

**Patient Safety Research in
Australia, United Kingdom, United States and Canada:**

**A Summary of Research Priority Areas, Agenda-Setting Processes
And Directions for Future Research in the Context of their Patient
Safety Initiatives**

Lianne Jeffs
Madelyn Law
G. Ross Baker
University of Toronto

Peter G. Norton
University of Calgary

February 20, 2005

This document was prepared for the Canadian Patient Safety Institute, Canadian Health Services Research Foundation and the Canadian Institutes of Health Research for the research priority setting retreat on February 28 and March 1, 2005

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Introduction to Background Materials

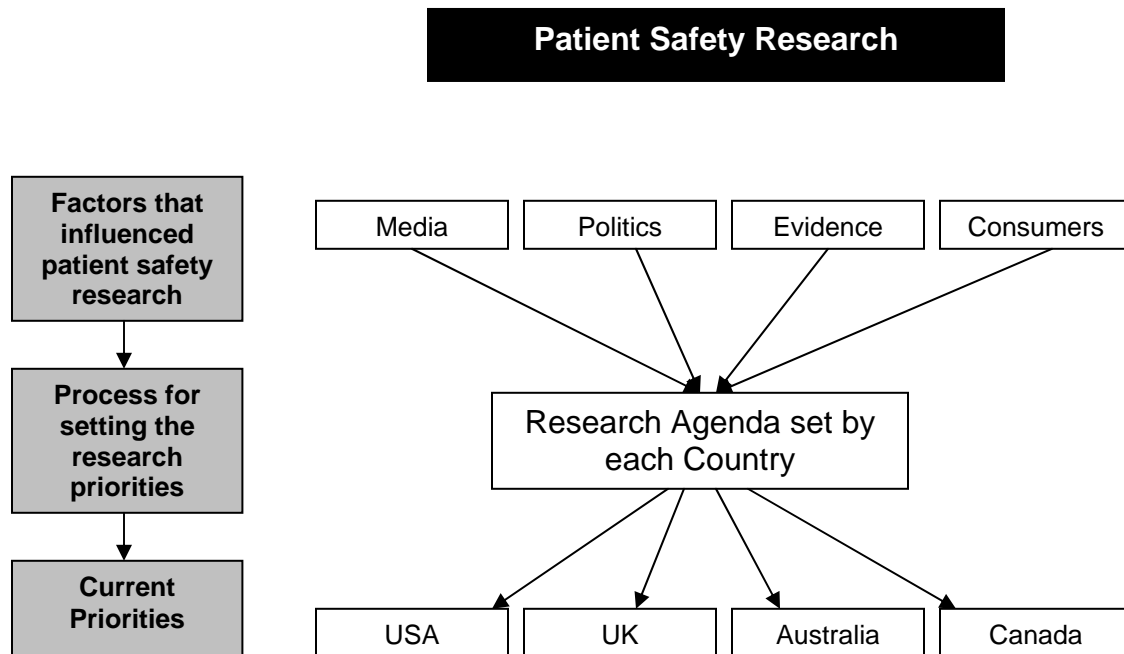
To support the CPSI, CHSRF and CIHI two-day meeting on setting a patient safety research agenda with researchers and decision-makers, a variety of background materials have been compiled and synthesized, including:

- 1) Overviews of individual countries (Australia, United Kingdom, United States and Canada).
- 2) Summary of research priority areas, agenda-setting processes and directions for future research.
- 3) In addition, binders of more detailed information organized by each individual country (Australia, United Kingdom, United States and Canada) included as Appendices A, B, C and D respectively in a binder that will be available onsite.

Introduction to Summary: Framework for Analysis, Agenda-Setting and Action

The following framework has been developed from the summary of literature of the four countries (Australia, United Kingdom, United States and Canada).

Figure 1 Framework for Analysis, Agenda-Setting and Action



Evolution of Patient Safety as a Global Health Policy Issue

Although efforts to improve healthcare quality have grown over the last two decades, patient safety as a health policy issue is relatively new. The evolution of patient safety as a health policy issue is rooted in the release of the Quality in Australian Health Care Study (Wilson et al. 1995) and the “To Err is Human” report from the Institute of Medicine in the United States (Kohn, Corrigan, & Donaldson, 1999). The incidence of adverse events (AEs) in acute care hospitals has been reported in the USA (Brennan, et al., 1991; Thomas et al., 2000), Australia (Wilson et al, 1995), United Kingdom (Vincent, Neale, & Woloshynowych, 2001), and more recently Canada (Baker et al., 2004). These studies indicated that between 5 and 20% of patients admitted to hospital experience one or more AEs, that between 36.9% - 51% of these AEs are preventable, and that AEs cost health care systems billions of dollars in additional hospital stays as well as other costs to the system, patients and the broader society.

Leape et al. (1991) maintain that more than two-thirds of adverse events are preventable. Together, with reports in the media of deaths caused by health system error, consumer demand and political pressure (Barach, 2003) prompted national policy documents in United Kingdom (Department of Health, 2000), the United States (Institute of Medicine, 2001), in Australia (Australian Council for Safety and Quality in Health Care, 2001) and in Canada (National Steering Committee on Patient Safety, 2002). These policy documents provide plans and direction for policymakers, health care leaders, clinicians and regulators regarding system changes necessary to improve patient safety practices, the creation of patient safety cultures, and support for research and knowledge generation and translation around patient safety practices.

In October 2004 the World Health Organization (WHO) launched a World Alliance for Patient Safety. The following six action areas were identified, all with implications for patient safety research.

- Global patient safety challenge (health-care associated infection).
- Patient and consumer involvement.
- Developing a patient safety taxonomy.
- Research in the field of patient safety.
- Solutions to reduce the risk of health care and improve its safety.
- Reporting and learning to improve patient safety.

The following sections provide specific details for each country in relation to the evolution of the research in patient safety research priority areas, agenda setting processes and directions for future research. Common contributing factors/antecedents to priority settings in all four countries are media reports; political pressures from both government officials (e.g., Congress in the United States) and stakeholder groups (professional associations, etc.); empirical studies (epidemiological findings); and consumer pressures.

Brief History

The first study regarding healthcare quality in Australian Health Care was published in 1995 and revealed that 16.6 percent of hospital admissions were associated with a preventable adverse event (Wilson et al. 1995). In this study the greatest areas of harm were outlined as medication, health care associated infections, blood, patient falls and pressure ulcers.

In response to this study the Health Ministers developed a taskforce to make recommendations on how to reduce the factors that influence preventable adverse events. This task force recommended that there was a need to establish a national organization to address these factors. A National Expert Advisory Group was established to coordinate and oversee the national initiatives and implement the recommendations of the task force. In 1999, the Expert Advisory Group reported to the Health Ministers that it was important to create a national plan of action for improving the safety and quality. This required the establishment of the Australian Council for Safety and Quality in Health Care (ACSQHC) to facilitate the coordination of this national plan. This council now serves as the national body that provides leadership, funding, resources and support for improvement.

This council was guided by the work of Leape (1991) and the *To Err is Human* report in 1999 (Kohn, Corrigan, & Donaldson, 1999). The council subsequently focused on developing priorities around the importance of building awareness and creating a culture of safety where errors are recognized, reported and acted upon. This is coupled with the focus on the clinical governance and accountability, the better use of data and the need to redesign systems (ACSQHC, 2004). These five priorities are:

- Supporting those who work in the health system to deliver safer patient care.
- Improving data and information for safer health care.
- Involving consumers in improving health care safety.
- Redesigning systems of health care to facilitate a culture of safety.
- Building awareness and understanding of health care safety.

The following table provides an overview of the how the research agenda was determined in Australia.

Table 1 Evolution of Australia's Patient Safety Research Agenda

<p>1987</p> <ul style="list-style-type: none">• Symposium on patient safety and monitoring.
<p>1988</p> <ul style="list-style-type: none">• Incident monitoring study in anaesthesia.
<p>1989</p> <ul style="list-style-type: none">• Australian Patient Safety Foundation (APSF) is established.• AIMS (Australian Incident Monitoring System) set up by APSF.
<p>1991</p> <ul style="list-style-type: none">• Federal Ministers commissioned the Professional Indemnity Review (PIR) and provided funding for AIMS pilots.
<p>1993</p> <ul style="list-style-type: none">• More research funding obtained through the PIR for AIMS.• Funding obtained for generic incident monitoring.
<p>1994</p> <ul style="list-style-type: none">• AIMS - Identification of the lack of consistency in clinical classification for things that for wrong in health care that led to the Generic Occurrence Classification.
<p>1995</p> <ul style="list-style-type: none">• The Quality in Australian Health Care Study by Wilson et al.• The Health Ministers developed a taskforce to make recommendations on how to reduce the factors that influence preventable adverse events who recommended that there was a need to establish a national organization to address these factors.
<p>1996</p> <ul style="list-style-type: none">• National Expert Advisory Groups was established to coordinate and oversee the national initiatives and implement the recommendations of the task force.
<p>1999</p> <ul style="list-style-type: none">• National Expert Advisory Group reported the need to create a national plan of action and to develop a national organization to oversee these activities.
<p>2000</p> <ul style="list-style-type: none">• The establishment of the Australian Council for Safety and Quality in Health care to facilitate the coordination of this national plan.• Annual Report: Safety First.
<p>2001</p> <ul style="list-style-type: none">• First nationally agreed upon "blueprint for change".• Consumer Participation Conference.• Provides Scholarships for consumers to attend conferences.• To set priorities the council was made up of consumers, clinical and quality experts, private sector and public sector chief executive officers, and a representative from New Zealand Ministry of Health. They used the report from the National Experts Advisory Group that contained information from extensive consultations with international leaders in patient safety, research evidence. As well the Council relied on personal expertise, support from State Quality Officials Forums, and working with clinicians, consumers and experts in the states and territories.• Annual Report: Safety in Practice: Making Health Care Safer.
<p>2002</p> <ul style="list-style-type: none">• Annual Report: Safety Through Action: Improving Patient Safety in Australia
<p>2003</p> <ul style="list-style-type: none">• Annual Report: Patient Safety: Towards Sustainable Improvement• Measuring Quality for Improvement Workshop to discuss and share ideas on the way forward for Australia
<p>2004</p> <ul style="list-style-type: none">• Annual report: Maximizing National Effectiveness to Reduce Harm and Improve Care
<p>(ACSQHC, 2004)</p>

Current Research and Policy Initiatives

The following table provides an overview of patient safety research and policy areas for Australia.

Table 2 Australia's Current Patient Safety Research and Policy Areas

Research and Policy Priority Areas	Funding Allocations
<p>Research Priority Areas (ACSQHC, 2004)</p> <ul style="list-style-type: none"> • Supporting those who work in the health system to deliver safer patient care. • Improving data and information for safer health care. • Involving consumers in improving health care safety. • Redesigning systems of health care to facilitate a culture of safety. • Building awareness and understanding of health care safety. <p>Policy Priority Areas</p> <ul style="list-style-type: none"> • Supporting the workforce. • Investment and governance. • Measurement for improvement. • Working with consumers. • Practice improvements. • Redesign and Information Technology. • Building awareness. • Strategic directions and partnerships. 	<p>\$55 million support from the government \$ 2 Million for Centre of Research Excellence</p>

Centre of Research Excellence in Patient Safety, Australia (December 20, 2004)

Recently the Australian Council for Safety and Quality announced the first Centre for Research Excellence in Patient Safety to be housed in Melbourne's Monash University. The primary investigator Professor John McNeil will head this 2 million dollar, five-year research grant. The research will focus on major risk areas including trauma resuscitation, clinical hand over and medication delivery. The aims of the centre are to undertake high quality research in the field of patient safety, build capacity by developing the next generation of research leaders to ensure that high quality patient safety research is continued into the future, facilitate better practice through dissemination of knowledge through a range of mechanisms and engage stakeholders through national and international collaborations.

National Patient Safety Education Framework (Draft November 2004)

The National Patient Safety Education Framework has been developed as an initiative of the Australian Council for Safety and Quality in Health Care. The goal of this project is to develop an educational framework that will identify the knowledge and performance required by all health workers in relation to patient safety, identify the key skills, knowledge, behaviors and attitudes related to patient safety for all health care workers. The goals of this framework are to develop a simple flexible framework that will act as a benchmark for training, educating and assessing health care workers in patient safety, help make patient safety concepts easy for everyone to understand and apply and help

ensure all workers in the health system are equally competent and supported in adopting a patient centred approach to their work.

List of Health Reform Actions agreed by Health Ministers (April 23, 2004)

The following are recommendations for hospitals to:

- Have a common medication chart will be in use by June 2006.
- Have a process of pharmaceutical review of medication prescribing, dispensing, administrating and documenting processes for the use of medicines in place by December 2006.
- Have an incident management system in place by January 2005 incorporating incident management, monitoring, investigation, analysis and action rising.
- Report sentinel events, either to the state department or to an agreed third party no later than the end of 2005.
- Adopt the 5 step right, right site, right procedure protocol.
- Provide patients with a copy of the consumer booklet 10 tips for safer health care by December 2004.
- Have in place a patient safety risk management plan by the end of 2005.

In addition, all states and territories will contribute to a national report on sentinel events to be produced by the end of 2005.

Below are some examples of research and projects based on the priority areas that were outlined in the Fifth Minister's report Maximizing National Effectiveness to Reduce Harm and Improve Care (ACSQHC, 2004). For a more detailed outline of the research projects in each state please see Appendix A, Sections 1 & 2.

Supporting those who work in the health system to deliver safer patient care

- Working with all areas and the Royal Australian College of Surgeons, the council has *ensuring correct patient, correct site, correct procedure protocol* that provides practical tools to help prevent procedures being carried out on wrong patient or body parts.
- A survey of health care professionals to identify barriers to and opportunities for the safer delivery of health care in hospitals.

Improving data and information for safer health care

- A national consultation was conducted providing valuable information about data collection, analysis and reporting on a state/territory and national level.
- The council provided seed funding for the establishment of a National Cardiac Procedures register. The aim of the Register is to improve the safety and quality for patients undergoing coronary revascularisation procedures performed by cardiac surgeons and interventional cardiologists by providing a tool for measuring and improving patient outcomes.

Involving consumers in improving health care safety

- Council produced, launched and distributed approximately 60,000 copies of the booklet, 10 tips for Safer Health care: what everyone needs to know.

- New South Wales Health has established a toll-free telephone number to assist patient, consumers and health care workers to notify the department of any concerns about services or the care received while undergoing treatment.

Redesigning systems of health care to facilitate a culture of safety

- The implementation of a hospital wide Medical Emergency Team System, that would reduce the incidence of unplanned admissions to intensive care units, cardio-pulmonary arrests and in-hospital deaths, is being trailed in 23 hospitals in Queensland, New South Wales, Victoria and South Australia and the Australian Capital Territory. See Appendix A, Section 3.
- Over 120 innovative local projects across Australia have been conducted in two rounds of Safety Innovations in Practice (SIIP) funding programs. See Appendix A, Section 4.

Building awareness and understanding of health care safety

- Conferences: 1st Australian Conference on Safety and Quality in Health Care (July 2003); Australian Aviation Psychology Association and the New South Wales Council for Quality in Health Care sponsored medical seminars; 1st Asia Pacific Forum on Quality improvement in Health care; Shared Meanings project brought together individuals to decide on the definitions of key terms to be used in safety and quality issues.

Australian Patient Safety Foundation

The APSF was developed by Dr. William Runciman who helped to develop software to collect and understand data related to incidents in a consistent and detailed way. This tool, called the Advanced Incident Management System (AIMS®) was designed to assist in the analysis and interpretation of the events. After the 1995 study on Quality in Australian Health Care, the state government of South Australia commissioned APSF to develop and implement the AIMS system for all public health units in SA. (<http://www.apsf.net.au/about.html#history>).

Brief History

In 1997, the UK government published a paper that detailed a ten year modernization strategy for the National Health System (NHS) of which one goal was to improve the quality of care (Department of Health, 2000). In response to this paper and the acknowledgement of serious failures in standards of care in NHS services (Department of Health, 2000) an expert committee led by Dr Liam Donaldson, Chief Medical Officer, was established to examine how organizations can learn from the incidents and failures in order to avoid a reoccurrence of these events. Studies from the United States (Brennan et al., 1991), Australia (Wilson et al., 1995) and in the UK (Vincent, 1997) were used as a basis from which to examine the current state of adverse events in the UK.

The publication *An Organization with a Memory* (Department of Health, 2000) resulted from the work this committee conducted and made 10 recommendations (Appendix B, Section 1). In general these recommendations outlined the need to learning from these incidents and to create organizational cultures of openness, reporting and safety. Within this report there were four areas where patterns of errors were most evident (badly administered spinal injections, negligence and harm in obstetrics and gynaecology; serious errors in the use of prescribed drugs, and design for safety and suicides of mental health in-patients).

The government accepted these recommendations and in May 2001 published *Building a Safer NHS for patients: Improving Medication Safety* (Appendix B, Section 2). This document outlined the implementation of a plan for safety requiring a commitment of all NHS staff and boards, a creation of a culture where staff could report incidents without the fear of retribution, the establishment of a national and local mechanism for reporting and analyzing data in relation to adverse events and learning lessons to prevent future harm to patients.

Several key outcomes followed from this report including the establishment of the National Patient Safety Agency in 2001 as a Special Health Authority in the NHS. The NPSA is responsible for co-ordinating the efforts in healthcare to learn from patient safety incidents occurring in the NHS. The Business Plan for the NPSA outlined their corporate objectives that would guide their work in 2004/2005 (Appendix B, Section 3). These consist of 1) collect and analyze information in relation to patient safety, 2) prioritize the action required to improve patient safety, 3) work with other to deliver the action required to improve patient safety, and 4) continuously learn how to improve patient safety.

The following table provides an overview of the how the research agenda was determined in the United Kingdom.

Table 3 Evolution of United Kingdom's Patient Safety Research Agenda

<p>1997</p> <ul style="list-style-type: none"> • Ten-year modernization strategy for the National Health System (NHS) of which one was to improve the quality of care. • Expert committee led by Dr Liam Donaldson, Chief Medical Officer. <p>1999</p> <ul style="list-style-type: none"> • The CMO published the report <i>Supporting doctors, protecting patients which led to the</i> led to the establishment of the National Clinical Assessment Authority. <p>2000</p> <ul style="list-style-type: none"> • <i>An organization with a Memory</i> published. <p>2001</p> <ul style="list-style-type: none"> • <i>Building a Safer NHS for patients: improving Medication safety</i> published. • The National Patient Safety Agency, Special Health Authority in the NHS and is responsible for co-ordinating the efforts in healthcare to learn from, patient safety incidents occurring in the NHS. • National Reporting and Learning System (NRLS) piloted in 28 hospitals and primary care units. • The establishment of the Patient Safety Research Programme, developed research strategy for the programme through the use of the information in "An Organization with a memory", consultation with experts around the world, a commissioned review of the literature and consultation within the UK (the NPSA, Commission for Health Improvement, Medical Research Council). <p>2002</p> <ul style="list-style-type: none"> • National Patient Safety Agency First National Conference. <p>2003</p> <ul style="list-style-type: none"> • National Patient Safety Agency (NPSA) Prioritization Consultation - a proposed process for deciding how the agency should prioritise its work in developing solutions to patient safety issues between November 2003 and March 2004. This involved a wide dissemination of the consultation document and a series of consultation events across England and Wales. <p>2004</p> <ul style="list-style-type: none"> • Pilot Prioritization Process. • NPSA to phase in this reporting system in England and Wales and is supporting training programmes and 32 patient safety managers. • Joining of the National Clinical Assessment Authority (NCAA) (dealing with physician and dentist performance), with the NPSA in 2004 that ensure the continuation of the centrally important work the NCAA has done to support an integrated NHS quality and safety agenda. • <i>Design for Patient Safety</i>, jointly commissioned by the Design Council and the Department of Health. • The NPSA established the National Reporting and Learning System (NRLS) that collects and assesses the causes of problems and helps to provide solutions. This system was piloted in 28 hospitals and primary care units in 2001. The outcome of this study revealed that linking existing data collection systems was possible and that health care practitioners were willing to report the NPSA. As part of the business plan the NPSA began to phase in this reporting system in England and Wales in 2004 and is supporting training programmes and 32 patient safety managers.
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(Lilford, 2004; NPSA, 2004; Department of Health, 2004)

Current Research and Policy Initiatives

The following table provides an overview of patient safety research and policy areas for United Kingdom.

Table 4 United Kingdom's Current Patient Safety Research and Policy Areas

Research and Policy Priority Areas	Funding Allocations
<p>Research Policy Areas</p> <p>An active research program including:</p> <ul style="list-style-type: none"> • developing a research strategy which will outline the NPSA contribution to the research agenda; • working with existing research funders to ensure that NPSA priorities identified from the NRLS and other services are funded; • beginning to develop capacity in the NRLS for the researchers of the future; and • Promoting an innovative multi-disciplinary environment in which the right research questions can be framed and then answered to promote improved patient safety. <p>Priority Policy Areas</p> <ul style="list-style-type: none"> • To set up and operate a national reporting and learning system (NRLS) for adverse events. • To provide practical solutions to improve patient safety. • To develop and support a culture in health care that is open and fair, where risks are assessed and patient safety is a high priority. • To engage patients and the public in our work; to work in partnerships with others. • To be a highly respected and influential organization; to be cost effective organization and deliver value for money. 	<p>£1.5 Million in budget for the Patient Safety Research Programme (NPSA, 2004b)</p>

Patient Safety Research Programme

The Patient Safety Research Programme is funded by the Policy Research Programme and the Department of Health, and reports directly to Sir Liam Donaldson, the Chief Medical Officer. This program builds on previous research and focuses on projects in the areas of; learning lessons from litigation arising from clinical negligence claims, using crisis simulations, team training and other methods to improve the ability of clinicians to respond to emergencies on labour wards; understanding better the engineering, psychological and social factors around safety in A&E departments and in operating theatres. (See Appendix B, Section 4 for a detail list of the research).

Safety Solutions – National Patient Safety Agenda (NPSA)

The Safety Solutions and Clinical Programmes directorates is a program that works to create solutions on a national scale to prevent incidents. The aim of this program is to understand why things go wrong, correct actions and make changes so that the incident will not reoccur. After an issue is identified solutions are designed by experts, partnerships and patients and tested. (<http://81.144.177.110/npsa/work/safety>)

Clinical Specialty Advisors - NPSA

The NPSA has established a network of 17 Clinical Specialty Advisors (CSAs) who work with the NPSA to ensure that there is bi-directional flow of information on patient safety issues within their specialty; collaborate on identifying and assessment of the scope of patient safety issues; participate in the development and implementation of solutions; and work to ensure that patient safety issues identifying ways of improving it. The implementation of clinical governance is being led and supported by a National Clinical Governance Support Team working as part of the Modernisation Agency.

Patient Safety Alerts

Alerts are being issued by the NPSA when there are specific risks to patients that health care practitioners must be aware of. See Appendix B, Section 5 for an example. The Medicines and Health care Products Regulatory Agency is working with the NPSA to ensure the availability of a broader range of diluted products and to develop distinctive packaging that will help reduce risk to patients.

Projects related to the report: An Organization with a Memory

Since this report and the identification of the consistent patterns of error in five areas the UK government has implemented various targeted projects.

Badly administered spinal injections. After a severe incident of badly administered spinal injection the Department of Health issued a guidance note about the safe administration of intrathecal chemotherapy and a toolkit was also developed. The NPSA also produced a risk assessment of spinal procedures (Department of Health, 2004).

Negligence and harm in obstetrics and gynaecology. The National Institute for Clinical Excellence issued guidelines and the Department of Health has also commissioned further guidelines to improve maternal and neonatal outcomes. As well the Patient Safety Research Programme has a number of projects funded to examine the cases where errors occurred and resulting litigation and another study to examine the quality of current practice in emergency obstetrics and audit maternal training.

Serious errors in the use of prescribed drugs. In 2002, the NPSA issued a patient safety alert about potassium chloride in regards to the identical package as saline solution. As well *the Building a safer NHS for patient: Improving Medication Safety* (2002; Appendix B, Section 2) outlined the various issues around medication safety and detailed recommendations.

Design for safety. Jointly commissioned by the Design Council and the Department of Health a report entitled the *Design for Patient Safety* (Appendix B, Section 6) was published and outlines the system approach to patient safety and provides practical ways in which design can be modified to avoid errors.

Suicides of mental health in-patients. All non-collapsible structures in acute psychiatric wards were to be removed by 2002. This was reported to have significant impact in the reduction of suicides (Department of Health, 2004).

Evolution of Research and Policy Initiatives (1978-2003)

During the past 25 years in the US, three large scale studies have examined the incidence of adverse events in hospitals (Brennan et al., 1991; Mills, 1978; Thomas et al., 2000). The first study, conducted in California (based on a review of 20,000 hospital records), reported that adverse events occurred in 4.5% of hospitalizations and negligent adverse events in almost 1% of cases (Mills, 1978). The second study, conducted in New York hospitals (a review of 30,000 hospital records) reported that adverse events occurred in 98,000 cases out of 2.8 million, of which approximately 37,000 involved substandard care (Brennan et al., 1991). Similar results were reported with a sample from Utah and Colorado involving a two-staged medical record review (Thomas et al., 2000).

Studies using other methods besides chart review have found even greater numbers of adverse events. For example, Andrews et al. (1997) using observational methods reported that 177 out of 1,000 hospitalized patients received inappropriate care that resulted in serious adverse events. Other empirical studies include investigations of preventable adverse drug events (e.g., Leape et al., 1991); the role of systems failures in the aetiology of medical errors (Leape et al., 1995); and the effects of the healthcare workforce on safety (Kovner & Gergen, 1998).

Until recently, the funding of patient safety studies was not based on any strategic commitment to addressing the patient safety challenge, but rather on traditional granting criteria with agencies soliciting or commissioning patient safety researchers to employ sound methods to address compelling issues (Meyer & Eisenberg, 2002).

In addition to empirical work, a public poll conducted in 1997 revealed that 42% of respondents indicated that they or a close friend experienced a medical mistake (Louis Harris & Associates, 1997). Collectively, scholarly inquiries and increased public expectation for accountability (Barach, 2003) has led to a growing number of research and policy initiatives over the last two decades.

Anaesthesiology has been a prime mover in the development of patient safety and patient safety research in the United States. In 1983, the Royal Society of Medicine of England and the Harvard Medical School jointly sponsored a symposium on morbidity and mortality associated with anesthetic accidents. A key result of the meeting was an agreement to share statistics and to define the parameters of future studies. Following this meeting, the American Society of Anesthesiologists, inaugurated the Anesthesia Patient Safety Foundation (APSF) in 1984. Since its inception, the APSF has promoted research in anesthesia safety by awarding four or five grants of up to \$65,000 per year. See (Appendix C, Section 1) for a description of research grants.

In October 1996, a groundbreaking conference was held at the Annenberg Center for Health Sciences (ACHS) that involved health care providers, clinicians, government, health care payers, consumers, educators, and the press. In addition, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) developed and adjusted its “Sentinel Event” monitoring program to emphasize patient safety concerns. In 1997, Harvard’s University Kennedy School of Government convened an Executive Session on Medical Error and Patient Safety, the American Medical Association developed and launched the National Patient Safety Foundation (July); and the Veteran’s Health Administration established the National Patient Safety Partnership (October) comprised of government agencies and private partners (Barach, 2003).

In April 1998, President Clinton’s Advisory Commission on Consumer Protection and Quality in the Health Care Industry designated the reduction of error as one of the eight goals for the assurance of quality in health care. In November 1998, a coalition of health care purchasers “Leapfrog Group” was created to coordinate initiatives that link health care plans and providers to improve patient safety. In October 1999, the Medical Group Management Association announced a new patient safety initiative that focused on reducing risk in office practice settings and the National Business Coalition on Health made patient safety a priority for its members (Barach, 2003).

In November 1999, the Institute of Medicine (IOM) released the landmark report that was funded by the Agency for Healthcare Research and Quality (AHRQ) “To Err is Human” (Kohn, Corrigan & Donaldson, 1999). Within a week of the release of this report, the Clinton administration issued an Executive Order directing federal agencies (Quality Interagency Coordination Task Force-QulC) to develop an action plan to implement the recommendations. In February 2000, President Clinton announced support for a state-based, nationwide system of reporting medical adverse events (Barach, 2003). In September 2000, AHRQ gathered together with public, private, and international partners (UK, Australia) for a summit. This summit focused on a user’s perspective, where groups that would use the products of patient safety research (patients, providers, plans, purchasers, and policy makers) were asked “What are the questions that could be addressed with research which you could use to make health care safer?” The following 7 key areas were identified from this summit.

- Epidemiology of errors.
- Infrastructure to improve patient safety.
- Information systems.
- Performance shaping factors.
- Evidence based interventions.
- Safety cultural issues.
- Educational tools.

One of the key highlights in the IOM report was to develop an evidence-based approach for safety improvement through research, moving the direction of funding patient safety research to a more strategic approach (Meyer & Eisenberg, 2002). In addition, the QulC report called for a more substantial targeted investment in patient safety research (Meyer et al., 2001). This strategic approach was reflected in AHRQ’s commitment to \$2

million investment (2000 budget) and \$50 million investment (2001 budget) in research on systems related to best practices in improving patient safety. The investment in patient safety research in 2001 used a portfolio of six complementary research solicitations that focused on the following five priority areas (Meyer & Eisenberg, 2003):

- Increase understanding of what is working in patient safety reporting.
- Support established and developing multidisciplinary teams to generate new knowledge to enhance patient safety.
- Examine the role of working conditions and performance shaping factors on patient safety.
- Evaluate information technology based interventions to improve patient safety
- Promote the dissemination of the results of this research through educational programs.

See Appendix C, Section 2 for a complete listing of AHRQ grants funded under the patient safety research initiative.

Challenges in implementing AHRQ's patient safety agenda included significant logistical challenges such as the evaluation of methodological approaches which were often unfamiliar to traditional health services researchers, difficulties in developing review panels with sufficient expertise (since many of those with expertise responded to the research solicitations themselves), and the lack of standardized approaches to measurement to judge research applications (Meyer & Eisenberg, 2002).

In 2000, The National Patient Safety Foundation released "Agenda for Research and Development in Patient Safety" which outlined a strategy for patient safety research. Specifically, seven key questions guided the tactical plan.

- What is patient safety and what is patient safety research?
- What are the goals of research concerning patient safety?
- How much of the NPSF's research agenda should be driven by a targeted agenda vs. the independent ideas of researchers?
- How much should research focus on underlying mechanisms of unsafe systems vs. the development and testing of remedies for specific safety problems?
- What methodologies are appropriate for research in patient safety?
- By what processes should the research strategy and agenda of the NPSF be developed, maintained, and updated so that it is consistent with contemporaneous needs of patient safety movement in NPSF?
- By what measures will we know if our goals are being achieved?

From answering these questions, two broad categories of issues needing research were identified for the focus of improvement: *safety problems* and *underlying mechanisms*.

- ***Learning about underlying systemic factors influencing performance*** ***includes:*** learning about when incidents and accidents occur; anticipating new areas of concern as change occurs; finding deeper and more generic patterns in failures; and developing, prototyping, and evaluating new approaches to safety.
- ***Interventions that may improve safety performance or help solve patient safety problems*** ***include:*** improving mechanisms of patient identification; using

computerized drug order entry systems; bar code scanning of blood products; addressing language barriers and cultural differences that may lead to poor provider/patient communications; designing new systems of safety reporting; and using new training modalities, such as simulation.

- **Research and development are needed to:** reveal the existence of and/or determine the frequency and magnitude of safety problems; evaluate the contribution of underlying human or system characteristics to safety problems; assess the prevalence of underlying human or system characteristics in health care analogous to those known to be important arbiters of safety in other hazardous industries; develop, pilot, and evaluate techniques or approaches to modify human or system characteristics (e.g., safety reporting, education and training, modified procedures for drug order entry); and develop, pilot, and evaluate techniques or approaches to maintain patient safety efforts as integral to the culture of health care delivery.
- **The following strategies are the basis for the Agenda for NPSF-sponsored research:** foster and encourage investigator-initiated research; target one or two special areas likely to achieve positive results in a few years; leverage NPSF's resources by convincing other funding sources of the importance and scientific validity of patient safety research topics; have a broad impact on the population; improve understanding of what is generally referred to as preventable problems, especially those brought about by human error and system failures; propose innovative and creative methods of study or solutions to problems; involve interdisciplinary research teams; and do not have other sources of funding.

See Appendix C, Section 3 for a complete listing of NPSF grants funded under the patient safety research initiative.

In January 2001, a "Current Research on Patient Safety in the United States" report commissioned by NPSF to guide its efforts was released (Cooper et al., 2001). See Appendix C, Section 4 for complete report. Twenty-three gaps were identified, key ones include:

- Need for different research methodologies to overcome barriers to access information about errors.
- Consumer-oriented research.
- Research about communication and information-sharing among health care providers.
- Basic research towards understanding the causes of medical error and systems' failure.
- Study of error, accident or event reporting processes.
- Medication errors in non-inpatient settings.
- Studies of workloads.

In addition, the authors concluded that the lack of definition may create confusion about what kinds of projects should be supported by the new funding that is expected to be designated for this purpose (Cooper et al., 2001).

In September 2002, in Reykjavik, Iceland, a joint workshop between the United States (AHRQ) and United Kingdom (Patient Safety Research Programme of the UK Department of Health) brought together 25 leading edge researchers in the area of improvement and safety (Battles, 2003). Key questions addressed included:

- What are the appropriate research methods for patient safety?
- Can issues of patient safety be addressed with traditional research methods associated with health services research?
- Are new methods and approaches required?
- If new methods and approaches are required, what are they and how can they be applied to patient safety issues and concerns?

Since 2003, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO-US accreditation body) continues to develop national patient safety goals. To date, the following national JCAHO goals have been identified:

- Improve the accuracy of patient identification (2003-2005).
- Improve the effectiveness of communication among caregivers (2003-2005).
- Improve the safety of using high-alert medications (2003-2005).
- Eliminate wrong-site, wrong-patient, and wrong-procedure surgery (2003-2005).
- Improve the safety of using infusion pumps (2003-2005).
- Improve the effectiveness of clinical alarm systems (2003-2005).
- Reduce the risk of health care-acquired infections (2004-2005).
- Accurately and completely reconcile medications across the continuum of care (2005).
- Reduce the risk of patient harm resulting from falls (2005).
- Reduce the risk of influenza and pneumococcal disease in institutionalized older adults (2005).
- Reduce the risk of surgical fires (2005).
- Implementation of applicable National Patient Safety Goals and associated requirements by components and practitioner sites (2005).

The following table provides an overview of the how the research agenda was determined in the United States of America.

Table 5 Evolution of United States's Patient Safety Research Agenda

1983

- Symposium on anesthesia accidents sponsored by the Royal Society of Medicine and the Harvard Medical School.
- Anesthesia Patient Safety Foundation is created.

1996

- Annenberg Center for Health Sciences conference involving a variety of stakeholders: health care providers, clinicians, government, health care payers, consumers, educators and the press.
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO) developed and adjusted its “Sentinel Event” monitoring program to emphasize patient safety concerns.

1997

- Executive Session on Medical Error and Patient Safety held, co-sponsored by Harvard’s University of Kennedy School of Government.
- American Medical Association developed and launched the National Patient Safety Foundation (July).
- Veteran’s Health Administration established the National Patient Safety Partnership comprised of government agencies and private partners (October).

1998

- President Clinton’s Advisory Commission on Consumer Protection and Quality in the Health Care Industry designated the reduction of error as one of the eight goals for the assurance of quality in health care (April).
- Leapfrog Group, a coalition of health care purchasers, was created to coordinate initiatives that link health care plans and providers to improve patient safety (November).
- NPSF starts funding annual research awards.

1999

- Medical Group Management Association announced a new patient safety initiative that focused on reducing risk in office practice settings (October).
- National Business Coalition on Health made patient safety a priority for its members (October)
- Institute of Medicine (IOM) released the landmark report that was funded by the Agency for Healthcare Research and Quality (AHRQ) “To Err is Human” /generates massive media coverage (November).
- Clinton administration issued an Executive Order directing federal agencies (Quality Interagency Coordination Task Force-QulC) to develop an action plan to implement the recommendations (November).

2000

- President Clinton announced support for a state-based, nationwide system of reporting medical adverse events.
- AHRQ gathered together with public, private, and .
- National Patient Safety Foundation released “Agenda for Research and Development in Patient Safety” which outlined their strategy for patient safety research.

2001

- Current Research on Patient Safety in the United States” report commissioned released by NPSF (January).

2002

- A joint workshop between the United States (AHRQ) and United Kingdom (Patient Safety Research Programme of the UK Department of Health) brought together 25 leading edge researchers in the area of improvement and safety in Iceland (September).

2003

- JCAHO develops national patient safety goals.

2004

- AHRQ released the mission statement for the Center for Quality Improvement and Patient Safety (CQIPs) (February).
- AHRQ in partnership with National Institutes of Health (NIH) issued a Request for Applications (RFA) “Partnerships in Implementing Patient Safety Grants” to implement safe practice interventions that show evidence of eliminating or reducing medical errors, risks, hazards, and harms associated with the process of care in health care organizations (September 24).

- AHRQ announced as one its four research priorities Patient Safety and Quality (November 24)
- Institute of Health Improvement (IHI) announced the “100,000 Lives Campaign” which aims to enlist thousands of hospitals across the country in a commitment to implement changes in care that have been proven to prevent avoidable deaths (December 14).

2005

- APSF announces 4 grants for 2005 competition.

(Anaesthesia Patient Safety Foundation, 2004; Barach, 2003; Meyer & Eisenberg, 2002)

Current Research and Policy Initiatives (2004-2005)

The following table provides an overview of patient safety research and policy areas for United States.

Table 6 United States’s Current Research and Policy Areas

Research and Policy Priority Areas	Funding Allocations
<p>AHRQ</p> <ul style="list-style-type: none"> • Support the development of multi-disciplinary research teams in building the knowledge base on the scope and impact of medical errors, particularly for diverse care settings and populations. • Identify the root causes of threats to patient safety and effective system approaches to prevent the occurrence of errors • Study the effectiveness of various interventions to capture information on medical errors • Evaluate the implementation of information technology to reduce errors and increase efficiency • Disseminate and evaluate the outcomes of promising interventions in a variety of health care settings and across a variety of health care professions • Increase understanding of what is working in patient safety reporting. • Examine the role of working conditions and performance shaping factors on patient safety. 	<p>AHRQ (2001) \$ 50 million annually for research on systems related to best practices in improving patient safety</p> <p>For fiscal 2005, AHRQ intends to commit up to \$3 million in total costs to fund up to 10-15 new grants.</p> <p>APSF-\$65,000 per application, funding has increased to \$75,000K per application for the 2006 competition</p> <p>NPSF- each research project can receive up to \$100,000 per a 2 year period.</p>

<p>APSF</p> <ul style="list-style-type: none"> • Explore new clinical methods for prevention and other methods that reduce error in anesthesia practice. <p>NPSF</p> <ul style="list-style-type: none"> • Explore the relationship between physicians and patients contributes to or inoculate against error. <p>Priority Policy Areas</p> <ul style="list-style-type: none"> • Need for different research methodologies to overcome barriers to access information about errors. • Consumer-oriented research. • Research about communication and information-sharing among health care providers. • Basic research towards understanding the causes of medical error and systems' failure. • Study of error, accident or event reporting processes • Medication errors in non-inpatient settings. • Studies of workloads. 	
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(AHRQ, APSF & NPSF, Cooper et al., 2001)

Agency for Healthcare Research and Quality

In February 2004, AHRQ released the mission statement for the Center for Quality Improvement and Patient Safety (CQIPS). The aim of CQIPS is to improve the quality and safety of all Americans through strategic partnerships through the following actions.

- Conducts and supports user-driven research on patient safety and health care quality measurement, reporting and improvement.
- Develops and disseminates reports and information on health care quality measurement, reporting and improvement.
- Collaborates with stakeholders across the health care system to implement evidence-based practices, accelerating and amplifying improvements in quality and safety for patients.
- Assesses our own practices to ensure continuous learning and improvement for the Center and its members.

On September 24, 2004 AHRQ in partnership with National Institutes of Health (NIH) issued a Request for Applications (RFA) "Partnerships in Implementing Patient Safety Grants" to implement safe practice interventions that show evidence of eliminating or reducing medical errors, risks, hazards, and harms associated with the process of care in health care organizations.

On November 24, 2004, AHRQ announced as one its four research priorities Patient Safety and Quality. This priority includes support the development of multi-disciplinary research teams in building the knowledge base on the scope and impact of medical errors, particularly for diverse care settings and populations, identify the root causes of threats to patient safety and effective system approaches to prevent the occurrence of errors, study the effectiveness of various interventions to capture information on medical errors, evaluate the implementation of information technology to reduce errors and increase efficiency, and disseminate and evaluate the outcomes of promising interventions in a variety of health care settings and across a variety of health care professions.

Anesthesia Patient Safety Foundation

2005 Grant Program (4 grants awarded) priority were given to: studies that address peri-anesthetic problems for relatively healthy patients; or studies that are broadly applicable and promise improved methods of patient safety with a defined and direct path to implementation into clinical care; or innovative methods of education and training to improve patient safety. Priority research areas include, but are not limited to: New clinical methods for prevention and/or early diagnosis of mishaps; evaluation of new and/or re-evaluation of old technologies for prevention and diagnosis of mishaps; identification of predictors of negative patient outcomes or anesthesiologist/anesthetist clinical errors; development of innovative methods for the study of low-frequency events; methods for measurement of cost effectiveness of techniques designed to increase patient safety; development or testing of educational content to measure, develop and improve safe delivery of anesthetic care during the perioperative period; and development, implementation, and validation of educational content or methods of relevance to patient safety. A call for 2006 competition has just been released. See Appendix 3, Section 4 for more details.

Institute of Health Improvement

On December 14, 2004, IHI announced the “100,000 Lives Campaign” which aims to enlist thousands of hospitals across the country in a commitment to implement changes in care that have been proven to prevent avoidable deaths. See Appendix 3, Section 5 for more details. The focus of the campaign is based on the following six quality improvement interventions:

- Deploy Rapid Response Teams
- Deliver Reliable, Evidence-Based Care for Acute Myocardial Infarction
- Prevent Adverse Drug Events (ADEs)
- Prevent Central Line Infections
- Prevent Surgical Site Infections
- Prevent Ventilator-Associated Pneumonia

National Patient Safety Foundation

November 10, 2004, NPSF announced the release of the “Hospital Survey on Patient Safety Culture”. This tool is a result of a partnership between Premier Inc., the Department of Defence, and the American Hospital Association.

December 15, 2004, NPSF announced the launch of an interactive Web site containing three education modules focused on physicians

(<http://www.npsf.org/html/mcw/physicians.html>), nurses

(<http://www.npsf.org/html/mcw/nurses.html>) and patients

(http://www.npsf.org/html/patients_web.html). This Web site was developed under a grant from the Agency for Healthcare Research and Quality (AHRQ) to research and create a standard method of patient education to reach large audiences.

2004 NSPF Research Awards. (To be announced). Key areas in the competition were projects that address how the relationship between physicians and patients contributes

to or inoculate against error. Specifically, how enhanced patient involvement in care may reduce errors, understanding symmetry errors in diagnosis or treatment (e.g., left vs. right errors), creating methods to alter the cultural (e.g., legal, professional and societal) barriers to reporting and openly discussing errors and preventable injuries, improving the coordination of care and teamwork in healthcare delivery, and understanding the multiple factors that contribute to errors and their interactions. See Appendix 3, Section 2 for more details around NPSF research initiatives.

Evolution of Research and Policy Initiatives in Canada (2001-2003)

In response to the gaining momentum of patient safety as a priority in health care, driven mainly by studies in the United States (Brennan et al., 1991; Leape et al., 1991; Thomas et al., 2000), United Kingdom (Vincent, Neale, & Woloshynowych, 2001) and Australia (Wilson et al., 1995), several initiatives (national, provincial/territorial and regional) have taken place in Canada in the past four years.

National Initiatives

Institute for Safe Medication Practices (ISMP) Canada

Founded in 2001, ISMP Canada's goals are to:

- Review medication errors submitted by practitioners to ISMP Canada and to make recommendations to reduce the probability of errors occurring.
- Publish and disseminate information to the health care community and practitioners through efficient electronic means in order to promote safe medication use and strategies for reduction of error-induced injury in Canada.
- Participate in cooperative programs with professional organizations in Canada in providing education about adverse drug events and their prevention.
- Act as consultants to institutions and other health care settings on safe medication use.
- Develop educational and quality improvement assessment tools for healthcare practitioners and institutions.
- Establish and maintain a strong partnership with the ISMP in the US, and other national and provincial patient safety initiatives.
- Provide educational programs for university and health professional constituents.

Canada Health Infoway Inc.

Established in January 2001, Canada Health Infoway Inc. (*Infoway*) supports the creation of an "infostructure" that provides Canadians and their health care providers with timely, appropriate and secure access to the right information when and where they enter into the health care system. It will foster and accelerate the development and adoption of electronic health information systems with compatible standards and communications technologies on a pan-Canadian basis with tangible benefits to Canadians. *Infoway* was created in response to a commitment of Canada's First Ministers to "work together to strengthen a Canada-wide health infostructure to improve quality, access and timeliness of health care for Canadians."

National Steering Committee on Patient Safety (2001-2002)

A national steering committee on Patient Safety was convened in the fall of 2001, following a symposium sponsored by the Royal College of Physicians and Surgeons of Canada (RCPSC). In September 2002, the steering committee released "Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian

Health Care” which provided a framework for an integrated national patient safety strategy. See Appendix D, Section 2 for the report. Enhancing the safety of patient is the result of three independent actions: preventing adverse events, making them visible, and mitigating their effects when they occur. The following were identified as principles for action.

- Complex national health care system, characterized by many competing pressures (balance of funding and quality care) that require high levels of collaboration across all sectors to ensure coordinated and effective strategy for improving patient safety.
- Safety is fundamental aspect of quality health care, health care system must develop, maintain and nurture as culture of safety.
- Public acknowledgement that human error is inevitable and that underlying systemic factors, including open system change, contribute to most near misses, adverse events and critical incidents.
- Evidence-based educational and professional development programs that are team-based can reduce likelihood of error.
- Identification and creation of a network of databases for adverse events
- Atmosphere of trust (vs. blame) is required.
- Partnerships among consumers and providers of care are instrumental in improving all operational/systemic deficiencies.
- Build on what is known in other safety industries.
- Promotion of appropriate disclosure to all partners of safety information.

The steering committee developed the following recommendations:

- Establish a Canadian Patient Safety Institute to facilitate a national integrated strategy for improving patient safety.
- Improve legal and regulatory processes.
- Improve the measurement and evaluation of patient safety.
- Establish educational and professional development programs.
- Improve information and communication processes.

Health Canada

Health Canada has an ongoing commitment to quality of care and patient safety. This is reflected in its multi-faceted role in legislation, regulation, surveillance, research, information dissemination and health care delivery to First Nations and Inuit populations. The following provides an overview of initiatives and partnerships associated with patient safety and Health Canada.

1) Patient Safety and Healthcare Error in the Canadian Health Care System. A Systematic Review and Analysis of Leading Practices in Canada with Reference to Key Initiatives Elsewhere. Released in 2002, Baker and Norton provided an annotated review of key initiatives, studies and research papers from the US, UK, Australian and other countries. See Appendix D, Section 3 for the report. Based on the literature review and survey results, the authors present the following key recommendations for future action.

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

2) Canadian Adverse Drug Reaction Information System (CADRIS). The Canadian Adverse Drug Reaction Information System (CADRIS) is the name of the computerized database that houses Canadian suspected adverse reactions (AR) which have been reported to Health Canada's Canadian Adverse Drug Reaction Monitoring Program (CADRMP). CADRMP collects AR reports for the following Canadian marketed health products: pharmaceuticals; biologics (including fractionated blood products, as well as therapeutic and diagnostic vaccines), natural health products; and, radio-pharmaceuticals. Adverse reaction reports are submitted by health professionals and consumers on a voluntary basis, either directly to Health Canada or via market authorization holders. It is mandatory for all Health Product Market Authorization holders (manufacturers) to report adverse reactions to Health Canada according to the *Food and Drugs Act and Regulations and the Natural Health Products Regulations*.

3) Look-alike/Sound-alike Health Products (LA/SA). Many health products are similar when written or spoken, which can create confusion and lead to injury. Health Canada critically reviews scientific information and works to ensure that health products in Canada are safe, effective and of high quality. To date, a Health Products and Food Branch inter-directorate working group has reviewed and analyzed issues associated with LA/SA similarities and has recommended a course of action to reduce the potential for LA/SA confusion between products.

4) Medical Device Problem Reporting by health care facilities, medical professionals and other device users. Manufacturers and importers must report problems with medical devices to Health Canada's Health Products and Food Branch Inspectorate (HPFBI). As a central clearing house for such reports, the HPFBI can link isolated reports to identify problems that would otherwise go unnoticed or be dismissed. It encourages anyone purchasing, using or maintaining these products to report problems.

Canadian Medication Incident Reporting and Prevention System (CMIRPS). CMIRPS was created in 2003 with the goal to assist health professionals, health organizations, community-based pharmacies and governments, among others, to recognize potential problems before they occur and implement appropriate preventative strategies. The main objective of the CMIRPS is the reduction of harm caused by preventable medication incidents. This will be accomplished through the collection and analysis of standardized incident data; and the development and dissemination of timely and targeted information to the health care community and consumers, including best practices in safe medication use systems. Health Canada has been integral in coordinating initial implementation of the system in conjunction with the Canadian Institute for Health Information (CIHI) and the Institute for Safe Medication Practices - Canada (ISMP-Canada).

Canadian Healthcare Association (CHA). In November 2002, CHA released Patient Safety and Quality Care: Action Required Now to Address Adverse Events. See Appendix D, Section 4 for report. This report provides an overview of academic, government reports and coroner's inquests that are associated with patient safety and adverse events. From the analysis, CHA puts forward the following strategies for improvement.

- **Organizational Initiatives.** Foster a culture of safety; enhance current surveillance practices; investigate more 'proactive' approaches to improving patient safety; examine organizational procedures and legal issues around reporting adverse events; consider innovative pilot studies respecting patient safety management techniques within the organization; and facilitate the development and implementation of information technology tools for patient safety.
- **Provincial/Territorial Initiatives.** Convene provincial and territorial stakeholders to develop a patient safety agenda; establish performance targets for the reduction of adverse events; work toward a national registry and oversight mechanisms; educate provincial/territorial stakeholders and the public to increase awareness and understanding of patient safety; develop systems and processes to enhance and integrate standardized reporting in the province/territory; address consistency and interoperability issues among reporting tools; and encourage the integration of adverse event reporting with other provincial/territorial mechanisms, such as accountability mechanisms.
- **National Initiatives.** Convene stakeholders to develop a national framework and action plan; support research regarding the extent of adverse events in Canada and data requirements for monitoring; participate in the development of consensus around national safety standards; encourage Canadian professional colleges and organizations to be active in the areas of disclosure policy and legislation; and educate stakeholders, including the public, and to increase awareness and understanding of patient safety.

The Canadian Patient Safety Institute (CPSI). In September 2002 the National Steering Committee on Patient Safety released the report, *Building a Safer System: A National Integrated Strategy for Improving Patient Safety In Canadian Health Care*, which made 19 recommendations, including the creation of a patient safety institute. The 2003 First Ministers' Accord on Health Care Renewal also acknowledged the importance of patient safety. In response, the Government of Canada's Budget 2003 provided \$10 million annually to support patient safety, including the creation of the Canadian Patient Safety Institute (CPSI). An Interim Committee comprised of groups interested in health care, provincial and territorial governments, and Health Canada oversaw the Institute's development. In December 2003, federal, provincial and territorial Ministers of Health announced the establishment of the CPSI in Edmonton, Alberta, as well as its founding Board of Directors. The Institute will help build a culture of patient safety and quality improvement throughout the Canadian health care system. A non-profit corporation at arm's length from government, it will promote best practices, raise awareness and advise on effective strategies to improve patient safety.

Health Council (HC). In December 2003, the government of Canada announced the creation of a national health council. The establishment of the HC was a key commitment of the February 2003 First Ministers' Accord on Healthcare Renewal as part of their efforts to improve accountability within the healthcare system, including a focus on patient safety. The mandate of the HC is to monitor and make public reports on the implementation of the Accord.

Canadian Council on Health Services Accreditation (CCHSA). In January 2005, CCHSA announced a Patient Safety Research Project: Assessing Patient Safety Culture within Canadian Health Services Organizations for its members to participate in. See Appendix D, section 5 for more details. In 2003, CCHSA developed accreditation standards that include structural elements (staffing, equipment, space and policy) and process and outcome measures (CCHSA, 2003). See Appendix D, Section 5 for report. Specifically, patient safety practices are incorporated in the following standards:

- Leadership and Partnership.
- Environment.
- Human Resources.
- Information Management.
- Client Services Standards.

Selected Provincial/Territorial Initiatives

Health Quality Council of Saskatchewan. Founded in 2002 the Health Quality Council of Saskatchewan is an independent agency that measures and reports on quality of care in Saskatchewan, promotes improvement, and engages its partners in building a better health system. The HQC links a data collection and analysis capability with a number of quality improvement initiatives including a quality improvement network, educational programs, drug monitoring and advice on drug prescribing practices, and links to key stakeholders and partners such as the Institute for Healthcare Improvement.

British Columbia. In May 2003, amendments to the Health Professions Amendment Act that increased patient safety and ensure uniform regulation of health professionals was introduced by the Health Planning Minister. The proposed changes include:

- Public access to information about health professionals' registration status and disciplinary records will be increased. The public will be able to contact the registrar of a professional college for information on a health practitioner's status.
- Health professionals and employers will be required to report health professionals who may pose a danger to the public as a result of an addiction or lack of competence.
- Regulatory bodies for health professionals will be required to establish quality-assurance programs that improve the way health services are delivered by setting standards for health-care practices.
- Cabinet may appoint a representative to inquire into the operations of a college or the practice of a health profession in the rare circumstance where there is a

failure to regulate or a lack of leadership, in order to protect the public interest and safety.

Selected Research Initiatives

University of Toronto (2002-2005). In April 2002, a multidisciplinary research cluster (a multidisciplinary team, drawing on expertise from nursing, medicine, pharmacology, hospital administration, engineering and humanities) at the University of Toronto (U of T), led by the Faculty of Nursing, received funding from U of T's Connaught Foundation, several hospitals of the Toronto Academic Health Science Centers (TAHSC), and the Government of Ontario. The researchers have worked on several projects that explore processes of care and factors influencing safer practices including team approaches to patient care (near misses, near miss reporting systems, team literacy, communications, and nursing interruptions in the health care system). See Appendix D, Section 6 for a detailed description of the pilot projects.

University of Alberta & Capital Health Authority Safer Systems Research Program: An Ecological Framework (Marck, Principal Investigator 2003-2005). In 2003, the *Safer Systems* Research program was created as a partnership between the Faculty of Nursing, University of Alberta and the Capital Health Authority, Edmonton, Alberta. Building on the principal investigator's doctoral work to draw on work in nursing, ecological restoration and health care ethics, an ecological approach to the design, conduct and dissemination of research on organizational ethics and patient safety is underway. Interdisciplinary research teams of faculty researchers and practitioners in nursing, medicine and pharmacy are involved to date, and the central goal of the research program is to use research to develop and sustain best practice environments. See Appendix D, Section 6 for a detailed description of the pilot projects.

Current Research and Policy Initiatives in Canada (2004 - 2005)

The following table provides an overview of patient safety research and policy areas Canada.

Table 7 Canada's Current Patient Safety Research and Policy Areas

Research and Policy Priority Areas
<p>Research Priority Areas</p> <ul style="list-style-type: none"> • Health Canada's Health Policy Research Program. "Governance Choices and Health Care Quality: A Focus on Patient Safety," are expected in 2005. • Canadian Health Services Research Foundation (CHSRF) including: development and evaluation of alternative system- and institution-level approaches to reducing the incidence and impact of institution-based adverse effects; assessment of the extent of healthcare adverse events outside hospitals and other institutional settings; development and assessment of the foundations for, validity and reliability of, and impact on quality of care of system-, institution-, and provider-level performance indicators; and evaluation of the impact of technology assessment as a tool for improving the quality of healthcare. CHSRF. One program of research will be awarded, with a maximum contribution to each of \$500,000 over four years. • Canadian Institutes of Health Research (CIHR) includes: <i>"Partnerships for Health System</i>

Improvement" funding opportunity to support teams of researchers and decision makers in conducting applied health services, systems, and policy research and "Team Grant Program" emphasis is on the production of new knowledge, and the translation of research findings into improvements in the Canadian health care system.

Priority Policy Areas

NPSSC

- Establish a Canadian Patient Safety Institute to facilitate a national integrated strategy for improving patient safety.
- Improve legal and regulatory processes.
- Improve the measurement and evaluation of patient safety.
- Establish educational and professional development programs.
- Improve information and communication processes.

Health Canada (Baker & Norton, 2002)

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

Canada Healthcare Association

- Convene stakeholders to develop a national framework and action plan; support research regarding the extent of adverse events in Canada and data requirements for monitoring; participate in the development of consensus around national safety standards; encourage Canadian professional colleges and organizations to be active in the areas of disclosure policy and legislation; and educate stakeholders, including the public, and to increase awareness and understanding of patient safety.

(National Patient Safety Steering Committee (NPSSC), Baker & Norton, 2002)

Current National Initiatives

Adverse Events in Canadian Hospitals Study. In May 2004, Baker, Norton et al. released the Canadian Adverse Events study. Funded by a partnership between the Canadian Institute for Health Information (CIHI) and the Canadian Institutes for Health Research (CIHR), the scope of the study was to determine: a) the extent of adverse events in Canadian hospitals and b) the availability of routinely collected data that could serve to monitor and reduce adverse events. Researchers from seven Canadian universities, led by the University of Toronto (U of T) and the University of Calgary (U of C), analysed the adverse event rate after reviewing 3,745 adult patient charts, randomly selected from 20 acute care hospitals across five provinces (B.C., Alberta, Ontario, Quebec and Nova Scotia). Key findings from this study include:

- Overall rate of adverse events in 2000 was 7.5 per 100 patient admissions, not including pediatric, obstetric or psychiatric admissions (185,000 of the almost 2.5 million medical and surgical admissions in Canada in 2000 were associated with an adverse event).
- Majority of adverse events resulted in temporary disability or prolonged hospital stay.
- Five per cent of patients who experienced adverse events were judged to have a permanent disability.
- Adverse events were associated with death in 1.6 per cent of patients admitted to acute care hospitals.
- Surgical care accounted for the largest number of adverse events.

- Close to 37 per cent of adverse events in the study were potentially preventable. Based on this, the researchers estimate there were 70,000 preventable adverse events across the country in 2000.
- Teaching hospitals had a higher rate of adverse events than other hospitals. The authors attribute this to several factors, including: patients with more complex illnesses may be treated in teaching hospitals; the complexity of care in teaching hospitals means patients may receive care from several care providers, thereby increasing the potential for adverse events relating to communication and coordination of care.

Health Care in Canada Report. In June 2004, the Canadian Institute of Health Information (CIHI) released its annual report *Health Care in Canada*. This report provides information at local, regional, national, and international levels from many different sources, including CIHI studies and from Statistics Canada data. The 2004 report included its first national patient safety indicators. These indicators include:

- *Foreign objects (e.g. a sponge or instrument) left in after a procedure* Between 2000–2001 and 2002–2003, an estimated one in every 6,667 surgical/medical patients had a foreign object accidentally left in them following a procedure.
- *Post-operative hip fracture.* Between 2000–2001 and 2002–2003, one inpatient sustained a hip fracture for every 1,124 surgical and medical hospitalizations among seniors.
- *Birth trauma.* Birth trauma (injury) occurs in about 11.6 of every 1,000 hospital births, or one birth trauma per 81 newborns.

Other key highlights from CIHI's *Health Care in Canada 2004's* patient safety chapters include:

- Experts say that under-reporting makes reducing the incidence of adverse events more challenging. In a 2003 survey, more than 70% of Canadian health professionals said that under-reporting of adverse drug reactions was a very or somewhat serious problem.
- About two-thirds of Canadians (67%) think that more litigation could result in physician shortages in some high-risk specialties, although an even greater number (76%) believe that the threat of litigation may help ensure quality care. According to the Canadian Medical Protective Association, malpractice claims in Canada have stabilized in recent years, and now range from 1.7 to 2.5 claims per 100 physicians annually.

The report also highlights examples of safe care strategies that have proven successful, such as using electronic tools to prevent medication errors and implementing procedures to reduce chance of wrong-side surgeries.

Health Canada's Health Policy Research Program. This program funds research with a broad socio-economic focus that will ultimately help Health Canada make policy decisions. The program, which enables Health Canada to enter into partnerships to achieve its goals, has connections to both national and international research. Results from the current research project, "Governance Choices and Health Care Quality: A Focus on Patient Safety," are expected in 2005.

Canadian Health Services Research Foundation (CHSRF). In September 2004, CHSRF identified Managing for Quality and Safety as a key research theme. As a result of national consultations, the focus within this research theme is exposing ameliorable 'system' sources of adverse events. Specific examples include:

- Development and evaluation of alternative system- and institution-level approaches to reducing the incidence and impact of institution-based adverse effects.
- Assessment of the extent of healthcare adverse events outside hospitals and other institutional settings.
- Development and assessment of the foundations for, validity and reliability of, and impact on quality of care of system-, institution-, and provider-level performance indicators.
- Evaluation of the impact of technology assessment as a tool for improving the quality of healthcare.
- On October 15, 2004, CHSRF announced its 2005 grants competition: Research, Exchange, and Impact for System Support (REISS) calling for interprofessional teams of researchers and decision makers to submit applications for research programs for Managing for quality and safety. One program of research will be awarded, with a maximum contribution to each of \$500,000 over four years. See Appendix D, Section 7 for more details. The funded programs will span four years and will include components in research, capacity development, and knowledge exchange, as well as periodic deliverables over the course the program.

Canadian Institutes of Health Research (CIHR). CIHR and its partners recently announced the inaugural launch of "**Partnerships for Health System Improvement**" funding opportunity to support teams of researchers and decision makers in conducting applied health services, systems, and policy research. Previously managed by the foundation as part of CHSRF Open Grants Competition, this initiative will support teams of researchers and decision makers interested in conducting individual applied health services research projects useful to health-system managers and/or policy makers over the next two to five years.

- In the Fall 2005, CIHR announced an inaugural competition of The CIHR "**Team Grant Program**". The objective of the CIHR Team Grant program is to strengthen Canadian health research by supporting teams of talented and experienced researchers conducting high-quality research and providing superior research training and mentorship. The program emphasis is on the production of new knowledge, and the translation of research findings into improvements in the health of Canadians and the Canadian health care system. See Appendix D, Section 8 for more details around CIHR funding.

Canadian Patient Safety Institute. In Fall 2004, CPSI released its first business plan. The following three overarching themes were identified:

- Define patient safety issues in the Canadian Health Care system.
- Identify leading practices and effective interventions.
- Champion necessary change through partnerships, stakeholder engagement and transparent communication.

Overall guiding principles of CPSI's work include:

- Involvement of patients, health-care providers and public.
- Independence from governments, stakeholders and regulatory bodies.
- Collaboration with existing initiatives so as not to duplicate roles and activities.
- Evidence-based decisions in order to maintain credibility with stakeholders and the public.
- Accountability to members, funding agencies/organizations and the public.
- Ongoing evaluation and assessment of CPSI activities.

Provincial/Territorial Initiatives

Alberta. In 2004, the Government of Alberta through the Minister of Health & Wellness created the Health Quality Council of Alberta (HQCA). The mandate of HQCA includes reporting directly to Albertans on the quality, safety and performance of health services. In addition, the Council identifies best practices and monitors the following dimensions of health care quality: access, acceptability, appropriateness, effectiveness, efficiency and patient safety.

Nova Scotia. In 2004, Nova Scotia identified Health Care Safety and Quality as a key health initiative and is in preliminary phases of activities aimed at improving quality and strengthening safeguards in our health system

Ontario. In March 2004, the Ministry of Health and Long-Term Care announced Canada's first province-wide Patient Safety Support Service to improve the safety and quality of health care for Ontarians. The Ontario Hospital Association (OHA) is overseeing the 2 year funded project that provides Ontario's hospitals with tools, education, information and training to strengthen patient safety and support an accountable and safe healthcare system. In October 2004 and November 2004, the Quality of Care Information Protection Act Definition of "Quality Care Committee" and "General" sections were released. Both sections provide direction to the mandate of quality care committees.

- **Saskatchewan.** In 2004, the Health Quality Council announced an Innovation Fund competition was announced that focuses on supporting innovative implementation of evidence-based quality improvement strategies in health services throughout Saskatchewan. Amount of funding includes: single region projects (\$20,000 for a 6 month timeframe) and multi-region projects (\$40,000 for a 12 month timeframe).

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