Building a Safer System

A National Integrated Strategy for Improving Patient Safety in Canadian Health Care

National Steering Committee on Patient Safety
Comité directeur national sur la sécurité des patients

NATIONAL STEERING COMMITTEE ON PATIENT SAFETY
COMITÉ DIRECTEUR NATIONAL SUR LA SÉCURITÉ DES PATIENTS

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A National Integrated Strategy for Improving Patient Safety in Canadian Health Care

Secretariat / Secrétariat
774, prom. Echo Drive
Ottawa, ON KIS 5N8

Tel:(613) 730-6201
Fax: (613) 730-8250
Email: ***patientsafety@rcpsc.edu***

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(Please see Appendices A and B for names and affiliations)

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Executive Summary

"We envision a system of care in which those who give care can boast about their work, and those who receive care can feel total trust and confidence in the care they are receiving."

Donald M. Berwick, MD, MPP
(as quoted by the Institute for Healthcare Improvement, 2002)

In April of 1992, a four-year-old girl in Halifax was scheduled to receive the last in a series of chemotherapy treatments for leukemia. She was diagnosed two years earlier but, on that day in April, her physicians considered her cured. The medications, including *Vincristine*, were administered in the operating room as she was also receiving dental surgery and one anesthetic procedure could allow both treatments to proceed at the same time. Unfortunately, several factors contributed to the *Vincristine* being injected intrathecally (into a spinal catheter) instead of intravenously (into a vein). *Vincristine* is lethal when injected intrathecally — she died a week later (Jones, 1996 as cited in Baker and Norton, 2001).

Regrettably, other Canadian patients[1] have subsequently died from a spinal injection of *Vincristine* and also many more Canadians are injured or die as a result of health-care errors. Dramatic advances in the diagnosis and treatment of disease have exponentially increased the complexity of care processes while outdated modes of communication, employee training, and product design persist. The aging population, resource limitations, a critical shortage of qualified health-care personnel in a growing list of locations and specialties, and challenges created by mergers and restructuring within health organizations are combining to create unequaled strain and an increasing likelihood of errors in the system.

Canadian health-care personnel are increasingly aware of the frequency and significance of these largely preventable adverse events. They want to move the discussion out from behind closed doors and devise workable solutions. International jurisdictions, such as the United States, have already recognized that health-care safety concerns are real, that their systems are prone to error and failure, and that measures must be taken to reduce the risk. Canada is significantly behind the United States, the United Kingdom and Australasia in accepting that patients are at significant risk, in wanting to learn about the relevant issues, and in investing in the creation of a culture of safety.

Recognizing the need for further dialogue, The Royal College of Physicians and Surgeons of Canada hosted a one-day forum on patient safety as part of their Annual Conference in September 2001. Over 50 leaders representing government, health-care associations, and other non-government organizations attended a roundtable discussion on developing a national strategy to improve safety. A National Steering Committee and five working groups were subsequently formed at the direction of the roundtable participants; their work is summarized within the report.

Building a Safer System: Principles for Action

Key assumptions have been described in the principles for action to provide a foundation for the specific strategies that will be recommended for implementation.

- The Canadian health-care system is guided by the principles of national health insurance as set out in the Canada Health Act, and is implemented primarily at the provincial/territorial level. The system is complex, dynamic and characterized by many competing pressures, particularly the relationship between funding and quality of care. An unprecedented level of collaboration across all sectors must occur to ensure a co-ordinated and effective strategy for improving patient safety.

[1] The term « patient » is intended to encompass everyone who receives health services across the continuum of care.

- Safety is a fundamental aspect of quality health care. To improve safety, the health-care system must develop, maintain and nurture a culture of safety.
- Health-care personnel, patients, and all others within the system must be informed participants in understanding that human error is inevitable and that underlying systemic factors, including ongoing system change, contribute to most near misses, adverse events and critical incidents.
- Specific educational and professional development programs that focus on evidence-based practice, periodic audit, and a team approach to practice and learning can reduce the likelihood of human error.
- The health-care system must facilitate comprehensive identification of hazards that pose threats to our people (e.g. patients, staff and health-care personnel). Systemic identification should be carried out reactively, in response to a recognized adverse event or outcome, and more importantly, proactively, before problems have occurred. This identification must be followed by reporting and recording of these hazards (and any associated adverse events and near misses) to a network of databases.
- The health-care system must develop an atmosphere of trust, in which openness and frankness in identifying and reporting problems or potential problems is encouraged and rewarded. No blame will be apportioned to individuals following reporting, subject to limited qualifications. These limited qualifications include failure to report safety hazards or critical incidents and premeditated or intentional acts of violence against people, equipment or property.
- The health-care system must encourage partnerships among all consumers and providers of care. Partnerships will require the health-care system to become more flexible, with a shift away from traditional hierarchical operating structures. These partnerships, including those of individuals, professions and organizations, are necessary for effectively improving all operational/systemic deficiencies.
- The health-care system must demonstrate its ability to build on what is already known in other sectors, learn from experience, and be willing and able to implement major reforms when indicated. Such a system will endeavor to analyze relevant information, develop cost-effective evidence-based safety initiatives and standards of care that are critical to the improvement process, and regularly receive feedback on the results of targeted strategies.
- The health-care system must promote appropriate disclosure to all partners (e.g. patients, the public, health-care personnel and governments) of safety information relative to health issues. Such disclosure must be supported by changes to the legal and regulatory systems that also facilitate effective systems for the prevention and/or management of hazards.

Key recommendations

Nineteen recommendations have been developed to represent the breadth of collaborative work that must be undertaken within the national integrated strategy. The recommendations, grouped into five major categories, are not all listed here in order of priority (please see page 34 for suggested governance and funding with priority recommendations).

Establish a Canadian Patient Safety Institute to Facilitate a National Integrated Strategy for Improving Patient Safety

(1) Establish and support a non-profit *Canadian Patient Safety Institute*[2] (draft title). Membership will be multidisciplinary and consist of clinical, academic and administrative experts in the fields of safety and health care from across Canada.

(2) Base new practices, technologies and programs that are recommended by the *Canadian Patient Safety Institute*, or other such bodies, on evidence, and subject them to scientific evaluation. The evaluation would include potential benefits and costs.

(3) Implement system changes that have a demonstrated ability to improve patient safety.

(4) Formalize responsibility and accountability for patient safety within the management structures and clinical processes of all health-care organizations.

[2] The term « institute » has been selected to reflect the collaborative and non-regulatory mandate of the proposed organization. The title should be considered as draft and for discussion purposes.

(5) Develop and implement responsive patient-focused programs for the receipt, review and management of concerns within health-care organizations.

Improve Legal and Regulatory Processes

(6) Adopt non-punitive reporting policies within a quality-improvement framework across the health-care system.
(7) Standardize the legislation on privacy and confidentiality of personal health information across Canada to facilitate access to patient-safety data, while respecting the privacy of patients and providers.
(8) Develop a greater focus on improvement through education and remediation, vs. blame and punishment, in legal, regulatory and human resource processes.
(9) Review, and where applicable, revise *The Evidence Act* and related legislation within all Canadian jurisdictions to ensure that data and opinions associated with patient-safety and quality-improvement discussions, related documentation and reports are protected from disclosure in legal proceedings. The protection would extend to this information when used internally or shared with others for the sole purpose of improving safety and quality. Wording within the applicable Acts should ensure that all facts relating to an adverse event are recorded on a health record that is accessible to the patient or designated next of kin, and are not considered privileged.
(10) Hold further discussions regarding the tort and health-care insurance systems and their effects on patient safety, with the aim of making recommendations that would contribute to a culture of safety in Canadian health care.

Improve Measurement and Evaluation Processes

(11) Undertake an analysis of the capabilities and cost of systems for monitoring adverse events, critical incidents and near misses.
(12) Recommend the types of surveillance systems, including relevant patient-safety indicators, to be developed and supported in Canadian health care. The recommendations would be based on the findings of the review proposed in Recommendation (11).
(13) Secure funding from federal/provincial/territorial jurisdictions to invest in information technology infrastructures that support the standardized identification, reporting and tracking of patient-safety data.
(14) Adopt "patient safety" as a cross-cutting theme or designated area for research competitions supported by the Canadian Institutes for Health Research, Canadian Health Services Research Foundation and/or other granting organizations, to encourage Canadian researchers to undertake studies in this area.

Establish Educational and Professional Development Programs

(15) Develop and implement health-care education and professional-development programs for improving patient safety.
(16) Develop educational and continuing professional development programs to improve patient safety in collaboration with national accrediting bodies, academic institutions, provincial licensing authorities (for peer-assessment reviews) and health-care facilities/organizations/scholarly societies.

Improve Information and Communication Processes

(17) Publicly report measures of health-care quality and safety.
(18) Develop educational materials on personal measures for improving safety in health care for distribution to the public.
(19) Create a website to facilitate the sharing of patient-safety resources and discussions.

The proposed national integrated strategy is a co-ordinated and comprehensive framework that builds on current structures and processes with a strong emphasis on providing multidisciplinary teams with the education and resources to diffuse patient safety expertise across Canada.

Immediate steps are being taken to begin the building of a safer system; however, these steps lack integration and co-ordination. For effective system-wide improvements, short- and long-term funding must be committed from federal and provincial jurisdictions. Other health-care stakeholders must identify and offer their expertise and participation in support of applicable recommendations.

Sommaire[1]

"Nous imaginons un système de santé dans le cadre duquel les prestataires de soins peuvent se targuer de leurs réalisations et les personnes qui reçoivent les soins se sentent en pleine confiance quant aux soins dispensés."

Donald M. Berwick, MD, MPP
(tel que cité par la Institute for Healthcare Improvement, 2002)

En avril 1992 à Halifax, une fillette de quatre ans souffrant de leucémie en était à sa dernière séance de chimiothérapie. Diagnostiquée deux ans plus tôt, la fillette était, en ce jour d'avril, guérie selon ses médecins. Les médicaments, notamment la *vincristine*, lui ont été administrés dans la salle d'opération où elle subissait également une intervention chirurgicale dentaire, car la procédure anesthésique rendait possible l'exécution simultanée des deux traitements. Malheureusement, la *vincristine* a été administrée en injection intrathécale (par un cathéter médullaire) plutôt qu'en injection intraveineuse (dans une veine). En administration intrathécale, la *vincristine* est mortelle, et la fillette est décédée une semaine plus tard (Jones, 1996, comme il est rapporté dans Baker et Norton, 2001).

Il est également déplorable que d'autres patients[2,3] canadiens aient perdu la vie par suite d'une injection rachidienne de *vincristine*, et que de nombreux autres subissent les répercussions d'une erreur médicale ou en décèdent. Des avancées spectaculaires dans le diagnostic et le traitement des maladies ont accru de façon exponentielle la complexité des processus de prestation des soins, pendant que persistent des modes désuets de communication, de formation des employés et de conception des produits. Le vieillissement de la population, l'amenuisement des ressources, la pénurie aiguë de professionnels de la santé qualifiés dans un nombre croissant de lieux et de spécialités, et les problèmes causés par les fusions et la restructuration dans les organisations de la santé sont tous des facteurs qui, combinés, exercent une tension sans précédent sur le système, d'où le risque accru d'erreurs.

De plus en plus, les intervenants canadiens en santé sont conscients de la fréquence et de la portée de ces incidents indésirables, évitables en grande partie. Ils souhaitent que le débat à ce propos ne se tienne plus à huis clos et que des solutions pratiques soient conçues. À l'échelle internationale, des pays, comme les États-Unis, admettent déjà que les préoccupations quant à la sécurité des soins de santé sont fondées, que leurs systèmes favorisent en quelque sorte l'erreur et la défaillance, et qu'il importe d'adopter des mesures pour réduire le risque d'erreurs. Comparativement aux États-Unis et à d'autres pays, le Canada stagne loin derrière quant à reconnaître que les patients courent un risque de taille, à connaître les divers aspects de la question et à s'engager dans la création d'une culture de la sécurité.

Conscient de la nécessité d'approfondir le débat à ce sujet, Le Collège royal des médecins et chirurgiens du Canada a organisé une tribune d'une journée sur la sécurité des patients dans le cadre de sa Conférence annuelle en septembre 2001. Plus de 50 chefs de file, représentant l'administration publique, des organisations de la santé et d'autres organisations non gouvernementales, ont participé à cette table ronde sur l'élaboration d'une stratégie d'amélioration de la sécurité d'envergure nationale. Sous l'impulsion des participants à la table ronde, le Comité directeur national et cinq groupes de travail ont vu le jour, et le présent rapport rend compte de leurs travaux.

[1] Le texte intégral du rapport est aussi disponible en français sur demande
[2] Le terme « patient » englobe ici quiconque reçoit des services dans tout le continuum des soins de santé.
[3] Noter que le générique masculin est utilisé dans le seul but d'alléger le texte

Accroître la sécurité du système : principes d'action

Les principes d'action s'appuient sur des hypothèses essentielles, décrites ici, qui forment le fondement des stratégies particulières dont la mise en œuvre est proposée.

- Le système de santé canadien est régi en vertu des principes de la *Loi canadienne sur la santé*, qui est appliqué principalement à l'échelle provinciale et territoriale. Le système, complexe et dynamique, subit de nombreuses tensions concurrentes, particulièrement celles créées par la relation entre le financement et la qualité des soins. Un niveau de collaboration inédit entre tous les secteurs est essentiel à l'élaboration d'une stratégie coordonnée et efficace d'amélioration de la sécurité des patients.
- La sécurité est un aspect fondamental des soins de santé de qualité. Pour améliorer la sécurité, le système de santé doit créer, maintenir et rehausser une culture de la sécurité.
- Les professionnels de la santé, les patients et tous les autres intervenants du système doivent être au fait que l'erreur humaine est inévitable et que des facteurs systémiques sous-jacents, notamment les changements perpétuels, contribuent à la survenue de la plupart des erreurs évitées de peu, et des incidents critiques.
- Les programmes d'éducation et de perfectionnement professionnel visant tout particulièrement la pratique et l'apprentissage fondés sur les résultats cliniques et scientifiques, sur des vérifications périodiques et sur le travail en équipe peuvent réduire les risques d'erreur humaine.
- Le système de santé doit faciliter le relevé exhaustif des risques qui mettent en péril les personnes qui y ont recours (p. ex. les patients, la direction et le personnel). Le relevé méthodique doit s'enclencher en réaction à un incident ou résultat indésirable connu, mais doit avant tout s'inscrire dans le cadre d'une démarche proactive, soit avant que les problèmes ne se produisent. Cette étape doit être suivie du signalement et de la consignation de ces risques (et de tous les incidents indésirables et événements évités de justesse qui y sont associés) dans un réseau de bases de données.
- Le système de santé doit créer un climat de confiance, où l'ouverture et la franchise dans le recensement et le signalement des problèmes ou problèmes potentiels sont encouragées et récompensées. Par suite d'un signalement, personne ne se verra reprocher quoi que ce soit, sauf dans des situations particulières, comme l'omission de rapporter des risques de sécurité ou des incidents critiques et la commission préméditée ou intentionnelle d'actes de violence à l'égard d'une personne, de l'équipement ou de biens.
- Le système de santé doit favoriser la formation de partenariats entre les consommateurs et les prestataires de soins. Pour ce faire, le système de santé devra être plus souple, en délaissant la structure opérationnelle hiérarchique au profit d'un mode de fonctionnement horizontal. Ces partenariats, qu'ils fassent intervenir des personnes, des professions ou des organisations, sont nécessaires pour corriger toutes les défaillances opérationnelles et systémiques.
- Le système de santé doit démontrer son aptitude à tirer parti de ce qui se fait déjà dans d'autres secteurs, à tirer un enseignement de l'expérience et à être disposé et capable de mettre en œuvre d'importantes réformes le cas échéant. Un tel système s'attache à analyser l'information pertinente, à élaborer des initiatives de sécurité et des normes de soins rentables et fondées sur des données probantes, qui sont essentielles au processus d'amélioration, et à examiner, à intervalles réguliers, la rétroaction sur les résultats de certaines stratégies.
- Le système de santé doit promouvoir la divulgation adéquate à tous les partenaires (p. ex. aux patients, au public, aux intervenants en santé et aux gouvernements), de l'information sur la sécurité en rapport avec les questions de santé. Cette présentation de l'information doit être favorisée par des changements dans les systèmes juridique et

réglementaire qui facilitent également l'instauration de mécanismes efficaces de prévention et de gestion des risques.

Principales recommandations

Dix-neuf recommandations ont été élaborées afin de représenter le plein éventail du travail de collaboration à entreprendre dans le cadre d'une stratégie nationale intégrée. Regroupées en cinq catégories principales, ces recommandations ne sont pas toutes présentées par ordre de priorité.

Veuillez consulter, à la page 34, les suggestions sur la gouvernance, les recommandations prioritaires et le financement.

Établir un Institut canadien sur la sécurité des patients afin de faciliter la mise en œuvre d'une stratégie nationale intégrée visant à améliorer la sécurité des patients.

(1) Établir et appuyer un *Institut canadien sur la sécurité des patients* [4] (appellation provisoire) sans but lucratif. L'Institut serait formé d'un regroupement multidisciplinaire d'experts cliniques, universitaires ou administratifs dans les domaines de la sécurité et des soins de santé, de toutes les régions du Canada.
(2) Fonder les nouvelles pratiques, technologies et programmes proposés par l'*Institut canadien sur la sécurité des patients*, ou d'autres organismes semblables, sur des données probantes et les soumettre à une évaluation scientifique. Cette évaluation comprendrait les avantages et les coûts éventuels.
(3) Mettre en œuvre des changements de nature démontrée à améliorer la sécurité des patients.
(4) Mettre en application de façon officielle la responsabilité et l'obligation de rendre compte quant à la sécurité des patients au sein des structures de gestion et des processus cliniques de toutes les organisations de la santé.
(5) Concevoir et instaurer des programmes adaptés aux besoins, centrés sur le patient, quant à la réception, à l'examen et à la gestion des préoccupations sur la sécurité dans les organisations de santé.

Améliorer les processus légaux et de réglementation

(6) Adopter des lignes directrices de signalement non punitif dans le cadre d'un mécanisme d'amélioration de la qualité à tous les niveaux du système de santé.
(7) Uniformiser la législation sur la protection de la vie privée et la confidentialité des renseignements personnels en santé au Canada pour faciliter l'accès aux données sur la sécurité des patients tout en respectant la vie privée des patients et des prestataires de soins.
(8) Mettre davantage l'accent sur l'amélioration par l'éducation et les mesures correctives, plutôt que par l'attribution d'un blâme ou des mesures punitives, dans les processus juridiques, réglementaires et de gestion des ressources humaines.
(9) Examiner et, le cas échéant, modifier la *Loi sur la preuve* et la réglementation apparentée dans toutes les provinces du Canada pour faire en sorte que les données et les observations personnelles quant à la sécurité des patients et à l'amélioration de la qualité, ainsi que la documentation connexe et les rapports sont à l'abri de la divulgation en cas de poursuite judiciaire. Cette information ne pourrait être divulguée si elle est utilisée au sein d'un établissement ou d'une organisation ou si elle est partagée avec d'autres personnes aux seules fins d'améliorer la sécurité et la qualité. La formulation des lois applicables devrait permettre que tous les faits en rapport avec un incident indésirable soient consignés dans un dossier de santé mis à la disposition des patients ou du plus proche parent désigné, sur demande, et qu'ils ne soient pas considérés comme étant confidentiels.
(10) Approfondir l'étude de la question de la responsabilité civile délictuelle et des régimes d'assurance maladie, et de son

[4] Le terme « Institut » a été choisi pour souligner l'aspect de *collaboration* et *de non-réglementation* du mandat de l'organisme suggéré. Son appellation n'est qu'une ébauche conçue afin de lancer un débat à ce propos.

incidence sur la sécurité des patients, en vue de formuler des recommandations contribuant à la création d'une culture de la sécurité dans le système de santé canadien.

Améliorer les processus de mesure et d'évaluation

(11) Entreprendre l'analyse des systèmes de surveillance des événements indésirables, des incidents critiques et des incidents évités de justesse.
(12) Proposer des types de systèmes de surveillance, comportant notamment les indicateurs pertinents de la sécurité des patients, à élaborer et à appuyer dans le système de santé canadien. Les propositions seraient fondées sur les constatations de l'analyse proposée au point (11).
(13) Obtenir du financement des gouvernements fédéral, provinciaux et territoriaux pour établir une infrastructure de la technologie de l'information nécessaire à l'uniformisation de la collecte, du signalement et du suivi des données sur la sécurité des patients.
(14) Que la « sécurité des patients » devienne un thème transversal ou un domaine désigné de recherche dans le cadre de concours soutenus par les Instituts canadiens de recherche en santé, la Fondation canadienne de la recherche sur les services de santé et d'autres organismes bailleurs de fonds, avec la volonté des chercheurs canadiens d'entreprendre des études dans ce domaine.

Créer des programmes d'éducation et de perfectionnement professionnel

(15) Élaborer et mettre sur pied des programmes éducatifs ou de perfectionnement professionnel sur l'amélioration de la sécurité des patients.
(16) Concevoir des programmes éducatifs et de perfectionnement professionnel continu sur l'amélioration de la sécurité des patients en collaboration avec les organismes d'agrément, les établissements universitaires, les ordres professionnels provinciaux (examen par les pairs) et les institutions, organisations et sociétés savantes en santé.

Améliorer les processus d'information et de communication

(17) Rendre compte publiquement des interventions axées sur la qualité et la sécurité des soins de santé.
(18) Concevoir de la documentation éducative sur les mesures personnelles d'amélioration de la sécurité des soins de santé et la transmettre au public.
(19) Créer un site Web pour faciliter la mise en commun des ressources sur la sécurité des patients et diffuser les débats à ce propos.

La stratégie intégrée d'envergure nationale proposée ici s'inscrit dans un cadre coordonné et global qui tire parti des structures et processus existants tout en insistant fortement sur la nécessité d'offrir aux équipes multidisciplinaires l'éducation et les ressources nécessaires pour rehausser l'expertise en matière de sécurité des patients dans tout le Canada.

On a déjà immédiatement entrepris des mesures visant à améliorer la sécurité du système; malheureusement, ces mesures manquent d'intégration et de coordination. Pour apporter des améliorations à tout le système, il faudra que les gouvernements fédéral, provinciaux et territoriaux y consacrent des fonds à brève et à longue échéance. La participation d'autres parties prenantes dans le domaine de la santé est également nécessaire à la mise en œuvre des recommandations applicables.

Introduction

"Never doubt that a small group of thoughtful, committed citizens can change the world. Indeed, it is the only thing that ever has."

Margaret Mead
(as quoted by Helvarg, 1995)

Health-care interventions such as the prescribing and administering of medications, surgical procedures, laboratory tests or radiological investigations often require complex interactions of personnel and technology to be completed safely and effectively. Although health-care professionals are dedicated to achieving positive patient outcomes, they are human and therefore fallible. An error in this setting can result in significant disability or death; yet the health-care industry continues to rely heavily on personal vigilance rather than implement known mechanisms that can significantly reduce unintended actions.

International jurisdictions such as the United States of America, United Kingdom and Australia have already recognized that health-care safety concerns are real, that their systems are prone to error and failure, and that measures must be taken to reduce the risk. The US Institute of Medicine Report *To Err is Human* (1999) was an important stimulus for a call to action and created unprecedented media, public, and political attention with the estimate that between 44,000 and 98,000 of their citizens die each year as a result of medical errors. Many of the report recommendations have received widespread support with federal, state and local health-care organizations implementing a variety of key strategies.

The British report, *An Organization with a Memory* (National Health Service, 2000), estimated that adverse events, in which harm is caused, occur in approximately 10% of patient admissions, or about 850,000 times a year. The National Health Service has developed, and is implementing, a comprehensive quality program that includes a major emphasis on improving patient safety.

The *Quality in Australian Health Care Study* (Wilson et al, 1995) reported that 16.6 % of admissions were associated with an adverse event, and, of these, 51% were considered highly preventable. The release of the study ultimately led to the formation of the Australian Council for Safety and Quality in Health Care (2000). The role of the Council is to lead national efforts to promote systemic improvements in the safety and quality of health care, with a particular focus on minimizing the likelihood and effects of adverse events.

There is an acknowledged lack of definitive information on the rate of adverse events in Canadian health care. One study (Wanzel, Jamieson, et al, 2000) examined the incidence and nature of complications on a general surgery service and found that 75 (39%) of 192 inpatients suffered a total of 144 complications. The complications were considered trivial in 42 cases (29%), of moderate severity in 90 cases (63%), life threatening in 10 cases (7%), and were fatal in 2 cases (1%). Of particular relevance is the finding that 26 (18%) of the complications were deemed potentially attributable to error.

The Canadian Institute for Health Information and the Canadian Institutes of Health Research recently announced a jointly funded research study to examine the extent of adverse events in Canadian acute-care hospitals and the availability of data that could be used to support continuous monitoring. The information

"In the course of reviewing our own mistake, we also sought information across the country about other, similar, tragedies...there have been at least three other child deaths in this country since 1989 as a result of *Vincristine* being injected in error into the spinal fluid. These occurred in Nova Scotia, Quebec and Ontario. Each was fully investigated in the institution where it occurred, both internally and by provincial coroners. Yet we found that the details of these errors have not been comprehensively shared between provinces, between coroners' offices or between hospitals. We were not able to learn from our mistakes, nor did we have the opportunity to learn from those of our colleagues."

Mrs. Lynda Cranston (1997)

will be obtained through a systematic review of hospital charts from various centres in five provinces. Drs. G. Ross Baker and Peter Norton will lead the study with the results, anticipated in 2004, providing an important baseline and reference for patient-safety activities.

A full appreciation of the impact of adverse events cannot be attained from statistics alone, but must also include the human perspective from the patient's viewpoint. Each person who receives health care brings his/her unique physical, mental and emotional characteristics to the interaction. Patients are vulnerable and rely on the educational, regulatory and organizational institutions to do all that is possible to ensure that each diagnostic and therapeutic intervention is as safe as possible. The circumstances surrounding the death of a four-year-old girl from Nova Scotia provide an example of where the health-care system failed to "First, do no harm."

In April 1992, a pediatric patient was to receive the last in a series of chemotherapy treatments for leukemia. She had been diagnosed two years earlier but, on that day in April, her physicians considered her cured. The medications, including *Vincristine*, were administered in the operating room as she was also receiving dental surgery and one anesthetic procedure could allow both treatments to proceed at the same time. Unfortunately, several factors contributed to the *Vincristine* being injected intrathecally (into a spinal catheter) instead of intravenously (into a vein). *Vincristine* is lethal when injected intrathecally — she died a week later (Jones, 1996 as cited in Baker and Norton, 2001). Although many health-care providers across the country had heard of this incident, no move was made to implement safety changes that could prevent such a tragedy from occurring again.

A very important lesson in patient safety was not applied across Canada; similar circumstances resulted in the death of a seven-year-old patient at the BC Children's Hospital in 1997. Mrs. Lynda Cranston, President and CEO of the facility at the time, publicly announced the error and revealed the disturbing news that the health-care system had not learned from the tragic mistakes of others.

The circumstances may vary from example to example, but the reality is that patients across Canada sustain injuries and in some cases die from preventable adverse events. A great deal of collaborative work has yet to be done to build a safer health-care system in Canada.

Amidst the reports of adverse events and examples of personal tragedies, there are examples of excellence in health care and other high-risk industries that can be used as models to improve patient safety. In preparing this report, individuals from a variety of health-care backgrounds and locations across Canada participated in a national collaborative to identify the key actions that will have the greatest impact on reducing adverse events. The National Steering Committee on Patient Safety is pleased to present this information within a comprehensive and integrated strategy for making patient safety a national priority.

Background to the Formation of the National Steering Committee on Patient Safety

Mandate, Structure and Deliverables

As part of its Annual Conference in September 2001, The Royal College of Physicians and Surgeons of Canada hosted a one-day forum on patient safety that was attended by national and international health-care leaders and other experts in the field. The same forum also featured a closed event entitled *Roundtable on Patient Safety and Error in Medicine: Toward a Canadian National Strategy*. Over 50 leaders from government, health-care associations and other non-government organizations attended the roundtable to discuss the development of a multidisciplinary approach to tackle the issue of patient safety in Canada (please see Appendix C). Several important results emerged from these discussions.

- **National Consensus**
  Participants reached a unique national consensus on the need to develop a co-ordinated strategy for the purpose of improving patient safety and, therefore, the quality of health care in Canada.
- **National Steering Committee on Patient Safety**
  Participants agreed to create a steering committee to develop an integrated national strategy for patient safety.
- **Five Working Groups**
  Participants recommended the creation of five working groups to address the key aspects of patient safety.

  - System Issues
  - Legal / Regulatory Issues
  - Measurement / Evaluation
  - Education / Professional Development
  - Information / Communication

- **Twelve-Month Timetable**
  Participants charged the Steering Committee with developing and proposing a framework for a Canadian solution in 12 months' time. The committee was mandated to work collaboratively and consult widely to develop a clear set of goals and objectives, detailed action plans and a realistic projection of the time, financial and human resources required to implement these plans.

The National Steering Committee on Patient Safety, a self-standing group reporting to participating organizations, announced its membership in October 2001:

- Dr. **John Wade**, FRCPC, Chair, Dean Emeritus, Faculty of Medicine, University of Manitoba
- **G. Ross Baker**, Ph.D., Associate Professor, Department of Health Policy, Management and Evaluation, University of Toronto
- Honourable Judge **Allan Lefever**, Judge, Provincial Court, Alberta; President, Heart and Stroke Foundation of Canada; Co-chair, Health Charities Council of Canada (to May 2002)
- Dr. **Larry Ohlhauser**, President and Chief Executive Officer, Healthcare Solutions and Innovations (to March 2002)
- Dr. **John Millar**, FRCPC, Vice-President, Research and Population Health, Canadian Institute for Health Information.
- Ms. **Wendy Nicklin**, Vice-President, Nursing and Clinical Programs, The Ottawa Hospital
- Dr. **Walter Rosser**, FCFP, Professor and Chair, Department of Family Medicine, Faculty of Medicine, Queens University
- Dr. **Denis Roy**, FRCPC, Chief Executive Officer, *Centre hospitalier de l'Université de Montréal*
- Ms. **Bonnie Salsman**, Pharmacist and Hospital Pharmacy Management Consultant

Dr. **Peter Fraser**, 1st Vice-President, Canadian Medical Protective Association, and a family physician in active clinical practice, Oromocto, New Brunswick, joined as a member of the Steering Committee in January 2002. In May 2002, Mr. **John Bulman**, C.M., Chairman of the Board, Wawanesa Mutual Insurance Company, and a Commissioner with the Manitoba Securities

Commission, succeeded Judge Allan Lefever as the public representative on the committee.

The mission of the Steering Committee was:

- To place patient safety at the top of the leadership and management priority list
- To promote a culture of patient safety in health care
- To create an accountability framework for patient safety
- To identify ways to collect data and information useful for improving patient safety
- To create a process for development of a research agenda for patient safety
- To create an agenda for educating the public, payers and providers about patient safety
- To identify tools and improvements that enhance safety for patients, clients and communities

An Administrative Group was also formed and included the chief executive officers of the Association of Canadian Academic Healthcare Organizations, Canadian Council on Health Services Accreditation, Canadian Medical Association, Canadian Medical Protective Association, Canadian Pharmacists Association, College of Family Physicians of Canada, and The Royal College of Physicians and Surgeons of Canada, and Assistant Deputy Minister Ian Shugart from Health Canada. Please see Appendix B. The role of this group was to ensure appropriate and effective administrative support for the activities of the Steering Committee and working groups.

Participating organizations at the September 2001 roundtable were invited to submit names for possible appointment to each of the working groups. Five members of the Steering Committee each acted as primary co-chairs with one other person appointed by each of the working groups. Each of the five working groups was given a specific question to answer within a report that clarified the relevant issues, recommended realistic solutions and projected the resources required to implement the plan within the larger framework developed by the Steering Committee.

Five Working Groups

- **System Issues:** To what extent does the design of the health-care system contribute to adverse events and how can new designs reduce or eliminate human error?
- **Regulatory / Legal Issues:** How can the manner in which the regulation and monitoring of health-care professionals and their institutions, and the legal systems, improve patient safety?
- **Measurement / Evaluation:** How can the scope and impact of the problem be better measured?
- **Education / Professional Development:** How can improvements to the education and continuing professional development of health-care professionals reduce adverse outcomes and enhance patient safety?
- **Information / Communication:** How can better communication between various players in the health-care system, and across jurisdictions, improve the quality of patient safety?

The working groups, laboring under very tight timelines, reported to the Steering Committee by early April 2002. Their hands-on expertise and experience in health care created invaluable insights and recommendations that have been incorporated throughout this report. Please see Appendix A for a complete list of the members of the working groups.

The work of the National Steering Committee on Patient Safety was initiated and has been supported by Health Canada, 8 provincial and territorial ministries of health, and 26 Canadian health-care organizations. Their collaborative approach and ongoing assistance were instrumental in the development of the enclosed report (Please see Appendix C for a list of the participating organizations at the 2001 closed roundtable on patient safety).

Understanding the System

"Adverse events result from the interaction of the patient, the patient's disease, and a complicated, highly technical system of medical care provided not only by a diverse group of doctors, other care givers, and support personnel, but also by a medical–industrial system that supplies drugs and equipment. Reducing the risk of adverse events requires an examination of all these factors as well as of their relation with each other."

Leape, L.L. et al (1991)

A High-Risk Environment

Health care is provided 24 hours a day, seven days a week. Dramatic advances in the diagnosis and treatment of disease have made care processes more complex; however, many organizations are hampered by outdated modes of communication, record keeping, employee training and traditional hierarchical authority structures. The aging population, resource limitations, a critical shortage of qualified health-care personnel in a growing list of locations and specialties, and challenges created by mergers and restructuring within health-care organizations, are creating unequalled strain on the systems, thus, increasing the likelihood of adverse events, sometimes with lethal consequences. Fortunately, due to the efforts and vigilance of health-care personnel, many of these events are prevented or mitigated.

How Hazardous is Health Care?

Most health-care encounters are error-free; however, international researchers have documented preventable injuries and deaths in every setting where measurement was attempted.[1] There is no reason to believe that the Canadian health-care system would be dramatically different. The anecdotal reports of patients and health-care professionals provide ample evidence of an environment prone to error.

No industry is more complex than the health-care industry. Yet, there has only been a recent acknowledgement that patient safety must be a high priority. Many methods and systems within health care are not capable of reliably delivering high-quality care to every patient (Leape as cited in *Lessons in Patient Safety*, 2001). While health-care workers have always tried to protect patients from harm in all aspects of care, the increasing complexity of processes and rapid changes within the system have contributed to the need for a stronger emphasis on patient safety. It is no longer appropriate to think that previous and current processes to ensure safety are still effective in controlling adverse outcomes. Overall, the health-care system has been slow to recognize that perfect human performance is not possible; however, other industries can provide useful insights into the design and implementation of high-reliability processes.

Aviation is an excellent example in which a high-risk industry implemented co-ordinated and comprehensive strategies to reduce preventable accidents. Also, the study of human-factors engineering has led to an understanding that, although adverse events will occur in any human endeavor, they can be minimized

[1] Examples include Brennan, T. A., L. L. Leape, et al. (1991), Vincent, C., G. Neale, et al. (2001), Wilson, R. M., W. B. Runciman, et al (1995). A good review of the evidence is also contained in Chapter 2 of the *Institute of Medicine Report*, Kohn, L. T., J. M. Corrigan, et al., eds. (1999).

through the design of equipment or tools, design of the tasks themselves, the environmental conditions of work, the training of staff, and the selection of workers.

Airline regulators, plane manufacturers, and commercial airline carriers have combined human-factors engineering with the knowledge that failures in communication and co-ordination among team members have led to tragic aviation accidents. Their collaboration resulted in a wide variety of mandatory and voluntary processes that have dramatically improved passenger safety:

- Redundancy in key operating systems
- Simulator training to improve teamwork and prepare for sudden emergencies
- Restrictions on the number of consecutive hours worked
- Mandatory reporting of designated aviation accidents / incidents
- Voluntary reporting of near misses
- Extensive use of information technology for the provision of flight information and weather conditions
- Comprehensive and objective investigation of accidents with reporting of the probable cause
- Procedural checklists with alarms for key equipment and/or human failures

Aviation and health care have many similarities; unfortunately, many of the actions that have effectively improved passenger safety have not yet been adapted and implemented in the health-care system.

A Complex System

All systems can be described as a set of interdependent elements interacting to achieve a common aim. There are three key components to a system:

Structure

Each organization has a supporting framework of essential parts that are present and/or contribute to all actions or activities:

- Personnel
- Equipment/tools
- Environment
- Administration

Managing risk within this component involves applying preventive measures, such as constantly evaluating, training and planning for the various elements:

- Personnel (evaluate to ensure optimal numbers for workload, proper credentials and staff physical / mental well-being)
- Equipment (evaluate to ensure that needed devices are present, functioning properly, monitored for safety and regularly serviced with a plan for phased and emergency replacement)
- Environment (evaluate for physical designs that may inhibit or increase risks to those receiving or providing care)
- Administration (create an organizational culture of safety, evaluate and plan for effective policies and procedures — including a policy for reporting actual and potential risks to those receiving or providing care)

Process

All care and/or service is provided within one or more steps of a process. Essentially, a process can be defined as 'what is done and how it is done'. Examples of processes within the health-care system include communication, problem solving, decision-making and conflict resolution. The detection, mitigation or recovery from preventable adverse events is possible in the process component. For example, a nurse does not administer a medication if she/he has detected a miscalculation in the preparation of the dose. Key strategies include identifying high-risk activities and intervening with known strategies for reducing the predicted hazards.

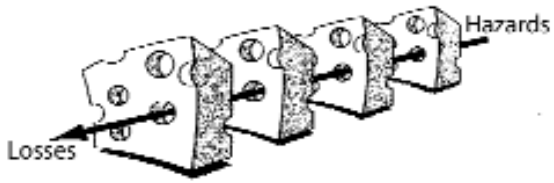
Outcome

The product, result or effect is also known as the outcome. In health care, outcomes may be measured in a variety of ways, but tend to reflect the physical and psychological well being of the patient, and also reflect associated costs. Efforts to manage risk within this component are focused on monitoring outcomes and decreasing the consequences of a preventable adverse event.

A systems approach to patient safety is based on the understanding that the individual practitioner is not a potential culprit to be blamed and punished, but rather that he or she is one participant interacting with many others in a highly complex environment. Adverse events are generally viewed as a consequence of the system; the goal is to improve the structure and/or process so the event is less likely to recur.

Hazards and Defenses

The "Swiss cheese" model of defenses (Reason, J.) illustrates the hazards of high-risk situations and the defenses created to reduce or block those risks. Defenses may be structural, such as staffing levels and equipment design, or process related, such as inter-professional communication and problem-solving skills.



The Swiss cheese model of how defences, barriers, and safeguards may be penetrated by an accident trajectory

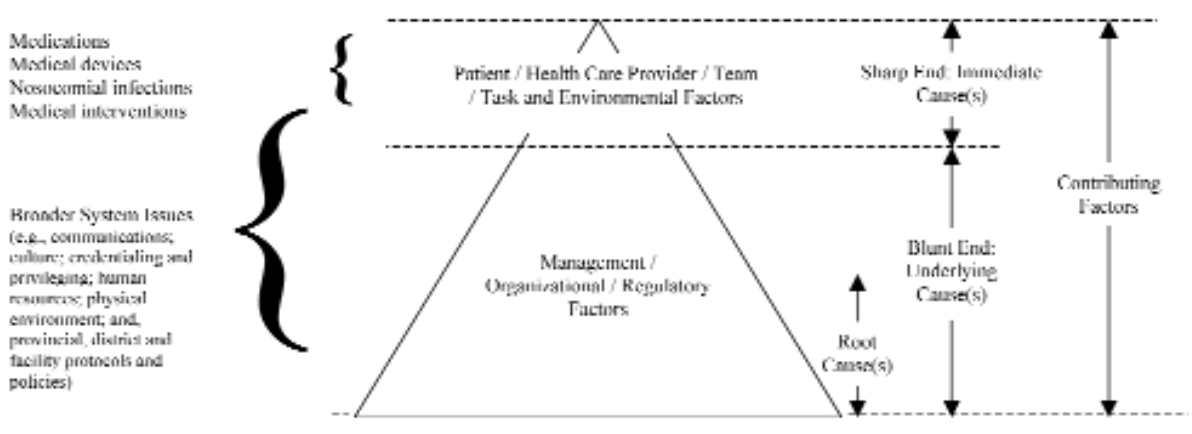
Reason, J. (2000)

Many layers of defenses work to reduce the chance of adverse events occurring, however, no single layer is totally effective, as there are "holes" or opportunities for failure at each point. On any given day, at any time, a circumstance may occur where the holes in the layers of defenses "line up" and error results.

An adverse event in health care is an injury related to health-care management, rather than to an underlying disease. The event is an unplanned and undesired harmful occurrence directly associated with care or services provided to a patient, such as an adverse reaction to a medication or a negative outcome of treatment. The occurrence may result from acts of commission (e.g. administration of the wrong medications) or omission (e.g. failure to institute the appropriate therapeutic intervention) and may be related to problems in practice, products, procedures, and/or other aspects of the system. The term 'medical error' is associated with a culture of blame, and is therefore not recommended for use.

The following model illustrates the key concepts of causation and contributing factors using five categories of adverse events (Medications, Medical Devices, Nosocomial Infections, Medical Interventions, and Broader System Issues) that are known at this time to have significant implications for patient safety. The five categories may evolve into a standardized adverse event classification system developed from national and international research in this field.

The model also incorporates the "sharp and blunt end" theory that has been accepted and broadly applied in health care as in other



Model of Types of Adverse Events

(Adapted by Saskatchewan Health, 2002 from the NIIS Report - Doing Less Harm, 2001)

industries (Reason, 1997). The sharp (proximate) end, where practitioners interact with patients and each other in the process of delivering care, is where the practitioner may be distracted and miss a warning label or forget a step in a process. Unfortunately, the sharp end is also where the search for "fault" is often conducted. Blaming, and then punishing individuals, is not an effective approach for improving safety within the system and understandably causes reluctance among health-care personnel to openly report and discuss adverse events.

At the blunt (remote) end of the system are regulators, administrators, policy makers and technology suppliers. The blunt end is the source of the demands, resources and constraints that form the environment in which the practitioners work. Human-factor engineers have consistently shown that the ability of sharp-end practitioners to avoid adverse events or near misses (a situation where the patient had a narrow escape from injury or death) depends directly or indirectly on a host of blunt-end factors, rather than on the isolated "error" of human practitioners.

The cause of an adverse event is described as an antecedent factor that contributes to an event, effect, result or outcome. A cause may be proximate in that it immediately precedes the outcome, such as an action (injection of the wrong drug). A cause may also be remote, such as an underlying structural factor that influences the action, thus contributing to the outcome. A root cause(s) analysis is a technique of systematic investigation of an adverse event or near miss to determine the immediate and underlying cause(s) and any other contributing factors.

Defining terms related to patient safety is a significant challenge as different individuals, professions, organizations and cultures have assigned their own interpretations to the various words. However, developing a shared, comprehensive understanding of nomenclature is essential for co-ordinating effective local, regional and national activities in the area of patient safety. (Please see Appendix D for a draft mini-glossary of patient safety terms for discussion purposes.)

The health-care system is a highly complex, integrated and interdependent environment. Broader system issues can significantly impact the number and type of adverse events associated with the delivery of health care. Some of the system issues that are relevant to the study of adverse events include:

- Reductions across the system in acute-care beds
- Increased complexity of diagnostic and therapeutic interventions that create a patient population with higher acuity
- Concerns regarding the safe and effective functioning of outdated equipment in a variety of Canadian health-care facilities
- Acknowledged shortages of qualified health-care personnel in specific sectors that increase workload pressures
- Less opportunity for the mentoring of novices in services with workload pressures and/or high turnover rates of staff
- Continual restructuring and non-stop change compromising the organizational ability to identify issues and implement timely and appropriate strategies to address deficiencies in a co-ordinated manner
- High-volume of interpersonal/interprofessional communications that may directly impact on the ability to detect, mitigate or recover from preventable adverse events
- A culture of blame and many traditional hierarchical organizational structures stifling the reporting of adverse events and any follow up quality improvement discussions
- Potential for inadequate processes for the credentialing and privileging of independent health-care professionals, as well as the credentialing and registration of self-regulated professionals who are employees, directly affecting the competency of practicing health-care personnel
- Health-care personnel who self-report that they are affected by excessive workload, burnout, fatigue, shifting work-hours, extended periods of on-call and weekend work
- Physical environment, such as technological developments that may enhance patient safety or add new risks if staff are not provided with appropriate orientation

- Environmental factors such as dim lighting and slippery floors that can increase hazards to patient safety
- The local, regional and provincial protocols and policies that include the regulation of practices such as the reuse of single-use medical devices / products
- The lack of a comprehensive information technology infrastructure that can identify, trend, and respond to adverse events

The deaths of two Ontario patients (1999 and 2002), caused by the accidental injection of undiluted potassium chloride, provide additional Canadian examples of how factors in the system can contribute to adverse events. Concentrated potassium chloride is often marketed in Canada in plastic ampoules and vials that resemble containers of sterile water, saline solution or other generally harmless substances. If a variety of vials are stored on the patient care unit, the staff are at risk of retrieving and injecting undiluted potassium chloride when another substance was intended. Removing the potassium chloride from the unit eliminates the possibility of this kind of unintended action.

The Ontario patients were in the same hospital approximately three years apart. Unfortunately, the potassium chloride was apparently not uniformly removed from unit stock after the first death. The same factors lay dormant until the next fatal injection. Learning from the experience of errors and sharing successful system remedies and effective safeguards in our medication-use systems will prevent recurrences of the same error (Cohen, 1999).

When different medications have similar product design and packaging, the system has created a greater likelihood of error. Manufacturers can play a key role in improving patient safety by collaborating with health-care personnel and developing unique containers, labels and packaging to easily differentiate the products.

The health-care system can be proactive and learn to seek out the contributing factors to prevent patient injury or death.

Improving the System

"Every process is perfectly designed to achieve the results it gets."

Paul B. Batalden, MD[1]

Building a Safer System: Principles for Action

Key assumptions have been summarized in the principles to provide a foundation for the specific strategies recommended for implementation:

- The Canadian health-care system is guided by the principles of national health insurance as set out in the Canada Health Act and is implemented primarily at the provincial/territorial level. The system is complex, dynamic and characterized by many competing pressures, particularly the relationship between funding and quality of care. An unprecedented level of collaboration across all sectors must occur to ensure a co-ordinated and effective strategy for improving patient safety.
- Safety is a fundamental aspect of quality health care. To improve safety, the health-care system must develop, maintain and nurture a culture of safety.
- Health-care personnel, patients, and all others within the system must be informed participants in understanding that human error is inevitable and that underlying systemic factors, including ongoing system change, contribute to most near misses, adverse events and critical incidents.
- Specific educational and professional development programs that focus on evidence-based practice, periodic audits, and a health-care team approach to practice and learning can reduce the likelihood of human error.
- The health-care system must facilitate comprehensive identification of hazards that pose threats to our people (e.g. patients, staff and health-care personnel). Systemic identification should be carried out reactively, in response to a recognized adverse event or outcome, and more importantly, proactively, before problems have occurred. This identification must be followed by reporting and recording of these hazards (and any associated adverse events and near misses) to a network of databases.
- The health-care system must develop an atmosphere of trust, in which openness and frankness in identifying and reporting problems or potential problems is encouraged and rewarded. No blame will be apportioned to individuals following reporting, subject to limited qualifications. These qualifications include failure to report safety hazards or critical incidents and premeditated or intentional acts of violence against people, equipment or property.
- The health-care system must encourage partnerships among all consumers and providers of care. Partnerships will require the health-care system to become more flexible, with a shift away from traditional hierarchical-operating structures. These partnerships, including those of individuals, professions and organizations, are necessary for making effective improvements to all operational/systemic deficiencies.
- The health-care system must demonstrate

[1] Paul Batalden, *Dartmouth Medical School* and the *Institute for Healthcare Improvement*, has made this point several times in his teaching about the improvement of healthcare.

its ability to build on what is already known in other sectors, learn from experience, and be willing and able to implement major reforms when indicated. Such a system will endeavor to analyze relevant information, develop cost effective evidence-based safety initiatives and standards of care that are critical to the improvement process, and regularly receive feedback on the results of targeted strategies.

- The health-care system must promote appropriate disclosure to all partners (e.g. patients, the public, health-care personnel and government) of safety information relative to health issues. Such disclosure must be supported by changes to the legal and regulatory systems that also facilitate effective systems for the prevention and/or management of hazards.

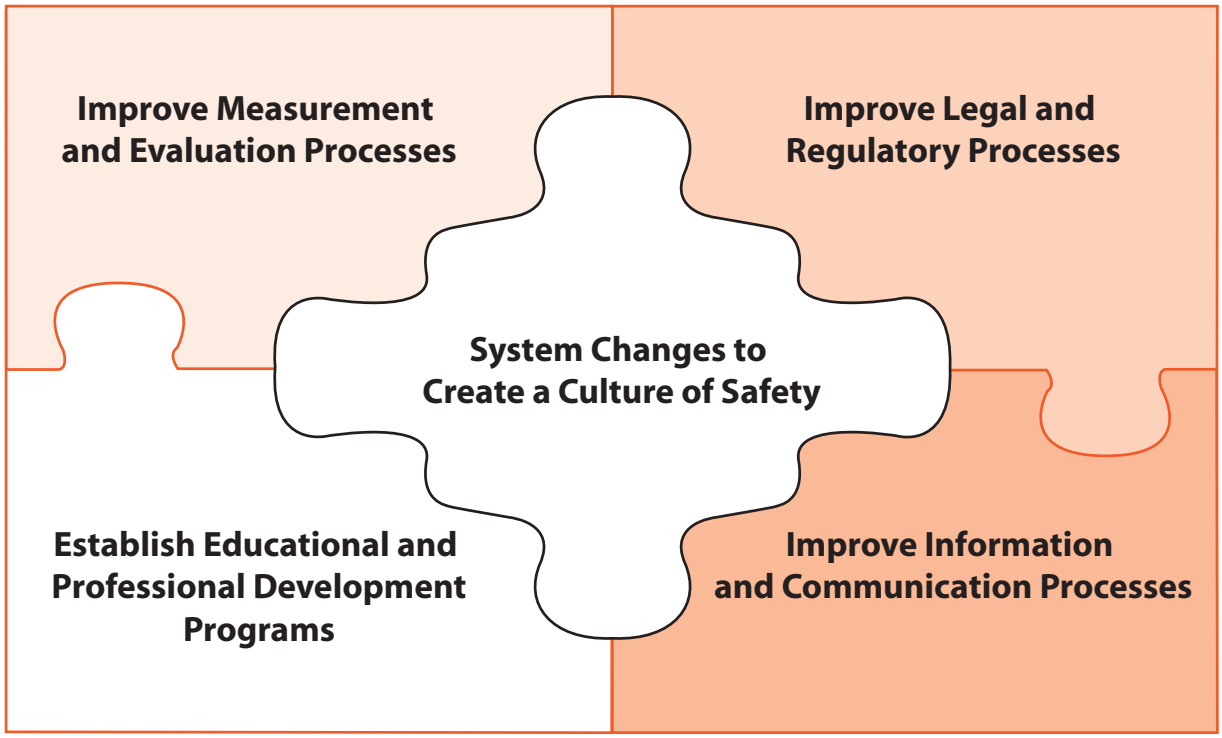
Building a Safer System: A National Integrated Strategy for Improving Patient Safety

Providing safe care is fundamental to providing high quality health care to Canadians. Understanding the complexity and issues within the system is the first step in building a consensus for system-wide change. The next step is to create and implement an integrated national strategy that gives a voice and role to patients; health-care personnel, organizations, educational institutions and professional regulatory bodies; and to federal/provincial/territorial levels of government.

Five major components to building a safer system

1. **Establish a Canadian Patient Safety Institute to facilitate a National Integrated Strategy for Improving Patient Safety**
   Current responsibilities for patient safety are widely distributed among various professional and regulatory jurisdictions that do not share a common understanding of the issues or a common vision for the future. One of the key system changes will be the creation of a co-ordinating body to facilitate an unprecedented level of collaboration among local, regional, provincial, territorial and federal health-care sectors.

Building a Safer System:
A National Integrated Strategy for Improving Patient Safety
in Canadian Health Care



Additional recommendations for system-wide strategies are included in this section.

2. **Improve Legal and Regulatory Processes**
   The current legal and regulatory environment in health care perpetuates a fear of blame and litigation. As a result, disclosure discussions and quality improvement processes may not involve an open dialogue and sharing of questions or concerns. Key recommendations will be made to create the environment for successfully improving patient safety.

3. **Improve Measurement and Evaluation Processes**
   The lack of a comprehensive information technology infrastructure limits our ability to identify, trend and respond to adverse events. Key recommendations will be made to provide the tools and resources for system-wide changes.

4. **Establish Educational and Professional Development Programs**
   The specific knowledge and skills to improve patient safety are currently not part of the education, training, and/or professional development programs for most health-care personnel. Recommendations will be made for a co-ordinated and multidisciplinary educational approach that will help to build a critical mass of expertise.

5. **Improve Information and Communication Processes**
   Access to accurate and understandable information will help the public and all other health-care stakeholders to first understand the system and then participate in improving it. Recommendations will be made to stimulate dialogue, understanding, and participation.

The five major components will lead to a culture of safety where words are translated into actions that reduce the risk to Canadian patients.

System Changes to Create a Culture of Safety

A culture and environment of safety cannot instantly be created, but will evolve over time under the guidance of a co-ordinating body, and with the commitment of all governments and health-care organizations to provide capital and operating resources for system reform.

Recommendation

1. Establish and support a non-profit *Canadian Patient Safety Institute* (draft title). Membership will be multidisciplinary and consist of clinical, academic and administrative experts in the fields of safety and health care from across Canada

The *Canadian Patient Safety Institute* will collaborate with the territorial, provincial and federal ministries of health and other authorities who may establish bodies, or designate patient-safety responsibilities to new or existing structures, such as the Health Quality Council in Saskatchewan. As safe patient care is fundamental to the provision of high-quality care, it is anticipated that the *Institute* will be part of, or closely related to, any national structures that may emerge for the purpose of measuring and/or improving the quality of Canadian health-care services. Integrating safety and quality discussions is an important aspect of recognizing and addressing the overlapping issues of misuse, overuse, and under use of health-care services, as well as other components such as patient satisfaction, access to and efficiency of health care.

The proposed *Institute* will focus on the role of facilitating rather than assuming operational responsibility for patient-safety actions. Recognized expertise in improving safety could be accessed by the *Institute* for the development of standardized templates and guidelines that could then be modified to meet the needs of local organizations across the country. Key templates would include reporting mechanisms, data collection terminology and strategies, and effective practices for reducing the risk of injury to patients. The

Institute will also work to minimize redundancy and overlap in patient-safety activities.

A number of clinical and organizational practices, new technologies or new programs, including educational programs and patient care activities, are likely to be recommended as a result of efforts to improve patient safety. Researchers, with established expertise and experience, should use appropriate research designs and analysis to evaluate these new practices, technologies and programs.

Recommendation

2. Base new practices, technologies and programs that are recommended by the *Canadian Patient Safety Institute*, or other such bodies, on evidence, and subject them to scientific evaluation. The evaluation would include potential benefits and costs

The *Canadian Patient Safety Institute* should collaborate with applicable researchers to ensure that these evaluations are readily available to interested health-care personnel and organizations. The Institute would not duplicate the work of existing assessment structures nor be involved in regulating the introduction of new products and/or procedures.

Recommendation

3. Implement system changes that have a demonstrated ability to improve patient safety

Canadian Patient Safety Institute
(draft title)

A *Canadian Patient Safety Institute* is needed to co-ordinate, facilitate, and stimulate designated activities within the national strategy. Actions would encompass a wide range of policy and evaluative responsibilities:

- Promote legal and regulatory changes that would enhance reporting of adverse events with multidisciplinary determination of contributing factors and recommendations for improvement.
- Liaise with governments and applicable health organizations for patient safety policy development or modification (including those on reporting and disclosure).
- Promote effective measurement and evaluation processes by
  - ➪ Collaborating with federal/provincial/territorial governments in establishing a comprehensive information technology infrastructure and reporting strategies that will facilitate improving patient safety
  - ➪ Reviewing the adequacy of Canadian data on patient safety as it becomes available, and providing feedback to local authorities on trends that are revealed
  - ➪ Facilitating the collection and dissemination of methods for effectively measuring adverse events as well as programs/projects for translating data into knowledge, and then action by all levels of health-care personnel
  - ➪ Recommending new practices or technologies with established effectiveness for improving patient safety
  - ➪ Contributing to the identification of a research agenda for measuring adverse events and gaining insights into causation (the detailed analysis to be done by academic evaluation units or consultants)
- Promote the development of national standards and benchmarks as well as process and outcome indicators of patient safety
- Support the development of a health-care education and professional development programs for improving patient safety
- Support the development of an information and communication program for improving patient safety.

Enhancing the safety of patients is the result of three interdependent actions: preventing adverse events, making them visible, and mitigating their effects when they occur. There is a growing body of evidence regarding the specific strategies that improve the system's ability to prevent, detect and moderate the effects of adverse events. Health-care organizations should review their processes for opportunities to improve and implement effective practices that are appropriate for their environment given practical and financial constraints

Medication administration is one example of a process that can benefit from system changes. Substantial evidence demonstrates that the rate of medication errors is lower in unit-dose systems than in traditional systems or ward-stock systems. A relevant study was conducted in 1991 at the Toronto Hospital for Sick Children (O'Brodovich and Rappaport, 1991), during their successful conversion to a unit-dose system. In this study, the observed medication-error rates (excluding wrong-time errors) decreased from 10.3% to 2.9% when the traditional drug distribution system was replaced with a unit-dose system. The study also demonstrated a 4% reduction in medication costs and a reduction in the percentage of nurses' time spent on medication-related activities.

In spite of the proven safety advantages and cost effectiveness of unit-dose systems, the majority of Canadian hospitals continue to utilize traditional medication-distribution systems that rely heavily on human vigilance. The *Hospital Pharmacy in Canada Annual Report, 1999/2000* states that only 26% of the 115 responding hospitals provide unit-dose drug distribution services or automated decentralized dispensing to 90% or more of their beds.

Recommendation

4. Formalize responsibility and accountability for patient safety within the management structures and clinical processes of all health-care organizations

As a key element of organizational and cultural change, clearly defined responsibilities and accountabilities must exist to ensure patient safety when adverse events, hazardous situations or near misses occur. Health-care organizations should reflect a commitment to patient safety in their vision, mission, values, budget, management structures and clinical processes.

Recommendation

5. Develop and implement responsive patient-focused programs for the receipt, review and management of concerns within health-care organizations

Complainants should be partners in the resolution process and participate in open communication with factual disclosure. Now, an adversarial system in which punishment is the desired end isolates the various players. A team meeting of stakeholders held in a timely manner after an adverse event has occurred will facilitate discussion, and in some cases mediation, with the objective of achieving a satisfactory resolution for all participants. Refusing to discuss concerns may result in the perception that legal action and/or a formal complaint to the licensing body are the only options for complainants.

Patients and their families may present their concerns to individual professionals (physicians, nurses, etc.), to management, to regulatory bodies, to governments, and perhaps to other stakeholders about the care received. Such concerns may expose hazards, adverse events or near misses related to system issues and/or problems in the performance of health-care personnel. As such, these concerns may provide an important opportunity for individual or system improvement.

A patient-focused concern management program with public reporting will help to build a transparent process for quality-of-care issues.

For additional information on understanding system issues, please see Appendix E — *The Framework Matrix: System Issues Working Group*.

Legal and Regulatory Processes

The current legal and regulatory environment in health care perpetuates a fear of blame and litigation that may result in adverse events not being recorded on the health record, or, at minimum, verbally communicated to an appropriate individual. Individual health-care personnel feel the burden to be 'perfect' in their knowledge, skills and judgment, and are generally not encouraged to openly disclose or discuss hazardous situations, adverse events or near misses. Even if the information is disclosed, there are competing interests. On the one hand, there is the necessity to be able to collect, analyze and share information; on the other, there is the need to protect the privacy and confidentiality of individuals, and to protect the information gathered in the organizational or regulatory review of an adverse event. Moving to a culture of safety will rely on improved reporting and discussion of contributing factors within and across jurisdictions.

Recommendation

6. Adopt non-punitive reporting policies within a quality-improvement framework across the health-care system

The health-care system must develop an atmosphere of trust, in which openness and frankness in identifying and reporting problems, or potential problems, is encouraged and rewarded. No blame or fault should be apportioned to individuals following reporting, subject to limited qualifications such as failure to report safety hazards or critical incidents, and premeditated or intentional acts of violence against people, equipment or property.

Recommendation

7. Standardize the legislation on privacy and confidentiality of personal information across Canada to facilitate access to patient-safety data, while respecting the privacy of patients and providers

Provincial and federal departments should establish the legislative authority to obtain and share patient-safety information across all relevant jurisdictions. The improved access to data on patient safety will result in a greater understanding of the specific hazards to patients and of what strategies have been effective in addressing these risks. Opening the doors of communication will reduce the sense of isolation that each individual and organization faces today.

Legislative changes should facilitate not only information sharing, but also the opportunity to co-operate in a review of a specific patient case. It is possible, for example, for a single adverse event to be examined by the medical examiner's office, medical and nursing regulatory bodies, and the hospital or regional health authority where the event occurred. A collaborative review will facilitate a multidisciplinary determination of the contributing factors and one set of recommendations to enhance individual and/or system performance.

There is a perception that regulatory bodies approach preventable adverse events in health care by searching for and culling "bad apples", rather than seeking improvement through education and remediation. The perception of a "bad-apple approach" impedes the ability of regulatory bodies to effectively search for systemic issues and other root causes. All health-care regulatory bodies should move toward and adopt the practice of regulation that includes an expectation of continuous improvement, learning from effective practices, use of evidence-based decision-making, and fostering innovation with creativity.

Recommendation

8. Develop a greater focus on improvement through education and remediation, vs. blame and punishment, in legal, regulatory and human resource processes

A shift towards understanding and improving the underlying causes of adverse events in health care will broaden the focus to structural and process dimensions, in addition to individual performance. Corrections should aim to make it easier for the individual health-care professional to do the right things correctly (e.g. product design, process design, standardization) within the system.

There is a balance to be achieved between evaluating and improving the performance of an individual and addressing system issues. Regulatory bodies will continue to evaluate and address the competence and performance of their individual members, in collaboration with other measures to help improve patient safety. Incompetence, once discovered, must be corrected. On occasion, correction will involve restrictions on practice or even withdrawal from practice. When possible, underlying problems that affect performance should be identified and remedied, and remain the primary objective when addressing performance problems.

In 1993, the Federation of Medical Licensing Authorities of Canada (FMLAC) launched a project to address the issue of ensuring that physicians in practice maintain an appropriate level of performance for the duration of their professional lives. Four major areas of physician performance were identified as competence, behaviour, health/fitness to practice and use of resources. A Canadian Model for Monitoring and Enhancement of Physician Performance (MEPP) was developed, with emphasis on the need for the FMLAC to work together with other medical organizations in the prevention, assessment and remediation of performance problems of physicians. The model identified the important role that the licensing authorities have in the monitoring and provision of feedback to all physicians.

Personal and professional ethical frameworks also guide the decisions and actions of health-care professionals, both as individuals and members of institutions. Ethical behavior is fundamental to building a culture of safety and should be clearly linked to strategies for improvement.

Successfully changing the emphasis from blaming the health-care professional to a quality-improvement approach with a focus on learning from preventable adverse events will rely heavily on the effective education of the public and their subsequent support. The media will play a pivotal role in providing a balanced understanding of the issue and measures for improvement.

The use of civil litigation to hold an individual practitioner and/or health-care organization accountable is a valid and recognized option within the framework of accountability. For example, although the physician has a significant responsibility for the well being of his or her patients (including applicable medical decisions made), the hospital or organization where care was provided also has responsibility for the actions of its employees. This arrangement often creates an environment where two separate insurers and various health-care personnel are anticipating a legal proceeding. There is an added layer of complexity if a regulatory body is also investigating the circumstances. The parties should strive for increased co-operation and communication to resolve issues through mediation where possible. Perpetuating the adversarial legal environment does not serve the interests of the patient.

Health-care personnel within this environment are understandably concerned with providing information and/or participating in quality-improvement discussions that may subsequently be used in some other forum against their interests. Effective change from the present culture of blame to one that encourages a forum of disclosure and discussion of adverse events will require the agreement and support of the affected health-care personnel. Their careers may suffer devastating consequences from hearsay or premature conclusions based on inadequate information; therefore, safeguards should be established to ensure effective peer review of the facts.

In varying degrees, health-care professionals perceive a lack of personal protection for information given within quality improvement and/or peer review processes in different jurisdictions. When it does exist, such legal protection (privilege) is usually contained in the respective provincial *Evidence Act*, which generally provides that documents and information collected by committees cannot be compelled to be produced in court. However, the legislation may be

outdated, is often inconsistent, and does not adequately provide for the multidisciplinary approach to health care, nor the full continuum of care (e.g. community clinics, home care and emergency medical services).

Recommendation

9. Review and, where applicable, revise *The Evidence Act*, and related legislation within all Canadian jurisdictions to ensure that data and opinions associated with patient-safety and quality-improvement discussions, related documentation and reports are protected from disclosure in legal proceedings. The protection would extend to this information when used internally or shared with others for the sole purpose of improving safety and quality. Wording within the applicable Acts should ensure that all facts relating to an adverse event are recorded on a health record that is accessible to the patient or designated next of kin, and are not considered privileged

The legislative changes will create an environment that is conducive to reporting and discussion of contributing factors and recommended practitioner or system changes. The information may then be added to a provincial or Pan-Canadian repository in a de-identified manner to ensure that the lessons learned are available across Canada without release of confidential patient or practitioner information.

Saskatchewan has introduced new requirements for critical-incident reporting that protect individuals and organizations from disclosing information about critical incidents and reports of those incidents. The facts of the incident remain available, but discussion about the events is protected. This legislation will facilitate centralized reporting of critical incidents and promote an environment where the health-care professionals involved can discuss their opinions and recommendations within a confidential quality-improvement environment.

Independent reports (e.g. Prichard and Dubin) have identified issues related to reform of the current tort system; insufficient attention has been paid to their content and recommendations. A wide variety of insurers are in place for independent practitioner and corporate liability concerns arising in health care. The competing interests and focus on litigation to obtain a settlement may deter open dialogue and discussion of an adverse event. A detailed review of the issues and possible solutions is beyond the mandate of this report; however, further research is clearly needed to examine the potential for tort and/or insurance reform to contribute to patient safety.

Recommendation

10. Hold further discussions regarding the tort and health-care insurance systems and their effects on patient safety, with the aim of making recommendations that would contribute to a culture of safety in Canadian health care

Although various legislative amendments are needed to change the legal and regulatory environment, building a culture of safety can, and should, proceed with the various strategies that can be implemented in the short term.

Measurement and Evaluation

An in-depth understanding of adverse events in health care will not be possible until comprehensive measurement and evaluation processes can identify where and why patients are at risk. Knowledge of the types of adverse events occurring in Canadian health care, and strategies for

reducing their incidence, should be shared among organizations across Canada. Strategies that contribute additional information and understanding should be given high priority.

Effective surveillance systems to assess the incidence of near misses, adverse events and critical incidents are important for assessing the performance of the system and for identifying areas for improvement. Critical incidents involve significant risk of or actual loss of life, limb, or function, and are considered 'critical' as they signal the need for immediate investigation and response. Existing mechanisms to identify these events and incidents are incomplete.

Canada lags behind several other countries in developing tools for measurement. A number of surveillance systems developed elsewhere may hold promise for local implementation; however, they must be evaluated to determine their usefulness in both hospital and ambulatory settings. Surveillance systems must also be comprehensive, accurate and incorporate safeguards for patient confidentiality.

Recommendation

11. Undertake an analysis of the capabilities and cost of systems for monitoring adverse events, critical incidents and near misses

The goal of the analysis is to identify which systems should be recommended for implementation in the Canadian health-care environment. There may be a need for several such systems to ensure that data can be translated to information, action and evaluation for all relevant processes. In addition, consideration of effective strategies for linking the information from surveillance to improvement activities is essential so that the results of these analyses contribute to improvements in care, not just to better reporting of adverse events.

A combination of Canadian, provincial, regional, organizational and program-based adverse-event surveillance and reporting systems will likely be necessary to obtain all relevant data. Key aspects to be reviewed include:

- Nature of participation (voluntary versus mandatory)
- Attitudes and perceptions of the health-care professionals
- Scope and coverage of the system
- Data ownership and reporting relationships
- Cost (including staff time and other resources)
- Definitions of events to be tracked and reported
- Timeliness and accuracy of the reports

The review should be contracted out to academic evaluation units or consultants who would be engaged to identify such systems and assess them based on comprehensive criteria and methodology. Since hospital-based surveillance systems are more advanced, it may be advisable to tender two assessments, one for institutional systems, and a second for community-based providers.

A report detailing the strengths, weaknesses and costs of each system should be forwarded to the *Canadian Patient Safety Institute* for further consideration. Health-care associations, professional groups and governments should also receive a copy.

Recommendation

12. Recommend the types of surveillance systems, including relevant patient-safety indicators, to be developed and supported in Canadian health care. The recommendations would be based on the findings of the review proposed in Recommendation (11)

The proposed review of surveillance systems will identify a number of highly rated options for implementation. However, the performance

of such systems needs to be tested prior to full-scale implementation by investing in pilot projects. Well-designed evaluations will identify the effectiveness of these systems in Canada and help to determine the resources necessary for their implementation. These pilots could include trials of organizational and regional reporting systems and the evaluation of computerized information and decision-support systems, including computerized physician order-entry systems. The evaluation should include:

- Assessments of feasibility
- Quality of data
- Cost effectiveness
- Contributions to identifying improvements to care

Pilot projects in different settings will help in assessing the compatibility of these systems with existing or planned regional health information networks and local information systems.

The development of patient-safety indicators should be linked to an appropriate framework in collaboration with the numerous other provincial and national activities in the area of indicator development.

Recommendation

13. Secure funding from federal/provincial/territorial jurisdictions to invest in information-technology infrastructures that support the standardized identification, reporting and tracking of patient-safety data

Fiscal pressures across all health-care sectors have resulted in a lack of funding for important information technology opportunities, and valuable health-care dollars continue to be wasted on information-technology systems that cannot easily share data. Monitoring and improving patient safety will be fragmented and parochial until co-ordinated reporting and data management occurs.

It is essential that the federal, provincial and territorial departments of health work together to create a comprehensive information-technology infrastructure to support a network of reporting systems. These efforts should be aligned with current work to develop electronic patient information through the Canada Health Infoway initiative. Efforts should be made to ensure that standard data definitions and data collection protocols are developed.

Recommendation

14. Adopt "patient safety" as a cross-cutting theme, or designated area for research competitions supported by the Canadian Institutes for Health Research, Canadian Health Services Research Foundation and/or other granting organizations, to encourage Canadian researchers to undertake studies in this area

Major granting councils, or other funding agencies in Canada, fund little scientific research on adverse events, patient safety and system improvement. Additional focus on and funding of these topics would increase the interest of Canadian researchers. Such research would provide valuable information for improving safety and evaluating the effectiveness of current and proposed activities.

The *Canadian Patient Safety Institute* should convene a meeting with the leaders of the granting councils to identify ways to increase the scale of research, including applied and policy-relevant research studies. Both Canadian and international experts should meet to set a research agenda in patient safety and reduction of adverse events.

Education and Professional Development

To be useful, information must be analyzed and translated into action. Teams, not individuals, often deliver health care. For improvement in

the safety and quality of health care, education, professional development, and practice review are necessary. Local actions need skilled, multidisciplinary health-care teams to effect improvements in patient safety.

A co-ordinated strategy highlights professional development and education. All personnel in health care will be targeted for training about the reporting, educating and measuring loop. Information and dialogue on personal disclosure of an adverse event and strategies for dealing with ensuing emotions will be emphasized.

Building on previous efforts within a co-ordinated approach will increase the likelihood of effective changes. Some of the earliest patient-safety activities occurred within the specialty of anesthesia:

- The first practically-applied studies of human error in medicine
- The study of malpractice claims to identify risks
- The wide dissemination of information on patient safety
- The development of standards of care
- The development of simulation for research and education

Other contributions to patient safety included the availability of more controllable drugs with fewer side effects, improved education and training, safety enhancements to anesthesia machines and connections to various medical gases, and the evolution of a culture that places safety as the highest priority.

Lessons learned in the field of anesthesia can, and should, be implemented across other specialties.

Recommendation

15. Develop and implement health-care education and professional development programs for improving patient safety

A health-care education and professional development program at the under-graduate, graduate and postgraduate levels should be undertaken with the support of the *Canadian Patient Safety Institute*, and in collaboration with a variety of health-care associations, academic institutions and regulatory bodies.

- Conduct an assessment of current educational efforts to identify effective practices and foster the building of a national system designed to provide health professionals with the knowledge, skills and attitudes required to ensure the delivery of safe health care
- Stimulate local and regional projects and ensure that what is learned from the experience is shared broadly
- Build on current knowledge and skills in addition to meeting the unique needs of various health-care professionals and specialties by using a 'Request for Proposal' approach to develop specific programs, including:
  - ➪ interdisciplinary simulations of high-risk health-care interventions and emergency responses
  - ➪ continuing education programs for specialties such as obstetrical services
- Recruit a community of multidisciplinary health professionals who will be trained to become recognized as "safety-educated" champions, and who shall have the mandate to:
  - ➪ Collaborate on the national education standards
  - ➪ Create a core curriculum applicable to all areas of expertise with applicable accreditation bodies in the health disciplines incorporating the standards for education into their accreditation programs
  - ➪ Identify the tools and data needed to support the curriculum
  - ➪ Identify the means by which to achieve this goal within specific educational settings
- Stimulate a leadership program to mentor the "safety-educated" champions. The objective over three to five years would be

to have at least one trained leader in every hospital and major medical organization within the country. The program would include specialty-specific disciplines, and would encourage participants to lead and co-ordinate patient-safety programs locally and nationally
- Evaluate regularly the impact of educational programs on reducing the number of preventable adverse events

Recommendation

16. Develop educational and continuing professional development programs to improve patient safety, in collaboration with national accrediting bodies, academic institutions, provincial licensing authorities (for peer-assessment reviews) and health-care facilities/organizations/scholarly societies

A network of provincial and local education leaders should lead the education and professional development initiatives necessary for a transformation to a health-care culture of safety. Strategies for developing and enhancing the network should include:

- Sponsoring provincial or university health science "implementation" conferences on patient safety; participants could vary from all health-care personnel to a specific discipline or specialty
- Incorporating a patient-safety theme into continuing professional development programs and related clinical guidelines facilitated by provincial medical organizations and national specialty societies
- Promoting the development of a provincial steering or local co-ordinating committee for education development and implementation on patient safety (structure may be similar to the Ontario Guidelines Council)

Building Knowledge Through Information and Communication

Timely access to relevant patient-safety information is a fundamental philosophy of the *Canadian Patient Safety Institute*. The public, health-care personnel, organizations, educational institutions, regulatory bodies, professional associations, governments and other partners in health care need to receive relevant information and discuss what their roles and responsibilities may include. The ensuing dialogue and debate will form an important foundation for the effective implementation of the national strategy.

Public input on the areas for potential harm within the health-care system and suggested improvements in patient safety are essential components of building knowledge through information and communication. Listening to patients and their families talk about their experiences and observations as they navigate the health-care system will provide unique and powerful insights.

Recommendation

17. Publicly report measures of health-care quality and safety

Publicly reported measures of health-care quality and safety should include background information on the overall benefits of health care, but the emphasis will be placed on understanding hazards, adverse events and near misses in the system. Reports will be incorporated into a variety of federal / provincial / territorial and nongovernmental publications (such as those released by the Canadian Institute for Health Information). Information will also include:

- Estimates of the frequency and impact (including financial) of adverse events in health care both within and outside Canada
- Description of measures undertaken to reduce preventable adverse events and related costs
- Highlights of previous and new patient-safety initiatives in Canadian health care
- Strategies for improving patient safety (including those presented in this report)

Recommendation

18. Develop educational materials on personal measures for improving safety in health care for distribution to the public

The *Canadian Patient Safety Institute* will facilitate the development of educational materials, including patient pamphlets. The content should include information on patient rights and responsibilities, communication strategies for talking about patient-safety questions or issues, and personal measures that the public can adopt to reduce their risk of incurring a preventable adverse event. The documents should ensure that the public can understand the information presented.

Recommendation

19. Create a website to facilitate the sharing of patient-safety resources and discussions

Information must be accessible to all partners in health care on a 24-hour, 7-day-a-week basis. As the Internet serves this purpose well, technology can be utilized to facilitate on-line chats and/or sharing of lessons learned. The website should be developed with the support of the *Canadian Patient Safety Institute*. (Please refer to Appendix F for a more extensive information and communication action plan.)

Governance

To improve patient safety, structures at the local, provincial and national levels must be informed and effective. Key attributes would include:

- Leadership committed to creating a culture of safety
- Patient safety defined as an organizational priority, with formalized responsibilities and accountabilities
- Resources dedicated to improving awareness of and understanding of hazards
- Sustained efforts that strive to identify and implement effective practices for improving patient safety
- The mentoring of novices and support of local patient-safety champions
- Participation in partnerships to enhance local, provincial and national patient-safety strategies

Canadian Patient Safety Institute (draft title) — Governance Structure

Further consultation will occur on the governance structure; however, guiding principles include:

- Membership in the governing body based on a broad range of leaders and stakeholders who have an interest and expertise in patient safety, and not determined by representation from organizations
- Public representation on the governing body
- Succession planning implemented to ensure knowledgeable and effective leadership
- Conflict of interest guidelines implemented to ensure open and transparent processes
- Health-care professionals, organizations (including insurers), regulatory bodies, associations, institutions (including the academic community), manufacturers, and pharmaceutical corporations invited to play a role in supporting the work of the *Institute*
- Accountability to the public and federal/provincial/territorial governments

- A structure at arm's length from government and regulatory bodies
- A strong role in public education and advocacy
- A review and evaluation of the *Institute*'s effectiveness in five years

There would be defined mechanisms for organizations, including those who supported the mandate of the National Steering Committee on Patient Safety, to be affiliated with the *Institute* in a voluntary and non-representative way. The affiliation would be for the purposes of providing advice, implementing programs and fostering collaboration across the health-care continuum. Examples of Canadian initiatives are listed in Appendix G — *National/International Summary of Key Initiatives in Patient Safety*.

Funding

Significant initial and ongoing funding (minimum of five years) will be required from governments to transform the strategy from the planning stage to action on priority recommendations. Additional sources of funding, such as research grants from private or public sources, will be pursued to supplement the federal, provincial and territorial contributions. Success in improving patient safety will rely on building new structures and resources into the existing framework of clinical, administrative, regulatory and health department activities. A proposed interim budget of $500,000 and an annual budget of up to 10 million dollars would be prioritized for the following key recommendations within the five major components of the strategy. Preliminary budget estimates have been included to stimulate further dialogue and input.

Budget (estimate)	Priority Recommendations	Estimated Timeline
PHASE I — (Rec. 1) Interim budget $500,000	(1) Establish and support a non-profit *Canadian Patient Safety Institute* (draft title).	Interim Phase: Winter of 2002/03 (approximately 6 months)
PHASE II (Recs. 8, 11, 13, 15, 17 19) Operational up to $10,000,000 per year (minimum of five consecutive years)	(8) Develop a greater focus on improvement through education and remediation, vs. blame and punishment, in legal, regulatory and human-resource processes.	2003/04
	(11) Undertake an analysis of the capabilities and cost of systems for monitoring adverse events, critical incidents and near misses. (13) Secure funding from federal/provincial/territorial jurisdictions to invest in information-technology infrastructures that support the standardized identification, reporting and tracking of patient-safety data.	2003/04
	(15) Develop and implement health care education and professional-development programs for improving patient safety.	2003/04
	(17) Publicly report measures of health-care quality and safety. (18) Develop educational materials on personal measures for improving safety in health care for distribution to the public. (19) Create a website to facilitate the sharing of patient-safety resources and discussions.	2003/04

Phase I

1. Interim Structure

- Establish an interim governance structure of approximately eight to ten members
- Establish an interim chief executive officer and other required secretariat staff
- Focus the responsibilities of the interim governance and staff on developing the business plan for Phase II, including:

  - Detailed strategic and operational plans for a *Canadian Patient Safety Institute*
  - Detailed budget preparation
  - Staffing requirements for Phase II (permanent secretariat)
  - Other resource requirements, e.g., information technology

2. Resource Requirements

Total **$500,000**

- Interim CEO
- Interim governance (based on eight to ten members)
- Consultations (including legal) and communications
- Interim secretariat and set-up

Phase II

The *Institute's* interim governance structure and staff will develop a detailed business plan for Phase II. A preliminary estimate of up to 10 million dollars per year, for a minimum of five consecutive years, is projected for the operation of the organization. Expenditures can be more accurately predicted within the Phase II business plan.

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Appendices

Appendix A

MEMBERSHIP OF WORKING GROUPS
TERMS OF REFERENCE
EXTERNAL CONSULTATIONS

January — April 2002

System Issues

Members:

Wendy Nicklin (Co-chair)	Vice-President, Nursing and Clinical programs, The Ottawa Hospital
Kim Vicente (Co-chair)	Professor of Biomaterial and Biomedical Engineering, University of Toronto
Jan Davies	Professor of Anesthesia, Foothills Medical Centre
Robin J.Ensom	Pharmacy Leader, St. Paul's Hospital-Providence Health Care (until March 2002)
Philip Hebert	Assistant Professor, Department of Family and Community Medicine, Sunnybrook and Women's Hospital
Carolyn Hoffman	Co-ordinator, Provincial Quality of Care, Saskatchewan Health
Gilles Lanteigne	Director, Canadian Council on Health Services Accreditation
Patricia Lefebvre	Pharmacist-in-Chief, McGill University Health Centre
Bonnie Salsman	Pharmacist and Hospital Pharmacy Management Consultant
Valerie Shannon	Director of Nursing, McGill University Health Centre
David U	President and CEO, Institute for Safe Medication Practices Canada
Ian White	Associate Professor, Department of Anesthesia, University of Manitoba
Carol Appathurai	Guest observer / Representative from Advisory Committee on Health Services, Conference of Federal/Provincial/Territorial Deputy Ministers of Health

Terms of reference:

To examine to what extent the design of the health-care system contributes to adverse events, and how new designs can reduce or eliminate human and system errors.

External consultations:

Jeannie Callum	Director of Transfusion Medicine, Sunnybrook and Women's College Health Sciences Centre
François Champagne	University of Montreal
Albert Eros	Regional Pharmacy Manager
Mita Giacomini	Affiliated with CHEPA and the Department of Clinical Epidemiology and Biostatistics, McMaster University
Michel P. Lalonde	Health Care Consultant

Shaun MacCormick	Chief of Staff / Medical Director, Colchester East Hants Health Authority
Clare MacNeil	Vice-President, Clinical Services, South Shore Regional Hospital
David McLeod	Vice-President, Ontario Hospital Association
Stewart McMillan	Medical Consultant, Saskatchewan Health
Joe Mikhael	Resident/CAIR
Heather Milan	Regional Pharmacy Manager, Winnipeg Regional Health Authority
Fiona Miller	Affiliated with CHEPA and the Department of Clinical Epidemiology and Biostatistics, McMaster University
Mike Opadiran	eChart, University Health Network
Linda Poloway	Canadian Society of Hospital Pharmacists
J. Dean Sandham	Executive Director, Quality Improvement/Health Information

Working Group on Regulatory / Legal Issues
Working Group on Measurement / Evaluation
Working Group on Education / Professional Development
Working Group on Information / Communication

Regulatory/Legal Issues

Members:

Larry Ohlhauser (Co-chair)	President and CEO, Healthcare Solutions and Innovations (to March 2002)
Trevor Theman (Co-chair)	Assistant Registrar, College of Physicians and Surgeons of Alberta (from March 2002)
Louise Sweatman (Co-chair)	Director of Regulatory Policy, Canadian Nurses Association
Allan H. Lefever (Assisting chair)	Judge, Provincial Court of Alberta; President, Health and Stroke Foundation of Canada
William Beilby	Director, Department of Research and Education, Canadian Medical Protective Association
Tim Caulfield	Research Director, Law Centre, University of Alberta
Gordon Crelinsten	Senior Physician, McGill University
Pierre Deschamps	Research Director, Faculty of Law, McGill University
Janet Harding	Manager, Department of Pharmaceutical Services, Royal University Hospital, Saskatoon District Health
Dennis Kendel	Registrar, College of Physicians and Surgeons of Saskatchewan
Ginette Lemire-Rodger	Chief of Nursing, Ottawa Hospital
Anu MacIntosh-Murray	Faculty of Information Studies, University of Toronto
William D.B. Pope	Registrar, College of Physicians and Surgeons of Manitoba
Catherine Tolton	General Counsel and Corporate Secretary, Winnipeg Regional Health Authority

Terms of reference:

To examine the manner in which the regulation and monitoring of health-care professionals and their institutions and the legal systems can improve patient safety.

External consultations:

Brian Carter	Director, Corporate and Government Relations, IMS Health (Canada)
James Clarke	President, Canadian Association of Internes and Residents
Joan Gilmour	Osgoode Hall Law School, York University
Bruce MacLeod	Emergency Physician, University of Calgary

Thomas Paton	Director of Pharmacy, Sunnybrook and Women's College, Health Sciences Centre
Robert J.Robson	Senior Health Care Liability and Risk Management Consultant

Working Group on System Issues
Working Group on Measurement / Evaluation
Working Group on Education / Professional Development
Working Group on Information / Communication

Measurement/Evaluation

Members:

G. Ross Baker (Co-chair)	Associate Professor, Department of Health Policy, Management and Evaluation, University of Toronto
Alan Forster (Co-chair)	Associate Scientist, Ottawa Health Research Institute
Lauren Donnelly	Executive Director, Acute and Emergency Services Branch, Saskatchewan Health
Ed Etchells	Sunnybrook and Women's Health Care Centre, Toronto, Ontario
Peter Norton	Chair, Family Medicine, University of Calgary
Judith Ritchie	Associate Director of Nursing Research, McGill University Research Centre
David Rosenbloom	Director of Pharmacy, Hamilton Health Sciences Centre
Robyn Tamblyn	Associate Professor, Department of Medicine, McGill University
Geoff Taylor	Professor, Infectious Diseases, University of Alberta

Terms of reference:

To determine the steps necessary to implement patient-safety monitoring systems in Canada. These systems will be used for both ongoing surveillance and evaluating interventions to minimize injury.

External consultations:

Geoff Anderson	Researcher, University of Toronto
Matt Bowes	Secretary, Canadian Association of Internes and Residents
Jafna Cox	Queen Elizabeth II Health Science Centre
Dale Dauphinee	Executive Director, Medical Council of Canada
Diane Doran	Associate Professor, Faculty of Nursing, University of Toronto
Ian Hart	Professor Emeritus, University of Ottawa
Lynn Johnston	Co-chair, Canadian Hospital Epidemiology Committee
Garry King	Hospital pharmacist
Harold Lopatka	Program Director, Alberta Drug Utilization Program
Linda McGillis-Hall	Assistant Professor, Faculty of Nursing, University of Toronto
Robert Reid	University of British Columbia
Supriya S. Sharma	Director, Marketed Biologicals and Biotechnology Products Division, Marketed Health Products Directorate, Health Canada.
L. Thompson	Health Services Utilization Commission, Saskatchewan
Rebecca Warburton	Health Economist, University of Victoria

Working Group on System Issues
Working Group on Regulatory / Legal Issues
Working Group on Education / Professional Development
Working Group on Information / Communication

Education/Professional Development

Members:

Walter Rosser (Co-chair)	Professor and Chair, Department of Family Medicine, Faculty of Medicine, Queen's University
Nadia Mikhael (Co-chair)	Director of Education, The Royal College of Physicians and Surgeons of Canada
Alecs Chochinov	Clinical Director, Emergency Program, St-Boniface General Hospital
Pat Croskerry	Clinical Consultant in Patient Safety, Capital Health, Dartmouth General Hospital Site
Dave Davis	Associate Dean, Continuing Medical Education, University of Toronto
Jean Gray	Associate Dean, Continuing Medical Education, Dalhousie University
Anil Gupta	Senior resident - Cardiology, University of Western Ontario
Wayne Hindmarsh	Dean, Faculty of Pharmacy, University of Toronto
Daniel Klass	Associate Registrar; Director, Quality Management, Registration, and Education, College of Physicians and Surgeons of Ontario
Marianne Lamb	Associate Dean, Health Sciences, Queen's University (from February 2002)
John Parboosingh	Consultant (Professional Development) to the CEO, The Royal College of Physicians and Surgeons of Canada
Jeff Turnbull	Chair, Department of Medicine, Ottawa Hospital, General Campus

Terms of reference:

To examine how enhancements to the education and continuing professional development of health-care professionals can reduce adverse outcomes and enhance patient safety.

External consultations:

Association of Canadian Academic Healthcare Organizations
Association of Canadian Medical Colleges
Canadian Association of Internes and Residents (CAIR)
Canadian Association for Medical Education
Canadian Association of University Schools of Nursing
Canadian College of Clinical Pharmacy
Canadian Council for Accreditation of Pharmacy Programs
Canadian Council on Continuing Education in Pharmacy
Canadian Council on Health Services Accreditation
Canadian Healthcare Association
Canadian Medical Association
Canadian Medical Protective Association
Canadian Nurses Association
Canadian Pharmacists Association
Canadian Society of Hospital Pharmacists
Collège des médecins du Québec
College of Family Physicians of Canada
College of Physicians and Surgeons of Alberta
Council on Medical Education
Federation of Medical Licensing Authorities of Canada
Medical Council of Canada
National Association of Pharmacy Regulatory Authorities
National Specialty Societies
The Royal College of Physicians and Surgeons of Canada

Dyanne Affonso	Faculty of Nursing, University of Toronto
Doug Craig	Department of Anesthesia, University of Manitoba
Lisa Crawford	Manager, Community Development, The Arthritis Society
Paul Davis	Heritage Medical Research Centre, University of Alberta
Dawn Frail	Manager, Drug Technology Assessment, Nova Scotia
Jill Kernahan	Department of Emergency Medicine, University of Manitoba
W. James King	Chief, Division of Pediatric Medicine, Children's Hospital of Eastern Ontario
James McCormack	Associate Professor, Pharmaceutical Sciences, University of British Columbia
David McLeod	Vice-President, Ontario Hospital Association
Karen Neufeld	St. Boniface General Hospital
Jill Newstead	Resident, CAIR
Lindsay Nicolle	Chair, Advisory Committee to Centre for Infectious Disease Prevention and Control
Beverley Orser	Sunnybrook and Women's College, Health Sciences Centre
Yvonne Steinert	Associate Dean, Faculty of Medicine, McGill University
Milton Tenenbein	Director, Emergency Services, University of Manitoba
John Turnbull	Faculty of Medicine, McMaster University
Sandra Winklebauer	Pharmacist and pharmacy consultant
James Wright	Department of Medicine, UBC Hospital Site, Vancouver Hospital

Working Group on System Issues
Working Group on Regulatory / Legal Issues
Working Group on Measurement / Evaluation
Working Group on Information / Communication

Information/Communication

Members:

John Millar (Co-chair)	Vice-President, Research and Population Health, Canadian Institute for Health Information
Bill Leslie (Co-chair)	Senior Advisor, Bureau of Licensed Products, Therapeutic Products Directorate, Health Products and Foods Branch, Health Canada
Michele Brennan	Quality Improvement Manager, Whitehorse General Hospital
Elizabeth Carlton	Senior Advisor, Legislation and Policy, Ontario Hospital Association
Hanif Chatur	Family Medicine resident, and Vice-President, Provincial Association of Internes and Residents - British Columbia (PAIR-BC)
Mary Ferguson-Pare	Vice-President, Nursing Services, University Health Network
Paula Hextall	Risk Manager, Regina Health District
Carol Kelly	Director, Insurance, Quebec Hospital Association
Anne McGuire	CEO, Annapolis Valley District Health Authority
Denis Morrice	President and CEO, The Arthritis Society (from February 2002)
Melanie Rantucci	Board member, Canadian Pharmacists Association
Mark Taylor	Deputy Head, Department of Surgery, St. Boniface General Hospital and University of Manitoba

Terms of reference:

To examine how improved communication among various players in the health-care system, including patients and the public, and across jurisdictions, can enhance the quality of patient safety.

External consultations:

Canadian Medical Association
Canadian Nurses Association
Canadian Healthcare Association
College of Family Physicians of Canada
Canadian Pharmacists Association
Canadian Society of Hospital Pharmacists

Ron Browne	CEO, Whitehorse General Hospital
John Gray	Executive Director, Canadian Medical Protective Association
Linda Hamilton	Manager, Professional Practice and Policy, College of Registered Nurses of Nova Scotia
Carolyn Moore	Executive Director, College of Registered Nurses of Nova Scotia
Supriya S. Sharma	Director, Marketed Biologicals and Biotechnology Products Division, Marketed Health Products Directorate, Health Canada.
Galt Wilson	Chair, Ethics Committee, College of Physicians and Surgeons of British Columbia
Lisa Crawford	Manager, Community Development, The Arthritis Society

Working Group on System Issues
Working Group on Regulatory/Legal Issues
Working Group on Measurement/Evaluation
Working Group on Education/Professional Development

Appendix B

ADMINISTRATIVE GROUP — PATIENT SAFETY

Dr. Michel Brazeau
Chief Executive Officer
The Royal College of Physicians and Surgeons of Canada

Mr. Glenn Brimacombe
Chief Executive Officer
Association of Canadian Academic Healthcare Organizations

Dr. John Gray
Executive Director and Chief Executive Officer
Canadian Medical Protective Association

Dr. Calvin Gutkin
Executive Director and Chief Executive Officer
College of Family Physicians of Canada

Ms. Elma Heidemann
Executive Director
Canadian Council on Health Services Accreditation

Mr. Jeff Poston
Executive Director
Canadian Pharmacists Association

Mr. Ian Shugart
Assistant Deputy Minister
Health Policy and Communications Branch
Health Canada

Mr. William Tholl
Secretary General and Chief Executive Officer
Canadian Medical Association

Terms of Reference:
To ensure appropriate and effective administrative support for the activities of the Steering Committee and five working groups. This will include management of the financial operations, provision of resources, the preparation of documents and reports, co-ordination and communication. The Administrative Group will report to the participating organizations. The group will not intervene in the activities of the Steering Committee or those of the working groups. The mandate of the Administrative Group will terminate with the activities of the National Steering Committee on Patient Safety on September 28, 2002.

Appendix C

PARTICIPATING ORGANIZATIONS AT THE 2001 CLOSED ROUNDTABLE ON PATIENT SAFETY

September 22nd, 2001

Federal Government
Health Canada

Provincial Governments
Alberta
Saskatchewan
Ontario
Québec
Nova Scotia

Territorial Governments
Northwest Territories
Nunavut

Health-care Organizations
Association of Canadian Academic Healthcare Organizations
Association of Canadian Medical Colleges
Canadian Association of Emergency Physicians
Canadian Association of Internes and Residents
Canadian College of Health Service Executives
Canadian Coordinating Office for Health Technology Assessment
Canadian Council on Health Services Accreditation
Canadian Healthcare Association
Canadian Institute for Health Information
Canadian Medical Association
Canadian Medical Protective Association
Canadian Nurses Association
Canadian Pharmacists Association
Canadian Society of Hospital Pharmacists
College of Family Physicians of Canada
College of Physicians and Surgeons of Alberta
College of Physicians and Surgeons of Manitoba
College of Physicians and Surgeons of New Brunswick
College of Physicians and Surgeons of Nova Scotia
College of Physicians and Surgeons of Saskatchewan
CQI Network
Federation of Medical Licensing Authorities of Canada
Institute for Clinical Evaluative Sciences
Institute for Safe Medication Practices Canada
Medical Council of Canada
The Royal College of Physicians and Surgeons of Canada

Appendix D

DRAFT MINI-GLOSSARY OF PATIENT-SAFETY TERMS
(For discussion purposes)

Defining terms related to patient safety is a significant challenge as different individuals, professions, organizations and cultures have assigned their own interpretations to the various words. However, developing a shared, comprehensive understanding of nomenclature is essential for co-ordinating effective local, regional and national activities in the area of patient safety. There is obviously not one right way to define these terms, but the following definitions attempt to capture the key aspects for a common understanding.

Terms are arranged alphabetically in the mini-glossary. In addition, each term is proceeded by an **'S*P*O'** icon, which relates each term to the "Structure, Process and/or Outcome" format, according to which letter(s) is/are bolded. (This format captures where, in the schema of events, attention needs to be directed for an understanding and correction of the problem.)

S*P*O

Active Failures

Actions or processes during the provision of direct patient care that fail to achieve their expected aims, for example, errors of omission or commission. While some active failures may contribute to patient injury, not all do.

S*P*O

Adverse Drug Reactions

Serious, undesired and/or unexpected reactions to a drug.

S*P*O

Adverse Effects (AEs)

Interchangeable with 'side effects', adverse effects result from drug treatment. AEs are the drug's secondary effects that are not intended for the patient. However, sometimes clinicians will use some or all of these known side effects to help in the treatment of a patient.

S*P*O

Adverse Event

Injury related to health-care management, rather than to an underlying disease process. An adverse event is an unplanned and undesired harmful occurrence, directly associated with care or services provided to a patient/client, such as an adverse reaction to a medication or a negative outcome of treatment. The occurrence may result from acts of commission (e.g., administration of the wrong medication) or omission (e.g., failure to institute the appropriate therapeutic intervention) and is related to problems in practice, products, procedures, and other aspects of the system.

S*P*O

Cause

An antecedent factor that contributes to an event, effect, result or outcome. A cause may be proximate in that it immediately precedes the outcome, such as an action. A cause may also be remote, such as an underlying structural factor that influences the action, thus contributing to the outcome. Outcomes never have single causes.

S*P*O

Close Call *(see also Near-miss)*

A situation in which the patient had a narrow escape from a serious complication.

S*P*O

Complication

A disease or injury consequent to another disease or injury and/or health-care intervention.

S*P*O

Contributing Factor *(interchangeable with Contributory Factor)*

An antecedent factor to an event, effect, result or outcome similar to a cause. A contributory factor may represent an active failure or a reason an active failure occurred, such as a situational factor or a latent condition that played a role in the genesis of the outcome.

S*P*O

Critical Incident

A type of incident in health care that involves the significant risk of loss of life, limb, or function. Critical incidents are considered 'critical' as they signal the need for immediate investigation and response, not only because of the potential or actual outcome for the patient, but also because of perceived problems with the process and underlying structure of care.

S*P*O

Error *(see also Unsafe Acts)*

Something that is or is not done, which is not intended, but which does not involve the breaking of a 'rule'. Human error can never be completely prevented, but many errors can be avoided, or trapped as they are made, or their effects can be treated and so mitigated.

S*P*O

Hazard

The major way in which death, injury or damage can occur. Hazards may be classified according to the amount of damage they may inflict (none, mild, moderate, severe) and by how frequently they may be encountered (never, rarely, sometimes, often).

S*P*O

Human Factors Engineering

A branch of engineering that specializes in designing efficient, human centred processes to improve reliability and safety.

S*P*O

Incident

An occurrence in which there is a problem with the process of care. If the incident leads to any harm, then the related injuries or complications may or may not be serious. If serious, the incident is 'critical.'

S*P*O

Lapse

A type of error that generally involves a failure of memory.

S*P*O

Latent Condition

The structural flaws in the system that contribute to error-producing factors.

S*P*O

Medical Error

A type of error that occurs in the context of the provision of health care.

S*P*O

Mistake

A type of error in which there is a failure with the mental processes involved in assessing information, developing plans, and judging the likely consequences of a planned action.

S*P*O

Multidisciplinary Case Review

An open discussion by the health-care team to identify the root causes of a critical incident and strategies to prevent a similar occurrence in the future. The proceedings are facilitated by trained personnel within a quality-improvement framework and opinions expressed during the course of the review are confidential.

S*P*O

Near Miss *(see also Close call)*

A situation in which the patient had a narrow escape from a serious complication.

S*P*O

Outcome

A product, result or effect. In health care, outcomes may be measured in a variety of ways, but tend to reflect the physical and psychological well-being of the patient, and associated costs.

S*P*O

Patient Safety

The state of continually working toward the avoidance, management and treatment of unsafe acts within the health-care system.

S*P*O

Preventable

A process or an outcome that is predictable, foreseeable, and capable of being forestalled. Not all incidents or adverse events are preventable, although the threshold of preventability changes with time and effort and is determined by the overall structure of the system.

S*P*O

Process

A course of action or proceeding, including what is done and how it is done. Examples of these interrelated activities within the health-care system include communication, problem-solving, decision-making, and conflict resolution.

S*P*O

Risk

The probability of danger, loss or injury within the health-care system.

S*P*O

Risk Management

Organizational activities designed to prevent patient injury or moderate the actual financial or organizational losses following an adverse event.

S*P*O

Root-Cause Analysis

A technique of systematic investigation of a critical incident to determine the contributing factors. The analysis focuses on identifying the latent conditions that underlie variation in performance and on developing recommendations for improvements to decrease the likelihood of a recurrence.

S*P*O

Slip

A type of error that relates to observable actions. A slip is commonly associated with a failure of attention or perception.

SP*O

Structure

The supporting framework or essential parts and includes all elements of the health-care system that exist before any actions or activities take place.

S*P*O

Unsafe Acts

An error represents something that is or is not done, which is not intended, but which does not involve the breaking of a 'rule'. There are three types of errors: lapses, mistakes, and slips. A violation represents the intentional breaking of a rule or the intentional deviation from safe operating procedures or standards; violations can be positive, if used, for example, to prevent harm to a patient. Sabotage is a malevolent act with the intent of causing harm or damage.

S*P*O

System

Represents a set of interdependent elements interacting to achieve a common aim. Within the system there are components that can be classified in various ways, such as socio-geographic factors: national, provincial, organizational / institutional, health-care provider, and patient / client / family. Although the term is used to indicate both the entirety of health care and the smaller components, ideally 'system' should be reserved for use when describing the former. Alternatively, a modifier should be used to ensure clear understanding of the term, e.g., surveillance system.

Other Terms:

In addition, certain terms carry both a dictionary definition and specific societal values, which may or may not agree. For this reason, we recommend that the following terms generally not be used when discussing patient safety.

Accident

An occurrence that results in death or injury to one or more individuals and/or damage to equipment / facilities. However, the term carries the connotation that the event proceeded from some unknown cause, without foresight or expectation. This assumed link with the concept of 'bad luck' is the reason the term should not be used.

Blame

Assigning of culpability to one or more individuals after an error or adverse event. However, assigning blame does not recognize the complexity of the health-care system and the impact of latent conditions on the events in question. Furthermore, the result of assigning blame is personal shame, which, in the context of making errors, may contribute to a culture of fear of reprisal.

Fault

Denotes a wanting in moral character or a blameable imperfection. Fault often carries the pejorative connotation of blame or responsibility. For this reason, it is better not to use the word when referring to the actions of individuals in the context of patient-safety activities.

Negligence

Want of attention to what ought to be looked after; carelessness, disregard, or lack of ordinary care. However, negligence also carries a legal definition and an individual's actions can only be determined to be negligent by a court of law if they meet four specific requirements. Thus, this word should not be used when describing the actions of health-care providers, unless those actions have been determined to be negligent by the courts.

Recklessness

To act without regard for the consequences or danger, to act rashly or carelessly. The term reckless or recklessness is applicable to a health-care professional only within very narrow circumstances, such as professional regulatory reviews or other legal proceedings. Unfortunately, many individuals are tempted to use the term to explain or attribute blame following an adverse event. This term also should be reserved for the courts and / or professional regulatory proceedings.

Appendix E

THE FRAMEWORK MATRIX: SYSTEM ISSUES WORKING GROUP

	STRUCTURE →	PROCESS →	OUTCOME
Socio-geographic COMPONENTS	**Rules & regulations** **Policy & procedures** (including methods of proactive and reactive evaluation of the system) **Administration** (including management authority) **Funding** **Culture** (including static and dynamic aspects) **Environment** (including sites, space, ventilation, light, heat, ergonomics) **Equipment** (including number, design, maintenance, availability, spare parts, consumables) **Personnel / Staffing** - Individuals (including numbers, training, experience, competence) - Teams (including composition, standard and emergency operating procedures) **Population/Patients/Clients/Families** (including numbers, sex, culture, characteristics)	**Tasks performed** **Specific methods** followed (including treatment spectrum; communication; problem-solving; decision-making; conflict resolution; reporting where possible of errors, near misses, occasions where someone 'saved the day'; and disclosure to patients/clients/families, staff and relevant authorities of these events)	**Positive/negative final results** (including death, disease, disability, discomfort, dissatisfaction and dollars), with disclosure to patients / clients / families, staff and relevant authorities of these outcomes **On-going systematic audit & evaluation** of outcome, relating back to structural and procedural indicators and to both internal and external benchmarks (including self-evaluation and peer review of individuals and team debriefing and evaluation) **Episodic reporting & investigation** of adverse outcomes **Development & implementation of recommendations** for improvement **Feedback** to involved parties **On-going review**
Federal			
Provincial/ Territorial	Please see examples on next page		
Organizational/ Institutional			
Personnel			
Patients			

Example: Application of the Patient Safety Matrix to the proactive review of drug safety

The following is an example of how the matrix might apply in practice to the proactive review of drug safety at the federal / provincial / territorial levels; at organizational / institutional levels, as well as at the levels of the patient / doctor / nurse / pharmacist. The safety of a drug relates to adverse drug events, of which there are two types: non- preventable and potentially preventable. Non- preventable ADEs are serious, undesired and/ or unexpected reactions to a drug. They are non- preventable and are known as Adverse Drug Reactions (or ADRs).

These include toxic or allergic reactions in patients without apparent risk factors. Potentially preventable ADEs result from medication errors that lead to patient harm. Not all medication errors cause harm (because of error trapping and mitigation). When they do, they are related to unsafe acts and to latent conditions in the system, and are potentially preventable through system improvement.

	STRUCTURE →	PROCESS →	OUTCOME
Federal / Provincial/ Territorial levels	**REVIEW**	**CONSIDER**	**EVALUATE**
	Policies & procedures - drug licensing - drug marketing drug prescribing - follow-up - alerts (professional, public) - drug recall **Drug** pharmacological characteristics - name (chemical, generic, trade) - appearance, labelling and packaging indications - contra indications adverse drug events (type, severity, frequency, duration) - warnings - storage (e.g., refrigeration) - administration characteristics (dosing, route, equipment, timing) **Information about drug** regulatory agencies (Canada, USA, Europe, Australasia) - pharmaceutical companies - adverse drug event / outcome - reporting agencies (Canada, USA) **Information about population** numbers - ages - sex - cultural factors Co-morbidities (e.g., pregnancy) - allergies - historical & current drug use	**Marketing activities** - pharmaceutical organizations (e.g., detail pharmaceutical representatives, media and advertising agents) - special interest groups (e.g., Arthritis Society) **Prescribing activities** different medical specialties - other licensed prescribers (dentists, chiropractors, etc) **Dispensing activities** - by pharmacists **Drug-acquiring activities by patients** - from pharmacies from other sources, including illegal internet shopping **Potential drug errors** - prescribing phase - interpreting phase - dispensing phase administering/taking phase - monitoring phase	**Results** - Outcome #1 – therapeutic effect of treatment **Safety** - Outcome #2 undesirable results of treatment or Adverse Drug Events **Costs** Outcome #3 – cost of treatment, including costs of side effects
Organizational / Institutional levels	**REVIEW**	**CONSIDER**	**EVALUATE POTENTIAL OUTCOMES**
	Reviewers - Pharmacy & Therapeutics (P & T) Committee Specialty Departments (e.g., Anesthesia, Infectious Diseases) - Pharmacy & Nursing Liaison Committee - MAC **Drug** - pharmacological characteristics name (chemical, generic, trade) - appearance, labeling & packaging - indications - contra indications adverse drug events (type, severity, frequency, duration) - warnings - storage (e.g., refrigeration) - administration characteristics (dosing, route, equipment, timing) **Patient** numbers - ages - sex - cultural factors co-morbidities, including pregnancy - allergies - other drugs	**Drug safety** - perform Failure Mode Effect Analysis (FMEA) on new drug to be considered as formulary items **Potential drug errors** prescribing phase - interpreting phase - dispensing phase - administering/taking phase monitoring phase	**Results** - Outcome #1 therapeutic effect of treatment **Safety** Outcome #2 undesirable results of treatment or adverse drug events **Costs** - Outcome #3 – cost of treatment, including costs of side effects **Drug removed from formulary** - cost savings - alerts to prescribers about lack of drug availability changes to computerized drug order sets - alerts to specific patients about lack of drug availability (as needed) **New drug added to formulary** - costs - alerts to prescribers about new drug availability changes to computerized drug order sets - alerts to specific patients about new drug availability (as needed)

Personnel (doctor / nurse / pharmacist) and patient levels	REVIEW	CONSIDER	EVALUATE POTENTIAL OUTCOMES
	Patient - age - sex - cultural factors - co morbidities, including pregnancy allergies - other drugs **Drug** - pharmacological characteristics - name (chemical, generic, trade) labeling & packaging - indications - contra indications - adverse drug events (type, severity, frequency, duration) - warnings - storage (e.g., need for refrigeration) - administration characteristics (dosing, route, equipment, timing) **Drug information sources** - health care professional (MD, Pharmacist, RN, other) non-professional (family, friend, colleague) - internet, library - disease association other	**Indication** - on-label - off-label **Administration characteristics** - dosing route equipment - timing **Potential drug errors** - prescribing phase - interpreting phase dispensing phase - administering/taking phase - monitoring phase	**Results** Outcome #1 – therapeutic effect of treatment (condition for which drug is prescribed: improved, no change, worsened) **Safety** - Outcome #2 – undesirable results of treatment or adverse drug events (delineate, treat, record, report) **Costs** - Outcome #3 – cost of treatment, including costs of side effects **Drug disposition** - Outcome #4 continue taking versus discontinue drug

Example: Application of the Patient Safety Matrix to the reactive review of a single adverse outcome – death of a patient

The following is an example of how the matrix might apply in practice to the reactive review of the death of a patient. Investigation shows that the patient's death was related to a medication error. Underlying contributory factors included similar labeling of the two drugs involved, as well as problems with drug storage. Recommendations from the investigation included the development and implementation of guidelines, to decrease the probability of a recurrence of the same or similar events.

	STRUCTURE →	PROCESS →	OUTCOME
Reactive loop	N/A ←	N/A/ ←	**Patient dies**
	Mechanism for notification of family defined in Policies and Procedures ←	**Task:** notification of family ← **Methods:** as detailed in Policies and procedures (includes facts about immediate pre-morbid events and plan for investigation)	**Family notified**
	Mechanism for filing of report of death ← defined in Policies and Procedures, including notification of Administration	**Task:** file reports of death with ← relevant committees / parties **Methods:** includes alerting them for follow-up report on investigation of death	**Report of death filed** (Coroner / Medical Examiner, institutional / organizational death review committee, provincial / national death database)
	Mechanism for the investigation of death ← defined in Policies and Procedures	**Task:** investigation of death ← **Methods:** review of Process for presence of unsafe acts, review of Structure for presence / contribution of latent conditions	**Death investigated** (Results of review: intravenous bolus epinephrine in error, contributing to MI, leading to death; epi label similar to glycopyrrolate; drug in wrong drawer; anesthesiologist alone) **Report of investigation results** disseminated (to family, institutional/organizational/provincial/ national health-care safety organization / agencies
	Mechanism for dissemination of investigation report defined in Policies and Procedures, including acceptance of responsibility for follow-up by Administration ←	**Task:** dissemination of ← investigation results **Methods:** special safety alert to all disciplines internally / external independent safety organization, as well as government drug safety monitoring agencies; patient-safety bulletin newsletters	
	Task Force for development and implementation of improvements, including new policies/procedures and guidelines, and on-going surveillance against recurrence defined in Policies and Procedures, including timeline for response by appropriate individuals / departments/ institutions / organizations / provinces / geographic regions / federal agencies ←	**Task:** development and ← implementation of improvements, including new guidelines and on-going surveillance against recurrence, including rewriting of Policies & Procedures, where necessary **Methods:** steps to ensure inclusion of internal and external expertise	**Development and implementation of recommendations for improvements**

Appendix F

WORKING GROUP ON INFORMATION / COMMUNICATION
Action Plan

Goals	Messages/Actions	Product(s)	Target Audience(s)	Partners/ Lead Agencies	Dissemination (Role of I.T.)
1. **Communicate** with the Canadian public, health–care personnel, health institutions/ organizations, regulatory bodies **as to realistic expectations of the risks and benefits inherent in the health-care system**	• Statement of problem/issue and why addressing it now • Meta-analysis of existing data/information (literature review) on medical errors • Characterize patient safety as systems issue and identify barriers to and opportunities for change • Overview of initiatives to promote safety in other jurisdictions (i.e. who's doing what?) • Estimate of incidence of adverse events in Canada and discussion of existing efforts to ensure patient safety • Outline proposed strategies to enhance patient safety in Canada and identify opportunities for stakeholders to work collaboratively • Invite commentary from readers and suggestions for ways to improve system	• National Report on Patient Safety (nature of Backgrounder or Discussion Paper)	• Public • Health-care personnel[1] • Regulatory colleges • Health organizations/ facilities	• CIHR • Health Canada (pursuant to mandate of health promotion and health protection) • Consumer groups	• Published by partners • Publicly available on-line • Widely disseminated
2. **Communicate** with the public **as to personal measures** they can adopt to reduce the potential for problems with the provision of care and any resultant adverse outcomes	• Statement of problem • Identify current methods to reduce adverse events and promote patient safety • Outline rights and responsibilities of patients in the health-care setting • Highlight known methods of reducing risk and encourage patients to take an active role in their care • Customize for specific patient populations • Invite commentary from readers/suggestions for ways to improve system	• Pamphlet • Public Service Announcement (PSA)	• Public	• Health Canada (under mandate of health promotion) • Provincial/territorial ministries of health • Consumer groups	• Availability to public in physician offices, hospitals, LTC facilities and community agencies • Dissemination to patient rights' organizations and patient advocacy groups • Distribution to disease-specific advocacy organizations • Availability on-line
3. **Communicate** with the Canadian public and health-care personnel **strategies to improve the safety of health care** in various health-care settings	• Data must be gathered on all near misses and incidents and their outcomes and contributory factors (where apparent) in all health-care settings from large institutions to patient's home. • Data gathered (in 1st bullet) must be analysed for contributing factors including environmental, technical, personal, etc. • Data gathered and analyzed must be communicated to all levels of the health-care system and to all settings with recommendations on changes that should be instituted to prevent adverse events. • Government regulators and health professional regulatory bodies to consider information (in 3rd bullet) to determine if regulatory interventions are needed or to issue standards of practice and cautions • All institutions and individual health-care personnel have responsibility for being aware of above information and acting on recommended changes. • Producers of health-care products identified in data (in 1st bullet) need to be informed that products can contribute to errors and changes may be recommended • Communication mechanisms must be established so that patient data is transferred between settings in a timely and efficient manner, while recognizing need for assurance of patient confidentiality • Invite commentary from readers and suggestions for ways to improve system	1. National database of all near misses and incidents and their outcomes and causes (where apparent) in all health-care settings from large institutions to patient's home. 2. Research conducted by national database organizers with input from a research advisory committee to identify research goals. 3. Regular reports of data, analysis and recommendations 4. Regulations or standards of practices 5. Include requirement in regulations/ standards of practice that institutions and individual health-care personnel have responsibility for being aware of above information and acting on recommended changes. 6. Reports developed (in no. 3) that involve health-care products to be distributed to producers. 7. Seamless care framework that outlines mechanisms and policies to ensure patient data is shared across all health-care settings; communication mechanisms including paper and electronic where possible	1, 2 & 3 - To be accessed for input and reporting by national and provincial organizations and governments, professional organizations, institutions, teams of health-care personnel and patients 4 & 5- National and provincial organizations and governments, professional organizations, institutions, teams of health-care personnel and patients 5 & 6 - Health-care product producers, e.g. pharmaceutical industry 5 & 6 - Health-care personnel and institutions and organizations, e.g. hospitals, clinics, individual practitioners	1. National and provincial governments and health professional organizations (associations and/or colleges), CIHI 2. Health research centres e.g. ICES, universities 3. Educational institutions for undergraduate and graduate programs 4. Governments and health professional regulatory bodies 5. Input from representatives of health-care product producers 6. Professional and institutional regulators and organizations and patient groups, e.g. consumer associations	• Publications (journals, newsletters) and websites of partners and lead agencies (National and provincial governments and health professional organizations, CIHI, CMPA) • Reports developed and sent by mail directly to producers. • Electronic communication means preferably, and paper documents where necessary, Smart Cards (carried by patient)

[1] Definition of health-care personnel: includes, but is not limited to, physicians, nurses, pharmacists, and other medical and support personnel involved in the delivery of health care.

4. **Communicate** with local, regional, provincial, territorial, national organizations, and educational and regulatory bodies' **about best practices** with respect to the management of the best provision of care, including the management of adverse events (through avoiding, trapping and treating)	• Develop standards, data bank/clearing house of good/best practice approaches to patient safety and reduction of adverse events • Concept of good/best practice needs to be imbedded in accreditation standards (CCHSA, RCPSC, etc.) • Best practice is interdisciplinary, team oriented, and collaborative • Encourage appropriate research to develop standards where they don't exist • Invite commentary from readers and suggestions for ways to improve system	1. Questionnaire (survey re best practice, novel approaches in order to begin to build data bank) 2. Possible creation of link/ collaboration with Cochrane Library 3. Creation of website (e.g. – hosted by CHA), staffed and resourced 4. Joint statement development by medical/legal/ insurer groups	1. Professional associations, regulatory bodies 2. Schools: medicine/allied health 3. Accrediting bodies 4. Barristers' societies/insurers (discussion of "no fault" approach)	1. Health science centres/educational institutions 2. CIHI 3. National health research agencies (e.g. CIHR) 4. Professional and regulatory bodies	• Need discussion/debate on timing of public dissemination until database/consensus initiatives well underway
5. **Develop strategies to** guide health-care personnel, institutions/ organizations, provinces and jurisdictions to **improve communication and information sharing** to reduce the potential for adverse events	1. Recommend that HC teams be included in educational and clinical forums such as morbid/mortality rounds, CE, etc. 2. Develop culture of learning and sharing through shared educational opportunities as above 3. Encourage sharing of patient data through secure means 4. Clarify that all health-care personnel have patient confidentiality as part of their professional codes and ensure that it is maintained 5. Standard formats for electronic exchange of information must be developed and supported by health-care personnel groups and computer software developers	1 & 2 - Communiqué to institutions and CE providers, health-care personnel associations, pharmaceutical companies, educational institutions 3 - Develop guidelines for inter-professional communication 4 & 5 - Include in guidelines in number 3	1 & 2 - Institutions and CE providers, health-care personnel associations, pharmaceutical companies, educational institutions 3, 4 & 5 – Health professionals, health-care personnel associations 4 - Governments developing privacy legislation 5 - Electronic communication developers, software developers	1. Educational institutions 3. CMPA	• Mail, journals, articles, conferences
6. **Develop standards, guidelines and policies in relation to appropriate disclosure** of adverse outcomes and any contributory factors within the health-care system, and **communicate this with the Canadian public,** health-care personnel, regulatory authorities and the legal profession	• Develop policy guidelines on disclosure of adverse events including policy on responsibility and disclosure • Include national standards on adverse-event recognition/reporting in policy guidelines in previous bullet • Include national and/or institutional standard on debriefing members of HC team of an adverse event (in policy guidelines in first bullet)	• Policy guideline booklet • Plan for full disclosure in accreditation standards	• Health-care personnel managers	• Health-care personnel and regulatory authorities • CCAPP • CCHSA • CMPA	
7. Develop strategies to **facilitate communications** among health-care personnel **when adverse events occur,** and with patients and families when a patient suffers an adverse outcome	• Include in all health-care personnel curriculum training on how to recognize, record, report and disclose adverse events. What is appropriate when an adverse event has occurred? • Develop national guidelines on adverse events communication that includes health-care teams and patients • Develop national guidelines to clarify a pro-reporting, no-fault process for health-care team personnel involved in adverse events • Provide information on safeguards to limit litigation, e.g. regarding recording of events • Develop scenarios for health-care personnel to use in training programs	• Develop curriculum objectives and send to all health-care personnel faculties and training facilities • Guidelines on adverse-event communication and a brochure detailing them • Guidelines and brochure detailing pro-reporting, no-fault process for health-care team personnel involved in adverse events • Include scenarios for health-care personnel to be used in training programs and include them in communication guidelines and brochures mentioned in previous two bullets	• Health-care personnel, educators • All health-care personnel and regulatory bodies • Regulatory bodies, employers, institutions and ultimately health-care personnel	• Health-care personnel, educators, organizations, e.g. Association of Faculties of Pharmacy in Canada (AFPC) • Health-care personnel, associations involved in CE • Regulatory bodies • Health-care personnel, associations and regulatory bodies	• Through partners and directly to educational institutions • Regulatory bodies, directly to health-care personnel conference programs • Health-care personnel and associations, regulatory bodies, directly to health-care personnel

Appendix G

NATIONAL / INTERNATIONAL SUMMARY OF KEY INITIATIVES IN PATIENT SAFETY

National

Health Canada

Health Canada is responsible for funding the research of the Canadian Institutes of Health Research[1] (CIHR) and the Canadian Institute for Health Information[2] (CIHI) and other studies related to patient safety. For example, Health Canada recently awarded a contract to review the feasibility of establishing a national incident-tracking and reporting system for medications. Health Canada has also recently sponsored a national survey to gather information on the prevention of 'error' in health-care delivery and the extent to which organizations are reporting and addressing incidents.

The Canadian Institutes of Health Research and the Canadian Institute for Health Information

CIHR and CIHI have awarded a jointly funded research study to examine the extent of adverse events in Canadian acute-care hospitals and the availability of data that could be used to support continuing monitoring to reduce these events. The results of this study, the first of its kind in Canada, are expected to be released to the public in 2004.

Canadian Council on Health Services Accreditation (CCHSA)

The CCHSA is a national, independent, non-profit organization whose role is to objectively review the care and quality of services provided by a specific health-care organization. The CCHSA surveyors compare the findings obtained within the accreditation process to national standards. The assessment deals with all forms of risk that may occur within a health-care organization, but most particularly with clinical risk. Requirements for the measurement and management of risk may be found within the national accreditation standards. CCHSA is participating in national collaboratives on patient safety/error and is considering modifying the standards to reflect a greater focus on these issues.

Canadian Coalition on Medication Incident Reporting and Prevention (CCMIRP)

In the fall of 2000, an invitational workshop was co-hosted by the Canadian Society of Hospital Pharmacists (CSHP) and Health Canada's Bureau of Licensed Product Assessment (BLPA) to address a number of key questions related to medication incident reporting and prevention. One of the outcomes of the workshop was the recommendation to establish a coalition of stakeholders - Canadian Coalition on Medication Incident Reporting and Prevention (CCMIRP). The Coalition was formed in February 2001 with the mandate to develop options, in the form of a business plan, for a comprehensive, viable,

[1] The Canadian Institutes of Health Research (CIHR) is Canada's premier federal agency for health research. Its objective is the creation of knowledge and its translation into improved health for Canadians, more effective health services and products, and a strengthened Canadian health-care system.

[2] The Canadian Institute for Health Information (CIHI) is an independent, non-profit organization that provides accurate and timely information needed to develop health policies, manage the Canadian health system effectively and create public awareness of the factors affecting good health.

sustainable and affordable medication-incident reporting and prevention system for Canadians. The desired outcome is a program that manages the risks inherent in medication use and moves toward a goal of risk prevention. Members of the Coalition include representatives from consumers, medicine, nursing, pharmacy, healthcare associations, information management, governments, and the pharmaceutical industry.

Sierra Systems Inc. was selected through a Request for Proposal process to assist with development of the report. Consultations with over 50 national and international stakeholders were undertaken during the development of the report. The report was released to Coalition members and external stakeholders on July 24, 2002. A copy is available.

Canadian Healthcare Association (CHA)

The CHA is a federation of provincial and territorial hospital and health organizations across Canada. Through its members, it represents a broad continuum of care, including acute care, home and community care, long-term care, public health, mental health, palliative care, addiction services, children, youth and family services, housing services, and professional and licensing bodies. The organization is a recognized national leader in advocating for a coordinated and effective response to "medical errors".

The CHA has initially identified the following categories of system issues (a more comprehensive policy brief to be issued in the near future):

- Cultural Barriers (promoting a "culture of safety" that encourages openness and objective analysis of error)
- Adoption of a "Systems" Approach (recognizing that most errors occur as a result of a sequence of failures in the complex processes of care)
- Reports of error (need to develop and implement comprehensive reporting standards and enforcement mechanisms related to 'medical errors')
- Governance and Leadership (a co-ordinated and effective response to medical errors in Canada is required)

The Institute for Safe Medication Practices (ISMP Canada)

The Institute for Safe Medication Practices (ISMP Canada) is an independent Canadian non-profit agency established for the collection and analysis of 'medication error' reports and the development of recommendations for the enhancement of patient safety. Like its sister organization, the ISMP in the US, ISMP Canada strives to promote safe-medication practices throughout health care communities in the country.

Specific goals include:

- To review medication errors submitted by practitioners to ISMP Canada and to make recommendations to reduce the probability that such errors will happen again
- To publish and disseminate information to the health-care community and its practitioners through efficient electronic means in order to promote safe medication use and strategies for reduction of error-induced injury
- To participate in co-operative programs with professional organizations in Canada in providing education about adverse drug events and their prevention
- To act as consultants to institutions and other health-care settings on medication use
- To develop educational and quality-improvement assessment tools for health-care professionals and institutions
- To establish and maintain a strong partnership with ISMP in the US, and the other national and provincial patient-safety organizations
- To provide educational programs for university and health-professional constituents

ISMP Canada has a variety of instruments for improving patient safety, including:

- Distribution of the ISMP Newsletter (provides alerts on identified drug errors such as those related to labelling and packaging problems)
- A Medication Safety Self-Assessment (a tool designed to help organizations self-

assess the safety of medication practices, identify opportunities for improvement, and compare the results with the aggregate experience of demographically-similar hospitals)
- A medication-error reporting and analysis software program (Analyse-err). The two components to the program are an objective factual reporting section and a root-causes analysis exercise (in use at several Canadian hospitals)

Further information may be obtained from the ISMP Web Site: http://www.ismp-canada.org

International

UNITED STATES

The Institute of Medicine Report (IOM)

The impetus for the United States to focus its attention on preventable medical errors began with the release of *To Err is Human: Building a Safer Health System* in 1999 - a report by the Institute of Medicine.

The IOM is a private, non-governmental organization created to advise the US federal government on scientific and technical matters. It reviewed major US studies of adverse events and medication errors, and from this analysis, estimated that between 44,000 and 98,000 people die in hospitals each year as a result of medical errors in that country. Even using the lower estimate would make medical errors the eighth leading cause of death in the US — above motor-vehicle accidents, breast cancer and AIDS. The study estimated that about 7,000 people per year die from medication errors alone. The report suggested a variety of strategies to improve patient safety, including implementation of safer medication-use systems and a national reporting system for medical errors.

Three months after the publication of the IOM report, an interagency federal government group, the Quality Interagency Coordination Task Force (QuIC) released its response, *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact*. This report, requested by the American President, provides an inventory of on-going federal actions to reduce adverse medical events and recommendations for more than 100 actions to be undertaken by federal agencies.

In January 2001, the Agency for Healthcare Research and Quality (AHRQ) commissioned the Stanford University Evidence-Based Practice Centre to review scientific literature regarding safety improvement. The report, *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*, provides an extensive appraisal of the evidence on best safety practices for the delivery of health care.

In March 2001, the IOM released a second and final report, *Crossing the Quality Chasm: A New Health System for the 21st* Century. This report, building on the IOM's first report, provides bold recommendations to redesign the American health-care system, including specific direction for policy makers, health-care leaders, clinicians, regulators, purchasers and others. This comprehensive report includes:

- A set of performance expectations for the 21st century health-care system
- A set of 10 new rules to guide patient-clinician relationships
- An organizational framework to better align payment and accountability with quality improvements
- Key steps to promote evidence-based practice and strengthen clinical-information systems

The latest IOM report recognizes that health care is a complex system; IOM identifies practices that impeded quality care and explores how system approaches can be used to implement change.

Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

The Joint Commission evaluates and accredits nearly 18,000 health-care organizations and programs in the United States. An independent, not-for-profit organization, JCAHO is the predominant standard-setting and accrediting body for health care in the United States. Since 1951, JCAHO has developed state-of-the-art, professionally-based standards and evaluated the compliance of health-care organizations against these benchmarks. Their mission is to continuously improve the safety and quality of care provided to the public

through the provision of health-care accreditation and related services that support performance improvement in health-care organizations.

This organization undertook root-cause analysis in 64 cases of surgical and post-operative adverse events and identified the following 8 root causes:

- Poor communications among caregivers
- Failure to follow established procedure
- Necessary personnel not available when needed
- Pre-op assessment incomplete
- Deficiencies in credentialing and privileging
- Inadequate supervision of house staff
- Inconsistent post-op monitoring procedures
- Failure to question inappropriate orders.

The National Patient Safety Foundation (NPSF)

The NPSF seeks to be a catalyst and a force for improving patient safety. They have four primary objectives within this process:

- Raise awareness
- Build a knowledge base
- Create a forum for sharing knowledge
- Facilitate the implementation of practices that improve patient safety

Over the past several years, NPSF has become known for its work in facilitating dialogue and co-operation on patient-safety issues; work on building a knowledge base has proceeded in full force. An example is the NPSF Clearinghouse, which aims to grow into the most comprehensive collection of patient-safety literature in the world. The Foundation also strives to develop the patient's role in improving safety in health care.

Further details may be found at the web site: *http://www.npsf.org*

Institute for Healthcare Improvement (IHI)

The Institute for Healthcare Improvement is a non-profit organization that supports integrative and collaborative efforts to improve health-care systems in the United States and Canada. IHI has produced a series of documents titled the *Breakthrough Series*, with each publication focusing on improvement in a single area of health care. For each document, 20 to 40 health organizations are brought together to study the latest information on improving a special clinical or operational area and to learn effective means to apply that information for rapid improvement. This guide includes IHI's well-recognized Plan-Do-Study-Act (PDSA) model for accelerating improvement and a step-by-step guide for reducing ADEs while addressing the barriers to change.

Further details may be found at the web site: *http://www.ihi.org*

UNITED KINGDOM

In 2000, the National Health Service (NHS) published An Organization with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS. The authors reported that at least 400 patients died or were seriously injured and that nearly 10,000 people were reported to have experienced serious adverse reactions to drugs (not all of which are preventable) in 1999. The report estimates that adverse events occur in approximately 10% of patient admissions in the U.K. This report recommends the creation of a new national system for reporting and analyzing adverse health-care events to ensure that lessons are identified and learned. Additionally, the recommendations put forth in this report support the analysis of adverse events at the local level for the purpose of improving care outcomes. Development of a strategy to build local capability for analysis is integral within the nation-wide implementation plan.

The NHS has produced a number of other relevant reports. They include *Building a Safer NHS for Patients*, *Doing Less Harm - Key Requirements for Health Care Providers*, *and Measurement and Monitoring of Surgical Adverse Events*.

Information on the reports and activities of the NHS can be found online at: *http://www.doh.gov.uk*

AUSTRALIA

In 1994, the Quality in Australian Health Care Study was commissioned by the Commonwealth Department of Health to determine the extent of adverse events (AEs) in Australian hospitals. A review of hospital medical records was undertaken to estimate patient

injury that occurred in health-care settings. This study was modelled on the Harvard Medical Practice Study in the United States.

The results of this study were based on the review of 14,179 admissions to 28 hospitals in two states. The review process involved initial screening by Registered Nurses using standard and strict criteria followed by an independent review and documentation by two, or, in cases of disagreement, three medical officers. The data revealed that, of 16.6% of admissions attributable to AEs, 51% were deemed preventable. In 77.1% of the cases, the disability had resolved within 12 months, but in 13.7% the disability was permanent and in 4.9% the patient died (Wilson et al.,1995). Available online in the Medical Journal of Australia: *http://www.mja.com.au/*

The Australian Council for Safety and Quality in Health Care was established in January 2000 to facilitate and co-ordinate national action in safety in health care. The Council prepared its first report in July 2000 that sought funding for a five-year national work plan to improve safety and quality in the Australian health-care system. In February 2001, the Council produced a National Action Plan identifying the next steps in addressing national patient safety. The four priorities identified in its first year action plan included:

- Using data and information better throughout the system to support safer patient care
- Strengthening mechanisms to ensure safer clinical and organizational environments
- Actively promoting opportunities for consumer feedback and participation
- Redesigning of systems and processes of care to promote a strong culture of reliability and safety

Since then, the Council has established a website for promotion of its activities and feedback, surveyed health-care professionals on barriers to, and opportunities for, the provision of safer care, hosted a consumer conference and workshop, and produced two national reports on patient safety. In September 2001, the Council collaborated with the British Medical Journal and the Institute of Healthcare Improvement (USA) to organize the 1st Asia-Pacific Forum on Quality Improvement in Health Care.

Publications of the Australian Council for Safety and Quality in Health Care are available online at: *http://www.safetyandquality.org*

NEW ZEALAND

In March 2001, Hellen Cull, QC, released a report titled *Review of Processes Concerning Adverse Medical Events* that reviews current processes for reporting and investigation of adverse incidents undertaken by the following New Zealand agencies:

- The Health and Disability Commissioner
- The Medical Council of New Zealand
- The Medical Practitioners Disciplinary Tribunal
- The ACC Medical Misadventure Unit

Helen Cull, QC, identifies lessons that can be learned from this review. She recommends legislative and procedural changes that could ensure that adverse medical outcomes are identified and that appropriate, timely remedial action is taken. This information is intended to support the development of legislation, to improve the framework for the occupational regulation of health professionals, including processes for the reporting and investigation of adverse incidents.

Information on this report can be found at the New Zealand Ministry of Health website: *http://www.moh.govt.nz*