The United States Pharmacopeial Convention. National Council focuses on coordinating error reduction efforts. *Quality Review* (newsletter). 1997; 57:1-4.

Near miss

An event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention.

Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact.

Report of the Quality Interagency Coordination Task Force to the President, Feb 2000. Quality Interagency Coordination Task Force. Washington, D.C.

Negligence

Care that fell below the standard expected of physicians in their community.

Brennan TA, Leape LL, Laird NM, et.al.

Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med*. 1991; 324(6):370-376.

Normal accident

If interactive complexity and tight coupling - system characteristics -inevitably will produce an accident, I believe we are justified in calling it a normal accident, or a system accident. The odd term normal accident is meant to sign that, given the system characteristics, multiple and unexpected interactions of failures are inevitable... System accidents are uncommon, even rare; yet this is not at all reassuring, if they can produce catastrophes.

Perrow C.

Normal Accidents: Living with High-Risk Technologies. Princeton, NJ: Princeton University Press. 1999.

Organizational accidents

Comparatively rare, but often catastrophic, events that occur within complex modern technologies such as nuclear power plants, commercial aviation, the petrochemical industry, chemical process plants, marine and rail transport, banks and stadiums. Organizational accidents having multiple causes involving many people operating at different levels of their respective companies.

Reason J.

Managing the Risks of Organizational Accidents. Aldershot, UK: Ashgate. 1997.

Patient Safety

The avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of health care. These events include “errors," “deviations,” and “accidents."

Cooper JB, Gaba DM, Liang B, Woods D, Blum LN.

National Patient Safety Foundation agenda for research and development in patient safety. *MedGenMed.* 2000; 2(4). Available at; www.medscapc.com/MedGenMed/PatientSafety.

Potential adverse drug event

An incident in which an error was made but no harm occurred.

Bates DW, Spell N, Cullen DJ, et.al.

The costs of adverse drug events in hospitalized patients. Adverse Drug Events Prevention Study Group. *JAMA.* 199; 277(4):307-311.

Preventability

Implies that methods for averting a given injury are known and that an adverse event results from failure to apply that knowledge.

Leape LL, Lawthers AG, Brennan TA, Johnson WG

Preventing medical injury. *QRB Qual Rev Bull*. 1993; 19(5):144-149.

Risk management

In the context of hospital operations, the term risk management usually refers to self-protective activities meant to prevent real or potential threats of financial loss due to accident, injury, or medical malpractice.

Kraman SS, Hamm G.

Risk management: extreme honesty may be the best policy. *Ann Intern Med.* 1999; 131(12):963-967.

Root cause analysis

A process for identifying the most basic or casual factor or factors that underlie variation in performance, including the occurrence of an adverse sentinel event.

Joint Commission on Accreditation of Healthcare Organizations.

Conducting Root Cause Analysis in Response to a Sentinel Event.

Oakbrook Terrace, Ill: Joint Commission on Accreditation of Healthcare Organizations. 1996.

Sharp end

Where practitioners interact directly with the hazardous process in their roles as pilots, mechanics, air traffic controllers, and in medicine, as nurses, physicians, technicians, pharmacists and others.

Cook RI, Woods DD, Miller C.
A Tale of Two Stories: Contrasting Views of Patient Safety.
Chicago: National Patient Safety Foundation. 1998.

Slip

An unintended error of execution of a correctly intended action.

Senders JW, Moray NP.
Human Error: Cause, Prediction, and Reduction.
Hinsdale NJ; Lawrence Erlbaum Associates. 1991.

System

A system is a collection of elements that function together to achieve some objective. The elements of a system can be classified in one of four areas: Entities [including] humans, parts, phone calls; Activities [including] entity process, moves, resource usage; Resources [including] personnel, equipment, tooling time, money; [and] controls [like] process plans, work schedules, policies.

CIRAS Home Page, University of Iowa
http://www.ciras.iastate.edu/Simulation/system.htm

System errors

The delayed consequences of technical design or organizational issues and decisions. Also referred to as latent errors.

Battles JB, Kaplan HS, Van der Schaaf TW, Shea CE.
The attributes of medical event-reporting systems: experience with a prototype medical event-reporting system for transfusion medicine. *Arch Pathol Lab Med*. 1998; 122(3):231-238.

Systems approach

Using prompt, intensive investigation followed by multidisciplinary systems analysis...to [uncover] both proximal and systemic causes of errors.... It is based on the concept that although individuals make errors, characteristics of the systems within which they work can make errors more likely and also more difficult to detect and correct. Further, it takes the position that while individuals must be responsible for the quality of their work, more errors will be eliminated by focusing on systems than on individuals. It substitutes inquiry for blame and focuses on circumstances rather than on character.

Leape LL, Bates DW, Cullen DJ, et.al.
Systems analysis of adverse drug events. ADE Prevention Study Group. *JAMA.* 1995; 274(1):35-43.