Task Force on Adverse Health Events

Background Documents
Volume I: Public Submissions

December 2008

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Submitted by

Association of Registered Nurses
of Newfoundland and Labrador

ARNNL Brief to Task force on Adverse Health Events

The Association of Registered Nurses of Newfoundland and Labrador (ARNNL) is the regulatory body and professional organization representing all Registered Nurses and Nurse Practitioners in the province. In pursuit of its vision, "Excellence in Nursing", ARNNL exists so there will be public protection, quality health care, and healthy public policy.

The Association of Registered Nurses of Newfoundland and Labrador (ARNNL) welcomes this opportunity to comment on the management of adverse events as there is a lot of work to be done to move our health care system from the traditional culture of blame to a new client safety culture. We recognize and support the need to thoroughly analyze how government, regulatory bodies, health care authorities, and the professions can collaborate to create solutions that will establish the new culture of client safety required to prevent and effectively manage adverse events in the public interest.

As the regulatory body for Registered Nurses, ARNNL's primary responsibility is public protection through promoting excellence in nursing and quality health care. This responsibility is accomplished in part, through the setting of standards for licensure, education and practice, and a code of ethics. Patient safety is fundamental to nursing care and, as such, ARNNL clearly articulates that RNs have a professional and ethical obligation to identify potential and actual issues of patient safety and to respond appropriately. The significance of client safety is specifically articulated in the following ARNNL goals or Ends statements, which serve to direct our ongoing activities:

- RNs understand and act upon their responsibility as client advocates.
- Client safety is enhanced through a culture of discovery including a focus on root cause analysis, education, prevention, and remediation

(See Appendix A for more examples of ARNNL standards, indicators and responsibility statements related to client safety.)

Client safety is a pressing concern for Registered Nurses in our province. On an annual basis ARNNL receives over 200 consultation requests from nurses related to maximizing client safety. This demonstrates the inherent value nurses place in the prevention and mitigation of unsafe acts in their workplaces. Consequently, any means of improving the processes to enhance the prevention, early identification as well as managing of potential and actual adverse events is welcome.

Improving patient safety involves a wide range of actions at the individual, interprofessional, health authority and government levels. The focus of this response will be limited to the nursing profession's views on how to improve the management of adverse events as one aspect in the development of a culture of safety. ARNNL is making suggestions regarding the need to:

1. Create and sustain a safety culture,
2. Standardize policies and processes,
3. Enhance professional development and RNs' role,
4. Improve professional practice supports,
5. Enact legislation that supports the culture of safety, and
6. Support knowledge transfer.

1. **Creating and Sustaining a Safety Culture**

Continued attention and interventions are required to create and sustain a culture of safety in our health care system.

Anecdotal evidence indicates that despite the fact that an increasing amount of attention and resources are being dedicated towards client safety, we have not yet created a culture whereby healthcare professionals inherently feel safe to openly and thoroughly discuss and participate in measures to prevent and manage actual adverse events. Further interventions are required. In particular, ARNNL is suggesting four areas for consideration.

- Address the current and future leadership challenges.
- Include front line nurses in all relevant discussions on client specific incidences for which they were involved.
- Provide timely feedback to nurses on client safety initiatives that relate to their role and area of practice.
- Explore measures to capitalize on the value of clients as true partners in health care.

Address Leadership Challenges

Strong leadership at all levels is needed to create the required environmental attitude where staff believe in and endorse practices which support a culture of safety. In particular, attention is required to support the role of front line managers in implementing changes in practice and culture. Data from the ARNNL Survey of *Nurses in Management Positions* (2007b, 2008d) identify unreasonable spans of control; almost 75% reported having > 30 staff and, 80% has staff from more then one unit and/or geographical location. This impacts managers ability to nurture and support front line staff and others in making the required paradigm shift to achieve a culture of safety.

Experience and research tell us that the future generations of health care professionals will likely have a different perspective from those of today. Sustaining a culture of safety into the future will require that the potential implications of generational differences are explored. For example, future approaches in the management of adverse events must consider the value these professionals place on technology as the means for acting, communicating and learning. Their perspective must be incorporated into the planning of today to ensure that our future care providers remain positively engaged.

Include Frontline Nurses

There is still an element of role delineation between disciplines and even within the profession of nursing when it comes to managing adverse events. Historically, direct care nurses' primary role has been to identify and report concerns. The management or follow-up on reported events is frequently assigned to physicians or agency quality teams. Reporting refers to communication of information about an adverse event or near misses through appropriate channels in the organization for the purposes of reducing the risk of reoccurrence (Canadian Patient Safety Institute [CPSI], 2008). Although an important component of improving patient safety, reporting is a first step. Registered Nurses need to be a part of the entire process. Being respected and accepted into the team of responders can nurture the value of identifying and addressing concerns, build expertise, and enhance professional accountability. To achieve this, there needs to be a coordinated and comprehensive approach to managing adverse events, which incorporates true interdisciplinary

collaboration and team work. If a nurse has been involved in reporting the near miss or adverse event then he/she should play a more significant role in the entire process, including disclosure.

Provide Feedback on Safety Initiatives
RNs report limited knowledge about the outcomes of client safety initiatives that have been implemented in their area of practice. Data extracted from ARNNL and College of Licensed Practical Nurses of NL's Quality Professional Practice Environment (QPPE) sites indicated that 33.3% of the RNs and LPNs (n= 179) stated they did not have access to or did not know (11%), the results of quality improvement initiatives they participated in. Nurses described reporter fatigue, implying 'why bother' to continue to raise concerns or participate in initiatives if nothing is ever done [but it is more likely that nothing was ever reported back]. Reporter fatigue, when coupled with reports of excessive workload, can lead to under-reporting of concerns.

Involve Clients
Clients want and will increasingly desire to be more active participants in their health care. Consequently, exploration on how to maximize client engagement and self accountability in their healthcare needs to be explored. Client engagement supports social justice by encouraging equity in decision making, distributing power, and acknowledging human rights (SRNA, 2008). For example, clients require and often request information about their rights and responsibilities, including their role as a team member and their responsibility to question practices. To fully move away from the paternalistic model, or as stated by Herbert (2008) to move from the therapeutic approach where the client is included in what the provider determines is in their best interest, to the democratic approach, where all clients have a right to be truly involved in their care, will require reflection, planning, and courage. Client engagement in the prevention of adverse events is one of the most effective untapped prevention strategies available.

2. Standardize Policies and Processes
A standardized provincial template for addressing adverse events is required. This template needs to include policy direction and processes that promote the objective collection of data that can be shared and compared.

Critical to the client safety agenda is the need to develop policies and processes that support communication of concerns in a standardized, user-friendly, and effective manner. Furthermore the policies and processes must be utilized by all members of the health care team. Currently not all health care agencies have policies that clearly direct practice in this area. Those that do exist often do not reflect the relevant professional standards published by the regulatory bodies, and thus miss the opportunity to heighten practitioners' awareness of the magnitude of their accountability to participate in patient safety activities. In addition, there are a number of different forms and processes that supposedly serve a similar purpose, often with different titles and different implications based upon the setting, for example, incident, adverse, occurrence and professional practice forms (Burkoski, 2007). The lack of standardized policies and processes may also limit sharing of data between agencies locally, provincially and even nationally, as one cannot determine if apples are being compared to apples.

The CPSI *Guidelines for Disclosure* (2008) provide a template for health care agencies to develop their own policies on communicating with clients when an adverse or potential adverse event occurs. However, the guidelines do not address prevention, internal reporting, managing or informing the public. There is more

work needed to identify best practices in these areas and convert applicable recommendations into polices and processes within all healthcare settings.

3. Enhance Professional Development and RNs' Role

RNs can play a more prominent role in communicating with clients when actual or potential adverse events occur.

Client safety and the expectation to identify and act upon concerns about actual or potential adverse events are a professional and ethical imperative in caring for others. These concepts are embedded in both the undergraduate curriculum, as articulated in the ARNNL document, *Competencies in the Context of Entry-Level Practice in NL 2007-2010 (2006a)* , and the professional *Standards for Nursing Practice* (2007c) and *Code of Ethics* (2008) (see appendix A for specific indicators). However, both front-line and nurse managers report a need for additional education to become proficient in advanced communication techniques to effectively manage adverse events. For example, nurses have requested education on presenting information in a regretful but non- accusatory, objective manner. Nurse managers have specifically identified the need for continuing education to assist them in their role as leaders (ARNNL, 2007a). Appendix B provides a more detailed list of research that illustrates both the need for and value of enhanced communication education for nurses. As the need for education on the appropriate management of adverse events is likely shared by other disciplines, this topic would be an excellent focus for interdisciplinary education in both undergraduate and continuing education forums.

With appropriate education and support RNs can play a greater role in initial communication with clients. Research tells us that clients want to know sooner rather then later when an adverse event has occurred. Traditionally, RNs have not been given the autonomy or authority to initiate communication with clients when an adverse event occurs. This situation potentially conflicts with nurses professional and ethical obligations. The CPSI *Disclosure Guidelines* endorse the precautionary principle, which stresses the value of early communication and action. Nurses are the most frequent health care provider clients interact with, and are trusted by the public. The latest Ispos-Reid public poll that found that 84% of Canadians trust nurses' information compared to 77% for physicians and 60% for information originating from health ministers (ARNNL, 2008a). As nurses are also often the first to identify that a client has or could have experienced an adverse event, educating and supporting nurses to enhance their role in sharing appropriate information with clients can result in a more timely process for open and transparent communication. One supportive strategy is use of an interdisciplinary educational approach which incorporates role modeling and mentoring. Collaborating with professionals who have traditionally assumed this role is an excellent means of supporting nurses to enhance their role in client communication in adverse events.

4. Improve Professional Practice Support

Health care providers require the assistance of experts and mentors to maximize client safety.

In today's complex ever changing health care environment the demands have increased, yet practice supports have diminished. Quality of workload studies indicate that nurses are feeling the impact, which in turn, is impacting the quality of client care (Statistics Canada, 2005). Likewise there is evidence that the introduction of supportive roles such as educators, infection control practitioners, safety officers, and clinical leaders such as clinical nurse specialists, enhance the quality of care (ARNNL, 2006b). However the

implementation of these roles has been very limited in our province. To fully adopt a culture of client safety dedicated experts and mentors at the practice level are required.

The ARNNL and CLPNNL Quality Professional Practice Environment Program (QPPE) has made significant differences within the participating units (ARNNL, 2008b). The QPPE program and other initiatives, which support quality of worklife and quality care, need to be implemented in all health care agencies. This will require dedicated resources, both financial and human. ARNNL believes that the dedication of a person or persons responsible for creating quality professional practice environments is needed in all four regional health authorities. Such a role can effectively increase health care professionals' ability and authority to prevent and address situations that are known to be risky practices.

The value of creating a provincially mandated patient safety role or office should be explored. There appears to be significant improvement and standardization of policies occurring when a provincial position/ office has been created to address an important area of concern in the past. There are a variety of models available for consideration, for example, the role of the Primary Health Care Office or the Provincial Blood Coordinating Program. The introduction of an arms length publically supported structure such as a Quality Council, has shown success in other jurisdictions. Provincially mandated organizations who have been involved in client safety and quality of worklife issues, such as the Newfoundland and Labrador Health Boards Association, could be another approach for consideration to lead this initiative.

5. Enact Legislation that Supports the Culture of Safety

The introduction of legislation to support the identification, management, and disclosure of adverse events needs to be fully explored.

Legislation can serve a valuable role in supporting and protecting persons and agencies seeking to maximize their ability to appropriately and effectively address adverse events. There are several areas where legislation can be helpful:

- Protection of Information from Quality Initiatives
- Mandatory Reporting
- Whistleblowing
- Public Information
- Apology Protection

It is important to carefully consider the advantages and disadvantages and expected outcomes before the time and effort is invested in the creation or revision of any legislation. First and foremost, the merit of legislation to support the desired culture of safety must be validated.

Quality Initiatives

ARNNL supports the need to examine and revise as necessary the Evidence Act so that quality assurance / initiatives records and the release of information by individuals involved in quality assurance activities are protected from legal proceedings. We believe that peer review processes/documents are intended to improve client care outcomes and are therefore, a means to enhance care and protect the public. As the introduction of quality control measures within regulatory bodies and health care agencies continues to grow in response to the call to strengthen public accountability and maximize client safety, the type of information that is

considered to be "protected" needs clarification. ARNNL is in the process of developing a continuing competency program for RNs. With such a program nurses are encouraged to identify their strengths and challenges and to engage in learning activities to meet those challenges. If nurses are to participate wholly in this program they will require reassurance that the personal information they disclose will be used only for the intended purposes. Failure to provide that reassurance may limit nurses' willingness to fully disclose. A similar response could likewise be expected for participation in quality control initiatives undertaken in health care professionals' places of employment.

Mandatory Reporting

Legislation to mandate reporting of adverse or sentinel events has been implemented in other jurisdictions e.g. Saskatchewan. Although some provinces have established mandatory reporting to a provincial government structure, there appears to be more merit in mandating that health care agencies and professionals report potential and adverse events to an established arms length national database. National reporting supports the ability to share lessons learned. Entities such as, the Institute for Safe Medication Practices- Canada and Health Canada's Canada Vigilance Adverse Reaction Monitoring Program and Database are already funded and well situated to collect and disseminate data on adverse events and near misses with the goal of preventing reoccurrence in another setting or situation. These national databases are currently underutilized. Mandatory reporting to an appropriate national organization should be explored.

Whistleblowing

Whistleblowing is defined as the exposure of negligence, abuses, or dangers, such as professional misconduct or incompetence, which exist in the organization where the whistleblower works (CNA, 1999). There are two interpretations on what constitutes whistleblowing; internal and/or external reporting (Wikipedia, 2008). As there are no jurisdictions in Canada that have enacted such legislation, the Canadian interpretation of this term remains undefined. ARNNL, as the regulatory body for RN practice, supports the value of protecting a nurse who appropriately followed professional processes for addressing client safety concerns as outlined in the ARNNL document, *Registered Nurses Professional Duty to Address Unsafe and Unethical Situations* (ARNNL, 2008c), but who are unable to achieve effective results. (A brief description of this process is described in Appendix C). However, most references to whistleblowing refer to externally reporting or warning the public about a particular concern without first going through all the appropriate internal channels. ARNNL is concerned that whistleblowing legislation may be perceived as approval to bypass the expected internal reporting and thus used inappropriately. Inappropriate external or public whistleblowing often serves the opposite effect, causing undue public fear, jeopardizing client privacy, creating suspicion that can affect organizational functioning, and affecting the individual whistleblower's employment and/or professional status (ARNNL Disclosure Teleconference, February, 2007).

Public Information

The act of informing is normally the responsibility of an institution (not an individual function). The public sharing of information about a concern and the measures implemented to address a concern, is an important part of managing adverse events as it helps maintain the public's trust in the health care system (Espin, 2008). The CPSI *Disclosure Guidelines* (2008) identifies this level of accountability to senior administration. ARNNL supports the need for the CPSI or some other entity to develop guidelines which address the appropriate process for informing the public. These guidelines need to then be incorporated into health care policy.

Apology Laws
Saskatchewan, British Columbia and Manitoba have enacted apology laws which supports the merit and responsibility of an agency and/or individual to apologize while protecting the apologizer from the risk that this endeavor can be used as an admission of guilt (Robertson, 2008). This type of legislation supports early, open, and transparent communication with clients who experienced an adverse event. ARNNL supports the value of apology legislation.

6. Support Knowledge Transfer
Data are needed on what works and what does not work. Funds are needed to support what works in the management of adverse events and client safety.

The Canadian client safety agenda has been active for almost six years. Since then there have been a number of initiatives implemented both as research and pilot projects. There is an urgent need to formally share what projects worked and what did not, to articulate best practice evidence in this area, and to fund/support/promote programs that make a difference. ARNNL supports the value of creating or supporting a network for disseminating information that enhances client safety. Three areas are highlighted as examples. The work of the national organization, Quality Worklife: Quality HealthCare Collaborative, deserves consideration. There are a number of viable and practical solutions articulated in the document, *Within Our Grasp*- A Healthy Workplace Action Strategy for Success and Sustainability in Canada's Healthcare System (2007). The Registered Nurses Association of Ontario has developed over 29 best practice clinical guidelines and six guidelines to create healthy workplaces. To date there has been only limited uptake on these guidelines with our province. Finally, the 30 healthcare practices that have been proven to be effective in clinical settings to reduce the risk of client harm put together by the US National Quality Forum, could be reviewed for merit in the Canadian health care system.

Conclusion
ARNNL is pleased to see Government leadership on the management of adverse events in our health care system. The Association believes in the old adage, "leadership must come from the top" when a system is being asked to make the fundamental reforms needed to move from a culture of blame to one of discovery. Registered nurses are keen to work with all stakeholders to improve the management of adverse events and to create the quality of practice environments which are needed to address client safety. ARNNL's six suggestions for improving the management of adverse events are a good starting point for action.

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Appendix A

Enhancing, preventing and supporting a patient safety philosophy is a professional expectation for all registered nurses practicing in Newfoundland and Labrador. These expectations are clearly identified in several ARNNL key documents as described below.

Registered Nursing Act (2008)

20. (1) A registered nurse who has knowledge, from direct observation or objective evidence, of conduct deserving of sanction of another registered nurse shall report the known facts to the Director of Professional Conduct Review.

Association of Registered Nursing of Newfoundland and Labrador (ARNNL) Standards for Nursing Practice (2007)

Self Regulation and Professional Accountability.
1.5 Is accountable and responsible for own actions and decisions at all times.
1.8 Participates in the identification and resolution of professional practice issues, conflicts, and ethical dilemmas.
1.9 Responds to, and reports situations that may be adverse for clients and/or health care providers.
1.11 Documents adherence to responsibilities and accountabilities appropriately.

Specialized Body Knowledge
2.3 Uses reflective thought and feedback from others in assessing own practice, and provides feedback to others to support their professional development.

Competent Application of Knowledge
3.9 Recognizes any limitations to safe, competent, and ethical care and reports concerns, and consults and/or initiates appropriate changes as necessary.

Professional Interactions and Advocacy
4.1 Demonstrates honesty, integrity and respect for others.
4.11 Acts as an advocate to protect clients from harm due to unsafe situations and/or incompetent or unethical care

Professional Leadership
5.5 Questions practices and contributes to improvements to support client and nurse safety.
5.6 Advocates for and/or contributes to the development of organizational policies, quality improvement initiatives, and programs based on evidence/best practice standards.

Canadian Nurses Association (CNA) Code of Ethics (2008) select indicators:

Providing Safe, Compassionate, Competent and Ethical Care

> 3. Nurses build trustworthy relationships as the foundation of meaningful communication, recognizing that building these relationships involves a conscious effort. Such relationships are critical to understanding people's needs and concerns.

4. Nurses question and intervene to address unsafe, non-compassionate, unethical or incompetent practice or conditions that interfere with their ability to provide safe, compassionate, competent and ethical care to those to whom they are providing care, and they support those who do the same.

5. Nurses admit mistakes and take all necessary actions to prevent or minimize harm arising from an **adverse** event. They work with others to reduce the potential for future risks and preventable harms.

6. When resources are not available to provide ideal care, nurses collaborate with others to adjust priorities and minimize harm. Nurses keep persons receiving care, families and their employers informed about potential and actual changes to delivery of care. They inform employers about potential threats to safety

Preserving Dignity

4. Nurses intervene, and report when necessary, when others fail to respect the dignity of a person receiving care, recognizing that to be silent and passive is to condone the behavior.

Maintaining Privacy and Confidentiality

4. When nurses' are required to disclose information for a particular purpose, they disclose only the amount of information necessary for that purpose and inform only those necessary. They attempt to do so in ways that minimize any potential harm to the individual, family or community.

Ethical Endeavours

xii. Advocating for the discussion of ethical issues among health-care team members, persons in their care, families and students. Nurses encourage ethical reflections, and they work to develop their own and others heightened awareness of ethics in practice.

ARNNL Competencies in the Context of Entry-Level RN Practice in NL (2007-2010)

Professional Responsibility and Accountability

2. Recognizes limitations of practice and seeks assistance as necessary.

8. Exercises professional judgment when using agency policies and procedures, or when practising in the absence of agency policies and procedures.

12. Demonstrates an understanding of the concept of duty to report unsafe practice in the context of professional self-regulation.

13. Protects clients through recognizing and reporting unsafe practices when client or staff safety and well-being are potentially or actually compromised.

14. Questions are prepared to challenge, and take action as necessary, on questionable orders, decisions or actions made by other health team members.

15. Questions, recognizes and reports errors (own and others) and takes action to minimize harm arising from adverse events.

16. Identifies, reports, and takes action on actual and potential safety risks to clients, themselves or others.

18. Integrates quality improvement principles and activities into nursing practice.

Knowledge-Based Practice

24. Knows how and where to find evidence to support the provision of safe, competent, ethical nursing care.

30. Knows how and where to find evidence to ensure personal safety and safety of colleagues in the workplace.

52. Anticipates potential staff safety concerns and initiates appropriate action.

59. Incorporates evidence from research, clinical practice, client preference, staff safety and other available resources to make decisions about client care.

62. Recognizes, seeks immediate assistance, and helps others in a rapidly changing condition of clients that could affect client health or safety, (e.g., in situations of myocardial infarction, surgical complications, acute neurological event, shock, anaphylactic shock, acute respiratory event, cardiopulmonary arrest, perinatal crisis, premature birth, diabetes crisis, mental health crisis, and trauma).

72. Consistently applies safety principles evidence-informed practices and appropriate protective devices when providing nursing care to prevent injury to clients, self,, and other colleagues in the work place.

73. Implements preventive strategies related to the safe and appropriate use of medication.

74. Implements other preventive and therapeutic interventions safely (e.g., positioning, managing intravenous therapies, drainage tubes, skin and wound care).

Ethical Practice

84. Identifies effect of own values, beliefs and experiences concerning relationships with clients, and uses this self-awareness to support culturally safe client care.

87. Promotes a safe environment for clients, themselves, and other health care workers that addresses the unique needs of clients within the context of care and uses a culturally safe approach to nursing care.

Service to the Public

104. Uses established communication protocols within and across health care agencies, and with other

service sectors.

105. Uses safety measures to protect self and colleagues from injury or potentially abusive situations (e.g., aggressive clients, appropriate disposal of sharps, lifting devices, low staffing levels, increasing work-load and acuity of care).

107. Uses health care resources appropriately to ensure a culture of safety (e.g. patient lifting devices, safer sharps).

Appendix B

Communication Education for Nurses

- "Nurse's communication skills have been criticized for years, as have the theoretically weak approaches to communication skills training in nurse education."

  Quoted from: Bowles, N., Mackintosh, C., & Torn, A. (2001). Nurses' communication skills: an evaluation of the impact of solution-focused communication training. *Journal of Advanced Nursing, 36(3): 347-354*.

- Study of nurses' attitudes towards truthful communication found that most respondents reported that they did not feel sufficiently trained in communicating difficult news to patients.

  Georgaki ,S., Kaladipopulou, O., Liarmakopoulos, I., & Mystakidou, K. (2002). Nurses' attitudes towards truthful communication with patients with cancer. *Cancer Nursing, 25: 436-41*.

- "Oncology nurses may find communicating bad news difficult for several reasons. First, nurses may fear that sharing unfavorable medical information can cause harm such as hopelessness, depression or a sense of failure. Second, delivering bad news can be uncomfortable because of nurses' lack of practice or skill."

  Quoted from Radziewicz, R., Baile, W., Lockhart, L.S., & Oberleitner, M. (2001). Communication Skills: Breaking bad news in the clinical setting. *Oncology Nursing Forum, 28(6): 951-3.*

  Note: section on opportunities for RNs to deliver bad news in the article – discusses how RNs are in a position to deliver bad news because of role in care delivery (educator, supporter, advocate).

- "There is little evidence that practical advice and guidance exist for nurses in general and for emergency nurses in particular regarding the issue of medical error recognition, reporting, and resolution…There is a need for a practiced, standardized approach to medical error reporting that includes improved teamwork, conflict resolution, and appropriate reporting methodology education that should be paired with mandatory reporting laws."

  Quoted from: Hohenhaus, S.(2008). Emergency nursing and medical error – a survey of two states. *JEN: Journal of Emergency Nursing, 34(1): 20-25.*

- "Efforts to decrease errors in health care are directed at prevention rather than at managing a situation when a mistake has occurred. Consequently, nurses and other health care providers may not know how to respond properly and may lack sufficient support to make a healthy recovery from the mental anguish and emotional suffering that often accompany making mistakes."

  Quoted from: Crigger NJ, (2004). Always having to say you're sorry: an ethical response to making mistakes in professional practice. *Nursing Ethics, 11 (6):568-76*

- Study of ER physicians, RNs and EMTs using ten case vignettes involving medical errors found that 59% of RNs would disclose the error to patients (compared to 71% of physicians) and that RNs were more likely to indicate they would report the error to administrator/committee than physicians (68% vs. 54%).

  Hobgood C, Weiner B, Tamayo-Sarver JH, (2006). Medical error identification, disclosure, and reporting: do emergency medicine provider groups differ? *Academic Emergency Medicine, 13 (4): 443-51*

- A study investigating the effects of medical error disclosure training in a simulated setting for pediatric oncology nurses (n=16) found statistically significant increases in nurses' communication self-efficacy to carry out medical disclosure after training.

  Wayman KI, Yaeger KA, Sharek PJ, Trotter S, Wise L, Flora JA, Halamek LP. (2007). Simulation-based medical error disclosure training for pediatric healthcare professionals. *Journal for Healthcare Quality 29 (4):12-19.*

Appendix C

ARNNL Process: Supporting RNs to Identify and Address Client Safety Concerns.

RNs have a professional and ethical obligation to identify potential and actual issues of patient safety and to respond appropriately. These responsibilities are articulated in the document *Professional Duty to address unsafe and unethical situations* (ARNNL, 2007).

The primary responsibility of all RNs is to maximize client safety but to do so in a professional and efficient manner. The nurse is therefore directed to internally report any identified actual or potential issues of client safety up the line of authority within his/her organization. If the response is not reasonably efficient or the issue is of dire consequence, the nurse is further instructed on how to proceed. The nurse has the option to involve any and all applicable health professional regulatory bodies. ARNNL will confidentially advise any RN needing assistance with this process up to and including reporting to senior management. If necessary ARNNL will also support the nurse to bring his/her concern to an external body.

There may be a moral obligation to whistleblow if the following obligations are met:

- One reported up through the hierarchy as described.
- The harm or potential harm must be very serious: the more serious the harm the more serious the obligation.
- The employee must have a good reason to believe that the act of whistleblowing will significantly increase the probability of the desired change (CNA, 1999).

Submitted by

Canadian Institute for Health Information

June 13, 2008

Robert Thompson
Task Force on Adverse Health Events
Government of Newfoundland and Labrador
Suite 1100
West Block, Confederation Block
P.O. Box 8700
St. John's, NL
A1B 4J6

Dear Mr. Thompson:

Re: The Task Force on Adverse Health Events, Call for Submissions

The Canadian Institute for Health Information (CIHI) is one of Canada's premier sources of accurate, timely and comparable health information. CIHI offers an array of databases, registries and products, including standards, publications and analytic reports, which provide quality information to inform system improvements and to impact the quality and safety of health services provided to Canadians. This document outlines CIHI's patient safety resources which may be of relevance to the Government of Newfoundland and Labrador's Adverse Health Event Management Framework.

Canadian Medication Incident Reporting and Prevention System

CIHI has collaborated with the Canadian Patient Safety Institute (CPSI), the Institute for Safe Medication Practices Canada (ISMP Canada), Health Canada and other stakeholders to establish the Canadian Medication Incident Reporting and Prevention System (CMIRPS). Within this collaboration, CIHI's role has focused on the development of a Hospital Based Reporting System for the CMIRPS program. This is a free, pan-Canadian voluntary and anonymous incident reporting system, which hospitals will use to submit medication incident data for the purposes of 1) learning from breakdowns that occur in the medication-use system within facilities; and 2) supporting risk management and quality improvement activities at the local level.

The CIHI Hospital Based Reporting System includes a secure and confidential data entry tool, a query and analytical tool and a non-identifying communication tool. The reporting system has been designed to minimize the burden of data collection while maximizing its potential through standardized reports and tools. These tools will offer participating organizations an improved ability to submit medication incident data and to conduct local analyses, thus providing a stronger basis for decision-making and a broader capacity for knowledge sharing. Participating organizations will have access to their own data as well as pan-Canadian de-identified incident data. CIHI supports the Hospital-Based Reporting

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System with education and client support product/services, including a Resource Manual/User Guide, Standard Operating Procedures, and associated e-Learning Tools.

A four-month national pilot test of the CIHI Hospital-Based Reporting System is scheduled to begin in autumn 2008. It is anticipated that the reporting system will be ready for a phased in national implementation in 2009.

Safer Healthcare Now!

CIHI is a participant organization of the pan-Canadian Safer Healthcare Now (SHN!) campaign. This is a collaborative effort aimed at achieving measurable reductions in avoidable morbidity and mortality. In addition to supporting the campaign's goals and its measurement strategy, CIHI's Discharge Abstract Database (DAD) records acute myocardial infarction (AMI) measures for the campaign's data collection. CIHI has developed draft data collection guidelines for a project field in the DAD, which allows hospitals to enter the additional AMI data in a consistent manner.

Hospital Standardized Mortality Ratio

CIHI has led the effort in calculating the Hospital Standardized Mortality Ratio (HSMR) for Canada. The HSMR is an important new measure that can help support efforts to improve patient safety and quality of care in Canadian hospitals. The HSMR compares the actual number of deaths in a hospital with the average Canadian experience, after adjusting for several factors that may affect in-hospital mortality rates, such as the age, sex, diagnoses and admission status of patients. The ratio provides a starting point to assess mortality rates and identify areas for improvement, which may help to reduce hospital deaths from adverse events.

Publications & Reports

To date, CIHI has produced several reports addressing patient safety:

- *The Canadian Adverse Events Study: the incidence of adverse events in hospital patients in Canada*. G. Ross Baker, Peter G. Norton et al. Canadian Medical Association Journal • May 25, 2004; 170 (11).

  CIHI, along with the Canadian Institutes for Health Research (CIHR), jointly funded the first national study of patient safety in Canadian hospitals.

- *Health Care in Canada, 2004*. Ottawa, Ont.: CIHI, 2004.

  The first part of Health Care in Canada 2004 is devoted to safe care. It includes information on what safe care is, as well as both what is known and unknown about patient safety in Canada and worldwide.

- *Patient Safety in Canada, an Update*. Ottawa, Ont.: CIHI, 2007.

  This report measures the risk of a wide range of adverse events in Canadian health care delivery, including medication errors, in-hospital hip fractures, and traumas sustained during the birthing process. Focusing on results from recent surveys, as

well as several patient safety indicators, this CIHI analysis builds on CIHI's report Health Care in Canada 2004.

- *HSMR: A New Approach for Measuring Hospital Mortality Trends in Canada.* Ottawa, Ont.: CIHI, 2007.

  This is the first report in Canada on the hospital standardized mortality ratio (HSMR). It includes the first publicly available HSMR trends over three fiscal years (2004–05 to 2006–07).

- *Resident Safety: Characteristics Associated With Falling in Ontario Complex Continuing Care.* Ottawa, Ont.: CIHI, 2007.

  This report identifies characteristics associated with a continuing care resident's risk of falling in a facility.

- *Medication Incident Reporting and Prevention Systems Environmental Scan.* Ottawa, Ont.: CIHI, 2007.

  This document highlights relevant research and information management activities, as well as progress achieved to date related to medication incident reporting and prevention, both nationally and internationally.

- Health Indicators Report

  The Health Indicators Report aims to support regional health authorities in monitoring the health of their population and the functioning of their local health system through quality comparative information. The rate of in-hospital hip fractures for seniors is one of the patient safety indicators at the regional, provincial/territorial and national levels reported annually in this report.

- Hospital Report: Acute Care

  The Hospital Report series is a joint initiative of the Ontario Hospital Association and the Government of Ontario. Patient safety indicators presented in this report include indicators on nurse-sensitive adverse events (conditions captured in this indicator are widely considered to be sensitive to nursing care) as well as adverse events for labour and delivery, documentation and reconciliation of patient medications and reports on the adoption of patient safety policies and practices (Patient Safety Reporting and Analysis, Promoting a Patient Safety Culture and Hand Hygiene Practices Indicator.)

All CIHI publications and analytic reports are available at www.cihi.ca. If you require additional information or more detailed statistics, you may contact CIHI for a custom data request. All data requests are subject to CIHI's principles and policies for the protection of health information.

Through measurement strategies, data analysis and reporting, CIHI is committed to producing high quality information to assist decision makers and policy developers in their efforts to improve the quality and safety of health services. If CIHI can be of further assistance to the Task Force, please contact us at the information below.

Yours truly,

Stephen O'Reilly
Executive Director

Submitted by

Canadian Medical Protective Association

THE CANADIAN MEDICAL PROTECTIVE ASSOCIATION
L'ASSOCIATION CANADIENNE DE PROTECTION MÉDICALE

June 10, 2008

Via Mail & Email: ahe@gov.nl.ca

The Office of Task Force on Adverse Health Events
P.O. Box 8700
Confederation Building
St. John's NL A1B 4J6

Dear Task Force Members:

Re: Adverse Health Events

At the outset, I would like to thank you for the opportunity to participate in the recently held Provincial Forum on Health Adverse Events. In response to the invitation extended to me at the Forum and the Task Force on Adverse Health Events ("Task Force") public call for submissions, I am pleased to provide comments on behalf of the Canadian Medical Protective Association ("CMPA") with respect to how adverse events are managed within the health system.

As you may be aware, the CMPA is a not-for-profit mutual defence organization operated by physicians for physicians. It is the principal provider of medical-legal assistance to Canadian physicians, including those who practise in Newfoundland and Labrador. In addition to providing legal representation to its members, the CMPA also provides broader advisory services to its members on a magnitude of medical-legal issues including risk management, quality assurance, research and education. Informing physicians about their legal and ethical obligations with respect to the disclosure of adverse events is an important element of the CMPA's advisory services to its members.

While the CMPA is not in a position to specifically comment upon the questions posed by the Task Force in relation to how the health and community services system in Newfoundland and Labrador should appropriately address the management of adverse events, the CMPA is pleased to provide general comments regarding the disclosure of adverse events, particularly as this relates to quality assurance programs.

CMPA's Position on the Disclosure of Adverse Events

The CMPA has historically advised its physician members about the significance of disclosing adverse events to their patients. Most recently, the CMPA had the opportunity to be actively involved in the development of the Canadian Patient Safety Institute *Canadian Disclosure Guidelines* ("CPSI Guidelines"). The CMPA subsequently published a Toolkit for its members to assist them with meeting their patients' clinical, information and emotional needs following an adverse event. Many of the principles discussed in the CMPA's Toolkit align with those set out in the CPSI Guidelines. Moreover, the suggestions contained in the Toolkit are consistent with

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the College of Physicians and Surgeons of Newfoundland and Labrador's policy entitled "Disclosure of an Adverse Outcome".

It is uncertain whether the Task Force intends to recommend the publication of a provincial wide policy with respect to the management of adverse events. To the extent that a policy is developed in this regard, the CMPA submits that such a policy should be in accord with the CPSI Guidelines.

Distinction Between Disclosure and Reporting of Adverse Events

The CMPA is of the view that disclosing adverse events to patients and reporting such events to third parties (*i.e.* quality assurance committees) are separate and distinct processes. While the disclosure of adverse events to patients is an integral part of individual patient care, the reporting of adverse events to quality assurance committees is generally part of a much broader initiative aimed at identifying and addressing systemic problems. The ultimate goal of quality assurance activities is to critically review adverse events and to evaluate the effectiveness of the institution's practices and procedures in order to improve patient safety overall. The distinction between disclosing adverse events to patients and reporting adverse events to third parties is schematically depicted at page 23 of the attached 2005 CMPA publication entitled, "Medical Liability Practices in Canada: Towards the right balance". I would also direct the Task Force to pages 10 and 11 of this CMPA publication for a more fulsome discussion about the different responses that typically flow from an adverse event.

It is generally accepted that in order for quality assurance programs to be successful and effective, physicians and other participants must have satisfactory assurances that the reporting and subsequent investigation of such information will not be used or disclosed outside of the quality assurance process (either to patients or to other hospital departments or committees). If physicians and other health care providers are not confident that quality assurance information and documentation will be protected, they may be reticent or even unwilling to participate in the process.

The public policy objective of encouraging health care practitioners to participate in quality assurance processes is reflected in legislation that protects quality assurance records from being disclosed in legal proceedings. Such legislation has now been enacted in all Canadian jurisdictions. In Newfoundland and Labrador, quality assurance and peer review records are currently protected from disclosure in a legal proceeding pursuant to subsection 8.1(3) of the *Evidence Act*.

To ensure that the legislative protection of the *Evidence Act* may be invoked over quality assurance records, it is imperative that Newfoundland and Labrador's regional health care authorities and its hospitals conduct their quality assurance processes under the auspices of properly constituted quality assurance or peer review committees. Although the *Evidence Act* does not define "quality assurance committee" or "peer review committee", such committees likely need to be struck pursuant to the bylaws of the regional health care authority or the hospital and should have established terms of reference and written policies in order to be considered valid quality assurance and peer review committees for the purpose of the *Evidence Act*. Otherwise, as was recently found by the Court in *Eastern Regional Integrated Health Authority v. Commission of Inquiry*, quality assurance records will not benefit from the protection provided in subsection 8.1(3) of the *Evidence Act* and may be vulnerable to disclosure in subsequent legal proceedings.[1]

The CMPA recognizes that in an individual case it is natural that there may be a desire to provide a patient who has suffered an adverse outcome with as much information relating to the event as possible. However, in many cases the disclosure of quality assurance or peer review records will not necessarily assist the patient and could seriously undermine the laudable societal objectives of quality assurance activities. For this reason, the CMPA is of the view that only additional facts that are learned during the course of a quality assurance investigation should be subsequently disclosed to the patient. Moreover, participants in quality assurance activities should be advised of the importance of maintaining confidentiality over any information or documents provided to or generated by the quality assurance or peer review committee and should be discouraged from sharing these records with persons outside the committee.

It is also crucial that regional health care authorities and its hospitals are clear in understanding and maintaining the distinction between quality assurance processes and the investigation of particular incidents or adverse events for other purposes (*e.g.* investigations of particular cases following patient complaints, investigations by other hospital committees, etc.). Institutions that confuse these processes may struggle with the desire to disclose to patients some of the information uncovered by a "quality assurance committee", while also seeking to maintain quality assurance protection for other information uncovered by the same committee.

The CMPA submits that any guidelines, policies, *etc.* that might be developed based on the Task Force's recommendations, should clearly distinguish between adverse event disclosure to patients and adverse event reporting to quality assurance committees. This is important so that physicians and other health care practitioners, who may be required to comply with these policies, fully understand their specific purpose and potential implications. It is also crucial that

[1] 2008 NLTD 214.

physicians and other health care practitioners are aware of their obligations (*i.e.* what they must disclose and to whom).

Reporting Adverse Health Events to Government

At one of the workshops that I attended during the Forum, it was suggested by some individuals that there should be a mandatory requirement to report "critical incidents" to the government. To date, we are aware that only the provinces of Saskatchewan, Manitoba and Québec have enacted legislation that requires the reporting of "critical incidents" (referred to in Québec as "incidents" and "accidents") to government authorities.[2]

In the event that the Task Force does propose the implementation of a mandatory reporting requirement to government for critical incidents, it will be essential that any requirement clearly specify the types of critical incidents that must be reported, as well as the persons who are responsible for reporting these critical incidents to the government. The CMPA submits that any reporting obligations in this regard should fall upon the regional health authorities and its hospitals, rather than on individual physicians. Imposing a direct responsibility on physicians to report critical incidents to the government would place physicians in the tenuous position of having to breach patient confidentiality. It is significant that the legislation enacted in Manitoba, Saskatchewan and Québec recognizes that such a reporting obligation should not lie with physicians or any other health care professionals.

Conclusion

On behalf of the CMPA, thank you for the opportunity to participate in the Task Force's consultation with respect to the management of adverse health events within Newfoundland and Labrador's health system. While the CMPA has not specifically addressed each of the questions asked by the Task Force, we trust that the comments provided herein will be helpful for the purpose of creating a system that encourages physicians and other health care providers to participate in the disclosure, reporting and investigation of adverse events.

Respectfully submitted,

John E. Gray, MD, CCFP, FCFP
Executive Director/Chief Executive Officer

JEG/lg

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[2] *Regional Health Services Act*, s. 58(2) and 58(3) (Saskatchewan); *The Regional Health Authorities Act*, s. 53.3(1) and 53.3(2) (Manitoba); *Act Respecting Health and Social Services*, s.233.1 (Québec).

Enclosure: CMPA Publication —
Towards the Right Balance, 2005

C: Dr William S. Tucker, President
Dr Michael Cohen, Councillor

THE CANADIAN MEDICAL PROTECTIVE ASSOCIATION
L'ASSOCIATION CANADIENNE DE PROTECTION MÉDICALE

Medical liability practices in Canada:

Towards the right balance

A report prepared by

The Canadian Medical Protective Association

August 2005

Of interest to:

Advocates of the patient safety movement, who are working towards clearly defined relationships and information reporting protocols that satisfy both patient safety and accountability requirements;

Governments, whose mandate is to ensure that appropriate resources are applied to the delivery of health care services, including the maintenance of a sustainable medical liability system;

Patients, who are interested in seeing the number of adverse events reduced and, should such events occur, in ensuring appropriate compensation and accountability frameworks are in place and that measures are enacted to ensure those same events do not re-occur in the future; and

Physicians and other health care professionals, for whom the maintenance of a robust medical liability system is an important contributor to their ability to deliver care and to ensuring their right to due process.

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Medical liability practices in Canada: Towards the right balance

Ask any number of physicians what they hope and strive for when they treat a patient, and they will no doubt profess a profound desire for a positive or optimistic outcome and, at worst, that nothing will go wrong. This is the nature of medicine: "Cure sometimes, care always, but first, do no harm."

In an ideal world, no patients would suffer any harm from adverse events.

But the unfortunate reality is, from time to time, patients do suffer adversely from medical treatment, often because of a conjunction of circumstances, events and decisions that, individually, might not have resulted in a problem at all.

In an ideal world, the harm patients experience from an adverse event would never be the result of a physician's negligent breach of the duty of care. Unfortunately, however rare, negligence does sometimes occur.

In an attainable ideal and balanced reality,

- *patients would feel safer because adverse events would be minimized,*
- *patients suffering harm from an adverse event caused by negligence would be compensated quickly, appropriately and equitably,*
- *physicians' rights to due process would be respected,*
- *in the event physicians made an error, they would be held appropriately accountable, and*
- *the medical liability system would be both affordable and sustainable.*

The CMPA is continuously striving to support the balanced achievement of these ideals.

EXECUTIVE SUMMARY

One of the necessary components of an effective health care system is well-designed, functional medical liability protection that assures both health care professionals and their patients that their interests and access to due process will be protected. In the event of adverse health care outcomes resulting from practitioner negligence, it enables injured patients to receive appropriate compensation.

As the primary provider of medical liability protection to Canadian physicians, the CMPA believes that it is well positioned to contribute to discussions on improving the current Canadian system. CMPA's views are guided by five fundamental goals:

REDUCTION IN ADVERSE EVENTS
Improve the safety of patients and minimize the number of adverse events through risk management and education.

COMPENSATION
Ensure patients suffering harm as a result of physician negligence are compensated quickly, appropriately and equitably.

DUE PROCESS
Ensure physicians' rights to due process are respected and their integrity protected.

ACCOUNTABILITY
Recognize physicians' accountabilities.

AFFORDABILITY
Maintain a cost effective medical liability system in the context of available health care resources.

Striking a reasonable balance among these five goals is a key to ensuring both continued strength in Canada's medical liability system and improved patient safety.

LESSONS FROM CASE STUDY REVIEW

Different international jurisdictions use different medical liability models to meet their own specific national requirements. Based on a review completed, at CMPA's request, by Secor Consulting, the following lessons can be drawn from this international case study review:

- Medical liability forms one part of a complex health care delivery system and has multiple, interrelated components including the number of practising physicians, health care facilities, technology, patient compensation mechanisms, overall health care costs and other elements. *Changes to one element of the system inevitably impact on other elements, suggesting a progressive but evolutionary approach to change.*
- Medical liability models must be aligned with the prevailing health, social, legal and cultural environments. *Accordingly, there are "no plug and play" solutions that are easily transportable from one jurisdiction to another.*
- Notwithstanding the common use of the term "no fault" *there are no examples of pure no fault general medical liability systems as each of the international cases reviewed involved some element of fault determination.*

Four models

Four alternative models were applied to the Canadian context to determine if they offered advantages over the existing tort-based compensation model currently in use. The four models were:

No Fault
A no fault model based largely on the New Zealand experience.

Combination Fault/No Fault
Based in part on the Prichard Commission recommendations, a model providing access to both tort and no fault for significant avoidable adverse events.

Severely Compromised Infant program
Segregated dealings for severely neurologically impaired children, based in part on the impaired infant programs in Florida and Virginia.

Litigation Authority
Government sponsored indemnification of medical injuries, similar to the UK's National Health Service Litigation Authority (NHSLA).

When viewed against the five fundamental goals outlined above, each of these alternatives was found to be less satisfactory than the current model, in the Canadian context. In particular, these alternatives would cost more, thereby drawing resources away from direct patient care or from improving risk management and patient safety. Options that might appear to address one demand (such as the desire for increased access to compensation) result in negative impacts in other areas (such as greatly increased costs). Similarly, options that seek to improve patient compensation have unintended consequences and raise new challenges in other areas (such as patient safety and physician accountability). In addition, the effective portability of these models from one country or operating environment to another is questionable. Simply put, the results re-affirmed the view that the current model remains the most reasonable approach within the Canadian context.

Achievable initiatives

While the current medical liability system may be the best available solution, there are a number of achievable initiatives for improving it; these initiatives fall into four main categories:

- Addressing information reporting and improving processes to enhance patient safety efforts;
- Reducing transaction costs without negatively impacting patient compensation;
- Enhancing the judicial processes; and
- Further exploring a segregated compensation system for compromised infants.

Patient safety, physician accountability and patient compensation have competing information reporting imperatives. These competing imperatives should be addressed to encourage full and protected reporting for patient safety purposes while, at the same time, providing for legally prescribed reporting where accountability will be determined (in effect creating an information "firewall").

COMMON SENSE REFORMS

Within the realm of the current tort-based patient compensation system, common sense reforms are achievable in the near term that protect the interests of all parties yet reduce the non value-added transaction costs that do not compensate injured patients but draw valuable resources away from other health care demands. Action on these pressing and sensible changes (such as the use of structured settlements and the elimination of the practice of subrogation) need not wait for wider system improvements and could make a tangible difference in the short term.

In a resource-constrained environment, the sensible approach would be to refine the existing medical liability system while focusing effort and resources on patient safety and risk management. Only a reduction in the probability of adverse medical events within the health care system will ultimately lead to decreased system costs and improved patient outcomes.

6

Background

Quality health care is highly valued by Canadians and is widely considered to be an essential element of the Canadian way of life. However, increasing costs, shortages of health care professionals and long wait times for care are jeopardizing the effectiveness of the health care system. An effective health care delivery system is comprised of a number of interrelated components (facilities, skilled personnel, technology, medical knowledge, etc), each of which must operate in unison with the others.

One of the necessary components of an effective health care system is well-designed, functional medical liability protection that assures both health care professionals and their patients that their interests and right to due process will be protected. It also ensures injured patients receive appropriate compensation, in the event of adverse health care outcomes resulting from practitioner negligence. It is a necessary system component that engenders public trust.

Effective medical liability protection also complements an accountability framework that requires health care professionals to provide care to a commonly accepted standard.

Different medical liability protection models have been applied in jurisdictions across the globe — with varying degrees of success. In some jurisdictions, medical liability protection arrangements are in, or are nearing, states of crisis, threatening the effectiveness of the health care system.

As identified in research commissioned by the CMPA, other countries often view the Canadian medical liability protection model as being an optimal approach. Grounded in a tort-based compensation system, the Canadian system seeks to provide appropriate compensation to patients injured by physician negligence while protecting physicians' right to due process through a defined accountability framework. In Canada, the majority of physicians receive protection through the Canadian Medical Protective Association (CMPA), a mutual defence organization. Other health care professionals and hospitals access liability protection through a variety of arrangements.

While the Canadian model appears fundamentally sound, medical liability costs have been escalating, drawing on resources that might otherwise be available for health care delivery[1]. This reinforces the need to move forward with achievable initiatives that further improve the existing medical liability system.

1 Based on data from the past six years, the CMPA estimates that the cost of the current Canadian physician liability system (including indemnities, legal and administrative costs) to be approximately $225 million per year. In a study published in Health Affairs, the average annual real growth in total malpractice claims in Canada during the 1998-2001 period was 20% (almost 4 times higher than in the United States). See Anderson G.F., Hussey P.S., Frogner B.K., Waters H.R., "Health Care Spending in the United States and the Rest of the Industrialized World" *Health Affairs*, Vol 24, Number 4, pp 903-914, July-August 2005.

REPORT AIM

This report seeks to facilitate constructive discussion of both alternative patient compensation models and improvements to the existing tort-based system. These discussions will be positioned within a context that recognizes the complex relationship between patient safety, physician accountability and patient compensation. This report will examine the relevant issues by:

- Outlining the relationships between patient safety, physician accountability and patient compensation;
- Reviewing medical liability protection in a number of international jurisdictions, highlighting elements that might be relevant to Canada;
- Examining alternative models within a Canadian context; and
- Highlighting achievable changes that would have an immediate and positive impact on the current Canadian medical liability system.

As the primary provider of medical liability protection to Canadian physicians, the CMPA believes that it is well positioned to contribute to these discussions. Its views on the overall medical liability system are guided by five fundamental goals:

REDUCTION IN ADVERSE EVENTS
Improve the safety of patients and minimize the number of adverse events through risk management and education.

COMPENSATION
Ensure patients suffering harm as a result of physician negligence are compensated quickly, appropriately and equitably.

DUE PROCESS
Ensure physicians' rights to due process are respected and their integrity protected.

ACCOUNTABILITY
Recognize physicians' accountabilities.

AFFORDABILITY
Maintain a cost effective medical liability system in the context of available health care resources.

Striking a reasonable balance among these five goals is key to ensuring both continued strength in Canada's medical liability system and improved patient safety.

8

Building on previous research

This paper builds on the results of a comprehensive survey of medical liability systems in other jurisdictions completed, at CMPA's behest, by Secor Consulting. It also incorporates many of the findings of previous studies, including:

Prichard report on medical liability in Canada: The Prichard Report, commissioned by Canada's deputy health ministers in 1990, reviewed medical liability systems, literature and legal precedent, Canadian malpractice claims trends, and Canadian stakeholder opinion. One of its recommendations was the institution of a no fault based system, built in part on the notion of compensable 'avoidable medical events.' No fault was to be a central component of the scheme, with access to tort retained as an alternative. The Prichard proposals were not adopted.

Dubin report: In 1997 and in response to increases in medical liability damages/legal costs, the CMPA commissioned the Honourable Mr. Charles Dubin to examine the Canadian medical liability system. The Dubin Report found the existing approach to medical liability to be soundly based and it recommended against broad no fault initiatives. It did suggest exploration of limited designated compensable event approaches, such as those undertaken elsewhere for compromised infants.

The Canadian Adverse Events Study (by G. Ross Baker, Peter G. Norton et al): This report was the first Canadian study to provide a national estimate of the incidence of adverse events in patients admitted to Canadian acute care hospitals[2]. The overall incidence rate of adverse events was estimated to be 7.5%; the report estimated that, of the almost 2.5 million annual hospital admissions in Canada similar to the type studied, about 185,000 were associated with an adverse event and close to 70,000 of these were potentially preventable.

2 The results of the study were reported in the May 25, 2004 edition of the *Canadian Medical Association Journal (CMAJ)*. This study built on a previous study of leading patient safety practices in Canada by G. Ross Baker and Peter G. Norton (*Patient Safety and Healthcare Error in the Canadian Healthcare System*).

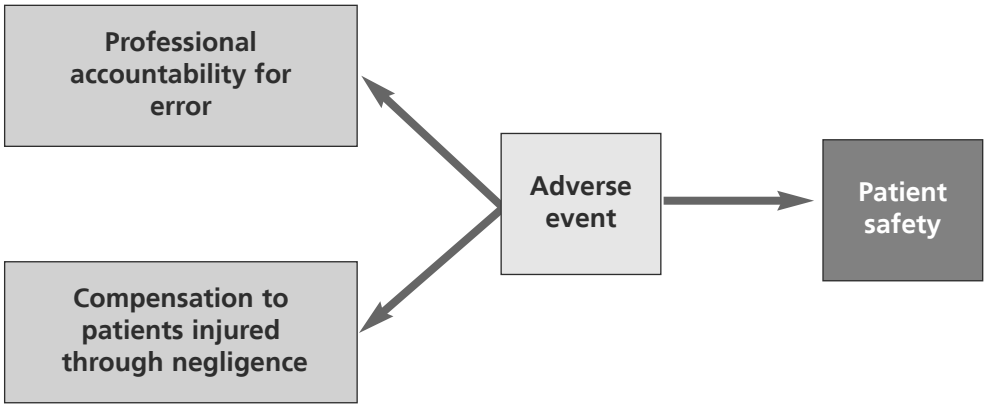
RESPONDING TO ADVERSE MEDICAL OUTCOMES: THE RELATIONSHIP BETWEEN PATIENT SAFETY, PHYSICIAN ACCOUNTABILITY AND PATIENT COMPENSATION

The initiating event within a medical liability system is an adverse medical outcome that may be either avoidable or unavoidable. Avoidable outcomes may result from a number of factors, including but not limited to system error or individual negligence.

THE MEDICAL LIABILITY SYSTEM

As depicted in the schematic below, three response elements potentially flow from an adverse event: patient safety, physician accountability and patient compensation. Appendix 1 provides a more detailed depiction of these responses.

APPENDIX 1
PAGE 23



PATIENT SAFETY: Patients want the safest health care system possible while physicians want to protect their patients from harm. Although the medical community cannot expect to ever completely eliminate the occurrence of adverse events, it continuously strives to identify and reduce the probability of adverse medical events through education and risk management. The primary aim of patient safety is to prevent adverse events from occurring and, accordingly, patient safety efforts seek to learn from both adverse events and "near misses" in order to identify their causes. This information should lead to changed procedures and system improvement that reduce the number of adverse events and enhance patient safety. Inherent in this approach is the *full and protected reporting of all information relevant to the adverse event*, regardless of whether it is avoidable or unavoidable or whether the system or one or more individuals may have been at fault.

Patient compensation: This response seeks to compensate the injured patient in a manner that is appropriate and equitable, given both the extent of the injuries and the circumstances involved. As with professional accountability, the tort-based approach to patient compensation is founded upon *legally prescribed reporting* and the accordance of due process to all involved parties.

Professional accountability: The sound practice of medicine, along with natural justice imperatives, requires health care professionals (including physicians) to be accountable for their actions. This imperative is a common requirement of self-regulating professions and is a necessary element in ensuring public confidence in the quality of care provided. For physicians, such accountability may take the form of licensing sanctions, accreditation issues, the withdrawal of practice privileges or other inquiries (such as coroner's inquests and human rights investigations). This accountability pillar entails due process, *legally prescribed reporting of information* and assessment of an individual's actions against an established standard of care — it is necessarily a fault-finding activity.

A system that does not effectively address each of these three responses is unlikely to engender public confidence or warrant public support. This creates a challenge for decision-makers who must, as described below, seek to achieve a workable balance between competing imperatives.

Competing imperatives and information reporting

Reducing the probability of adverse outcomes is dependent on consistent rule sets that encourage full, protected, information reporting

Each of the three responses to an adverse medical outcome has a distinct goal: reducing the number of adverse outcomes, compensating for injuries caused by negligence or holding a practitioner to account for error. While these three responses can and do operate largely in harmony, the imperatives underlying the reporting and use of information can be competing:

- Patient safety requires full and protected reporting not only of the outcome itself but also of all actions taken prior to and after the adverse event.
- Physician accountability and tort-based compensation are based on due process and legally prescribed reporting.

These challenges impact on key tenets of the existing Canadian medical and legal environments and the competing imperatives of the three responses to an adverse event must be considered in any examination of medical liability.

THE INTERNATIONAL MEDICAL LIABILITY ENVIRONMENT

The current state of medical malpractice protection is of serious concern to many governments, patients, medical organizations and physicians around the world. The CMPA commissioned Secor Consulting to examine representative medical liability models in the United Kingdom, France, New Zealand, Sweden, and the United States. Appendix 2 provides a country-by-country description, of which the following is a synopsis:

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THE UNITED KINGDOM: A tort-based, government-sponsored indemnity program run in parallel with a private system. National Health Service (NHS) Trusts manage public hospitals and clinics and the NHS Litigation Authority (NHSLA) is responsible for insuring all work done in the Trusts. Three medical defence societies[3] provide medico-legal protection and advice to physicians in private practice. While this system appears to be working effectively, costs are on the rise.

FRANCE: A system in flux, with elements of no fault, fault, public and private health care. A fault system exists for injured patients when the physician is unable to demonstrate that the injury was not caused by his/her actions. Injured parties have access to civil, criminal, administrative and professional tribunals. A no fault system is in place for injuries resulting in invalidity of at least 25% when no fault is declared. *L'Office National d'Indemnisation des Accidents Médicaux (l'ONIAM)* is responsible for no fault payments.

NEW ZEALAND: A restricted version of no fault that includes more than medical injury. Unless the medical injury is a rare complication, the injured party must establish fault in order to receive indemnification. Should a physician be found to be at fault, he or she is then open to professional, financial and legal sanctions (separate from patient compensation). A recently proposed change seeks to separate the patient compensation deliberations from the accountability process.

SWEDEN: A top-up 'no-blame' system built on a foundation of a particularly comprehensive social welfare program. To warrant compensation, the adverse outcome must have been "unintended and avoidable," with the test being whether an experienced doctor would have achieved a different result. This model has been replicated in Finland, Denmark and Norway.

THE UNITED STATES: A commercial liability insurance model in crisis. Multiple factors are contributing to a crisis situation in which medical liability costs have increased dramatically. These costs contribute to spiralling health care costs[4] and may be negatively impacting the supply of physicians, particularly in high-risk specialties.

3 The Medical Protection Society (MPS), the Medical Defence Union (MDU) and the Medical and Dental Defence Union of Scotland (MDDUS).

4 From 1994 to 2001, the median medical liability increased 176%, with awards jumping 43% within one single year, rising from $700,000 in 1999 to $1M in 2001. With these increases, the US Health and Human Services has estimated that medical liability costs add $60-$108B to the total cost of health care each year.

Lessons from the international environment

A systems approach

Health care is a complex system and adjusting one element of the system will inevitably lead to changes in the others. Medical liability protection does not exist in a vacuum but is inextricably linked with physician supply, overall health care costs and other elements of the health care delivery mechanism.

The French experience appears to highlight the dangers of proceeding without a full understanding of the system-wide implications of change. In this case, the uncertainty created by significant change has reduced the availability of specialist physician care. Within the American context, escalating liability protection costs are impacting the supply of specialist physicians and contributing to such undesirable and costly practices as defensive medicine. In the UK, the absence of a strong patient safety initiative may be contributing to rising costs.

These experiences suggest that changes should be well-considered not only from the perspective of the direct impact on liability protection but also in terms of secondary or tertiary impact on other elements of the system. In all but the most pressing circumstances, *this implies a progressive but evolutionary approach to system change.*

No "plug and play" solution

While the international review highlights certain practices that should be avoided, *it does not identify a single best practice model to be transported or 'plugged in' to Canada.* To be successful in Canada, a medical liability system must fit into our health, social, legal and cultural environment.

As an example, the Swedish model appears to work well within that jurisdiction as it forms one element of an extensive social welfare safety net. The Swedish model cannot however be viewed in isolation from that wider context and there could be significant consequences of assuming that one model is easily transportable to another jurisdiction.

It follows that an appropriate response is to examine elements of other models from a perspective of how they might work within the Canadian context. This entails an approach that builds on our existing foundations, applying international lessons where and when appropriate.

NO PURE "NO FAULT" SYSTEM

It is evident from the international review that there are no "pure" no fault systems operating within the medical liability arena. *The so-called no fault medical liability systems all include a significant aspect of fault determination and disciplinary referral of practitioners, sometimes without the same elements of due process that characterize the Canadian model.* For example, the New Zealand and Swedish models are often described as being no fault but both include a substantial element of physician fault finding. There are likely a number of factors that contribute to this reality:

Internationally, the so-called 'no fault' medical liability systems all include a significant aspect of fault determination

- It is human nature to want to know what went wrong and who or what was to blame.
- Unless patient compensation schemes are prepared to compensate all patients with an adverse medical outcome — whether unavoidable or avoidable — it becomes necessary to determine what is an "avoidable"[5] outcome.
- Self-regulating professions, such as medicine, require a mechanism to ensure that all of their members adhere to established standards of practice. Inherent in the maintenance of professional standards is the ability to identify fault and, when appropriate, take remedial action (additional training, discipline, loss of privileges, etc).

5 A clear and functional definition of what constitutes an "avoidable" outcome of medical care involves establishing whether the physician met the standard of care by determining whether an equally experienced physician would have made the same decisions in the same situation - a determination that must be made while disregarding any evidence gained from the benefit of hindsight.

Comparing Canada to other models

The current Canadian response to adverse outcomes, with its three elements of patient safety, physician accountability and tort-based patient compensation, appears to strike a reasonable balance between competing demands. Other countries view the Canadian system as being worthy of emulation.

However, other alternatives to tort-based compensation do exist and are worth exploring in the Canadian context. Accordingly, four models are considered based on results of the international review and prior studies performed on the Canadian situation. They are:

No Fault
A no fault model based largely on the New Zealand experience.

Combination Fault/No Fault
Based in part on the Prichard Commission recommendations, a model providing access to both tort and no fault for significant avoidable adverse events.

Severely Compromised Infant program
Segregated dealings for severely neurologically impaired children, based in part on the impaired infant programs in Florida and Virginia.

Litigation Authority
Government sponsored indemnification of medical injuries, similar to the UK's National Health Service Litigation Authority (NHSLA).

Secor Consulting has completed a comprehensive review of these four models and their implications within the Canadian context and a summary of this review is found at Appendix 3[6].

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Findings

The following section incorporates Secor's findings and examines the four models within the context of the five fundamental goals enunciated earlier (p. 8).

Reduction in adverse events

Learning from adverse outcomes and near misses is crucial to patient safety and error reduction. Given that each model examined (including no fault) inevitably involves elements of fault-finding, no single model is more intrinsically pre-disposed to supporting patient safety than any other. This finding mirrors the international experience.

6 The full Secor Consulting report is available at www.cmpa-acpm.ca.

Patient safety initiatives function most effectively when there is full and protected reporting of information. As patient safety initiatives can not be viewed in isolation from the accountability related responses, it is imperative that this full and protected reporting be accompanied by the knowledge that such information will be protected; this protection is a necessary element of the due process integral to an accountability framework.

Compensation

Within the current Canadian model, patients injured as a result of fault receive the compensation necessary to support an appropriate lifestyle. However, access is restricted to those injured as a result of fault, leading to concerns about patients experiencing adverse medical outcomes where fault did not occur.

Limitations on indemnity in the no fault model would necessarily result in lower compensation than that currently provided (albeit with a larger group being compensated). While such a system appears to work effectively in Sweden with its very strong social welfare system, such a safety net does not currently exist in Canada. Without other expensive system adjustments[7], this risks placing injured patients in the untenable position of receiving compensation that is inadequate to cover their real costs and falling back on an unprepared social safety net.

Lower compensation could create a perceived need for patients to acquire insurance to meet the gap between limited indemnification and actual compensation needs, creating potential inequities between those patients able to afford such insurance and those who are not.

Due process

By limiting compensation to patients with avoidable injuries, the no fault and hybrid models necessarily introduce fault-finding — but without the due process currently accorded to physicians and patients. This mirrors the evolution of both the New Zealand and Swedish models away from a pure no fault model to one that includes elements of fault-finding. The hybrid no fault/fault model also raises the likelihood of adversarial relationships between governments and physicians as each seeks to shift compensation responsibility to the other.

Accountability

Every model studied (either within the Canadian or international arena) involves elements of physician accountability, thereby debunking the assertion that "no fault equals no blame." Each model must therefore wrestle with and resolve the challenges associated with the competing information reporting imperatives associated with patient safety and accountability. No one model appears to have inherent advantages over any other in addressing this issue.

7 Secor estimates that if all medical treatment injuries were compensated, annual medical liability costs could rise from a current level of $225 million to approximately $40 billion. Even the application of "filters" requiring injuries to be "unintended and avoidable" could see annual system costs rise to $2.6 billion.

The deterrent, punitive and retributive aspects of the tort process meet a societal requirement for accountability and correction. It serves to:

- Deter malpractice;
- Deal with negligent practitioners when appropriate; and
- Allow a socially acceptable avenue for the retributive feelings of injured people.

The tort system has very clear processes for determining whether the physician provided the expected standard of care. It enables doctors to defend themselves against unwarranted allegations of negligence and respects due process and the requirements of natural justice. No fault and litigation authority systems offer little in the way of explanation to an injured patient and do not provide a strong deterrent effect; they may however significantly impair due process, with a resultant negative impact on a physician's professional standing.

Affordability

Even with the application of conservative estimates of compensation levels and the imposition of limitations to only avoidable injuries, the costs associated with the no fault, hybrid no fault/fault and litigation authority models represent a multiple-fold increase over those of the current system[8]. In an already stressed health care system, it is not apparent how such significant cost increases could be absorbed or how society would respond to this potential diversion of funds from either direct health care delivery or other national priorities. In the New Zealand experience, this appears to have led to the imposition of filters or stringent criteria to manage the number of compensation cases and the resulting associated costs.

Additional findings

A segregated compensation system for compromised infants, regardless of cause or fault, would be more costly than the current mode[9] but poses some potential advantages. The most appealing of these advantages might be a greater degree of societal equity, particularly in many of the circumstances where cause or fault is difficult to determine. However, careful consideration and clear delineation of parameters and responsibilities would be needed if the challenges experienced in US jurisdictions are to be avoided. A segregated compensation system must be an integrated element of a social safety net and as such, a decision to proceed in this direction is one largely of social (rather than medico-legal) policy and would require political will.

The litigation authority model implies a shift in the relationship between governments and physicians towards one in which physicians are "employees." This has impacts on the provision of health care and a patient's access to unbiased advice and treatment that extend far beyond considerations of medical liability.

8 Secor Consulting has estimated that the annual costs of a no fault system could range from $2.6 billion with filters to a high of $40 billion with no "filters". This latter figure can be achieved only by limiting both access to and the level of compensation. Depending on the criteria applied, a combination tort and no fault approach (the Prichard recommendations) could cost between $1.7 and $2.8 billion annually.

9 Secor Consulting estimates that a Canadian compromised infant program (similar to that operating in Florida) could add an additional $220 million in annual costs, approximately doubling currrent system costs of $225 million per year.

SUMMARY

The following table summarizes the impact of the current and alternative models on the three responses of patient safety, physician accountability and patient compensation:

Model	Patient safety	Physician accountability	Patient compensation (access and cost)
No fault	Does not intrinsically support patient safety but can be structured to do so.	Requires a parallel physician accountability framework and clear reporting rules.	Likely to increase the number of patients compensated and result in significantly increased costs.
Combination model (no fault and tort access)	Does not intrinsically support patient safety but can be structured to do so.	Requires a parallel physician accountability framework.	Likely to increase the number of patients compensated and result in significantly increased costs.
Government indemnification (Litigation Authority)	Does not intrinsically support patient safety but can be structured to do so.	Requires a parallel physician accountability framework.	Depending upon filters applied, could (but not necessarily would) result in greater accessibility and higher costs than the existing system.
Compromised infant	Does not intrinsically support patient safety but can be structured to do so.	Requires a parallel physician accountability framework.	Eliminates the perceived inequity of the existing system for one group of claimants but does so at an increased cost.
Current system	Requires clear reporting rules to encourage patient safety while safeguarding due process for accountability and compensation.	Has a strong physician accountability framework.	Provides for appropriate compensation but limits the number of injured patients receiving it.

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This examination of the existing and four alternative models highlight the challenges of dealing with a complex system of inter-related components. Options that might appear to address one demand (such as the desire for increased access to compensation) result in negative impacts in other areas (such as greatly increased costs). Similarly, options that seek to improve patient compensation have unintended consequences and raise new challenges in other areas (such as patient safety and physician accountability).

Achievable improvements

Secor Consulting reports that, while the Canadian medical liability system is considered to be a world-class model by other nations, it can be further improved to make it more effective and to reduce those costs that do not contribute directly to the practice of good medicine or to the compensation of injured patients. While there remains a great deal of work to be done in clarifying reporting rules and protecting information in order to meet the competing demands of the patient safety, physician accountability and patient compensation imperatives, positive changes are readily achievable in the short term.

It is believed that a select number of achievable, evolutionary changes can improve the existing system while slowing its rising costs. These changes have only positive impacts on the overall health care delivery system and the complementary responses of patient safety and physician accountability.

Opportunities for positive change

There are a number of achievable initiatives for improving the existing medical liability system; these initiatives fall into four main categories:

- Addressing information reporting and improving processes to enhance patient safety efforts;
- Reducing transaction costs without negatively impacting patient compensation;
- Enhancing the judicial processes; and
- Further exploring a segregated compensation system for compromised infants.

Information reporting

Patient safety efforts require full reporting and analysis of all relevant information from all adverse events and near misses and yet, as noted earlier, this often creates a perceived conflict with the right to due process imperatives of physician accountability and patient compensation. Legally prescribed reporting is necessary to enable physicians and others to adequately defend their integrity in either patient compensation proceedings or professional tribunals.

Canadian practices could be quickly improved by requiring health care professionals to fully report, within a patient safety context, all information concerning adverse events, while guaranteeing that none of this information will be made available for accountability or patient compensation processes. The two latter activities would continue to be guided by existing reporting rules. The impenetrability of this information "firewall" would largely resolve the competing reporting imperatives and greatly contribute to maintaining an appropriate balance in the system. This positive change can be readily achieved through amendments to legislation.

The Canadian medical liability system is considered to be a world-class model by many nations, but improvements are possible

Reduced transaction costs

There are also steps available to reduce the transaction costs associated with the current system:

- Some Canadian provinces have existing provisions that mandate the use of structured settlements within medical liability cases but such provisions are not widely used. Such settlements involve an annuity instrument, underwritten by the secure life insurers, that provides the injured patient with a life-time tax-free income stream. This approach ensures funds are available for the life of the patient while — in comparison with a lump sum payment — substantially reducing the costs of providing the same level of benefits. The injured patient receives the same benefit (with added benefit of it being guaranteed for life) while the medical liability system incurs lower costs[10].
- Many provincial governments currently include their costs of providing health and social services to injured patients as part of the legal settlement. This practice[11] necessarily increases settlements costs and, by extension, medical liability system costs. However, as a significant portion of medical liability system costs are paid by provincial governments in lieu of fee increases to physicians (through their reimbursement of physicians' CMPA membership fees), this produces a circular movement of money from one government department to another department. It is expensive to administer and represents "transaction" costs that are of no benefit to the injured patient.

In a resource-constrained environment, the sensible approach would be to refine the existing medical liability system while focusing effort and resources on patient safety and risk management

Judicial system enhancements

There are several discreet and attainable changes within the judicial system that would reduce transaction costs associated with civil actions while still protecting the rights of the parties, patient, physician and hospital. These changes include but are not limited to the availability of mediation or other pre-trial settlement opportunities; appropriate pre-trial production of expert opinion; access to case management particularly in high-severity cases; periodically reviewed guidelines for the courts on damage; and a code of conduct and scientific integrity for those who agree to function as experts in personal injury cases.

Segregation compensation system for compromised infants

The potential benefits of adopting a segregated compensation program for compromised infants are considerable and might address the social justice challenges inherent in determining fault in circumstances where such determinations are difficult if not impossible to achieve. While the cost and jurisdictional difficulties associated with this social policy initiative would be significant, these potential implementation challenges should not dissuade federal, provincial and municipal governments from collectively examining such a model in more detail.

10 A CMPA study, using benchmark assumptions, identified a potential savings of approximately $8.9 million would have been achieved in 2004 if structured settlements were used in cases where damages exceeded $250,000. In the province of Ontario, the projected $3.9 million in savings would have represented approximately 7% of the total damages paid out.

11 The process is known as "subrogation."

Conclusion

Medical liability is an essential element of any complex health care delivery system. As such, assuring an effective and efficient medical liability mechanism should be of utmost importance to Canadians, to decision-makers, be they federal or provincial governments, the judicial and legal communities, licensing and regulating bodies, professional organizations, practicing health care professionals, and those advocating the interests of injured patients.

The current Canadian system responds to adverse medical events in three separate but related ways by:

- Identifying the event's cause so as to reduce the number of future events and improve patient safety;
- Holding individuals accountable for errors made; and
- Compensating patients injured as a result of negligence.

While there are necessarily competing imperatives inherent in these responses, particularly in terms of information reporting and analysis, an improved version of the current medical liability system is likely to be the most effective within the Canadian context. When models used in other jurisdictions are applied to the Canadian environment, the likely results are less than those currently being achieved. A review of the international environment also highlights the need to fully consider the wider system impacts associated with making changes to medical liability regimes.

The competing information reporting imperatives should be addressed to encourage full and protected reporting and analysis for patient safety purposes while, at the same time, providing for legally prescribed reporting where accountability will be determined (in effect creating an information "firewall"). In the short term, the establishment of such a "firewall" protecting patient safety information would be a readily achievable first step.

Within the realm of the current tort-based patient compensation system, common sense reforms are achievable in the near term that both protect the interests of all parties yet reduce the non value-added, transaction costs that do not compensate injured patients and also draw valuable resources away from other health care demands. Action on these pressing and sensible changes need not wait for wider system improvements and could make a tangible difference in the short term. In addition, adopting a discrete number of enhancements to the judicial system would also have a positive impact.

Few services are more vital or prized by Canadians than the provision of effective and efficient health care. Canada can be rightfully proud of the system currently in place but must also be cognizant of the many pressures being exerted on it. While medical liability issues are but one area exerting such pressure, they form an important component of the overall system and should be addressed within the context of overall system dynamics.

The current medical liability system in Canada is fundamentally sound and is very likely the best possible model for our circumstances. Alternative patient compensation models require significant additional financial resources and yet do not, by themselves, advance patient safety efforts. While this realization should cause decision-makers to pause before considering drastic changes to the existing model, it should not deter the application of common sense reforms.

The sensible approach, in a resource-constrained environment, is to refine the existing medical liability system while focusing effort and resources on patient safety and risk management. Only by reducing the probability of adverse medical events will the health care system ultimately decrease system costs and improve patient outcomes.

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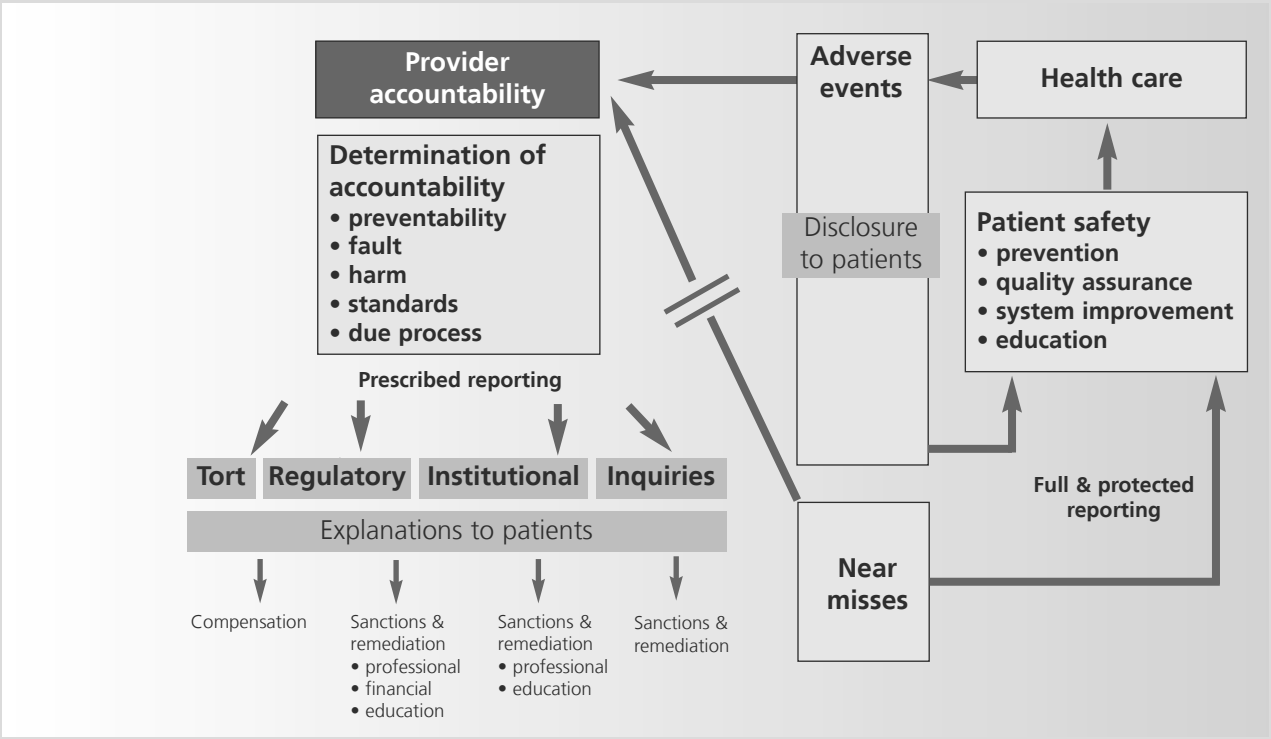
APPENDIX 1 — THE CANADIAN MEDICAL LIABILITY SYSTEM



The above diagram depicts the three responses that emanate from an adverse event:

- Patient safety related responses aimed at reducing the number and the magnitude of future adverse events;
- Accountability responses that include both:
  - Actions to ensure that, if a physician makes an error, that physician is held accountable; and
  - Patients injured as a result of negligence for which a provider has been found to be accountable are appropriately compensated.

APPENDIX 2 — INTERNATIONAL CASE STUDIES

Summary descriptions of five international medical malpractice models have been drawn, in part, from a more comprehensive study completed by Secor Consulting.

UNITED KINGDOM — a public run litigation program providing some insight into the financial commitment required to support such a program.

FRANCE — a system that incorporates elements of fault, no fault public and private health care but one that has not yet reached equilibrium.

NEW ZEALAND — accident compensation program, often referred to as comprehensive no fault but under which, for most cases, fault plays an important element.

SWEDEN — a comprehensive no-blame system, supported by the pillars of its culture and strong social net.

UNITED STATES — a tort-based system, with multiple states in "crisis."

UNITED KINGDOM: PUBLIC RUN LITIGATION

Health Care System

The National Health Service (NHS) was established in 1948 to provide free healthcare to residents of the United Kingdom (UK). Each time a patient visits a doctor in, or receives treatment at, a public hospital, the treatment is provided free of charge. The NHS is funded through general taxation and is administered by the Department of Health.

Patients also have the option of paying for private healthcare either through insurance or personal resources when they use medical services.

In recent years, the structure of the NHS has undergone considerable change. The private sector now has a role in supplying and funding some NHS buildings and services. The decision-making authority is being devolved to local communities and the NHS has adapted its practices to the different countries of the United Kingdom.

Medical malpractice environment

The medical malpractice system in the UK is tort-based, with government-sponsored indemnification for events occurring in public hospitals. Several groups participate in the system in the United Kingdom. These groups include the National Health Service (NHS) Trusts that manage public hospitals and clinics, and the NHS Litigation Authority (NHSLA), responsible for insuring all work done in the Trusts. There also are three medical defence societies, which provide protection to member physicians in private practice, assistance to all members with regulatory (General Medical Counsel) inquiries, and general medical-legal and risk management advice.

Performance of the system

In the opinion of the various stakeholders (doctors, claimants, defendants and hospitals), the present system is working well with claims being resolved relatively quickly and fairly. However, the Government's commitment to medical malpractice liability has risen to £7 billion (Cdn$ 15.2 billion) as of March 2005, and, in the private domain, fees have also increased.

Recommendations from the stakeholders for changes to the system include improvements in terms of patient safety and better dissemination of information. The National Patient Safety Agency (NPSA) is responsible for monitoring all adverse incidents in the NHS, regardless of whether they are linked to a claim. The NPSA's key priorities include setting up a national reporting and learning system for adverse events, providing practical solutions to improve patient safety and promoting their adoption, and developing an open and fair culture in the NHS that encourages all healthcare staff to report incidents without undue fear of personal reprimand.

Some groups have noted a large number of physician license suspensions in the UK. Both the Medical Protection Society (MPS) and the National Clinical Assessment Authority (responsible for helping resolve doctor performance issues) believe that doctors are facing high sanctions and that suspensions are being meted out for "system" errors. These suspensions have a profound effect on reputation. Moreover, physicians, having being sanctioned professionally, can also be tried in civil and/or criminal court.

FRANCE: A SYSTEM WITH MANY ELEMENTS

Health care system

In 2000, the World Health Organization (WHO) classified the French healthcare system as the "best health system in the world" and it permits all French citizens access to treatment. Medical care is either entirely free, or is reimbursed 100% for more than 96% of the population. The French also have the right to choose among healthcare providers (public, private, university, general hospital) regardless of their income level.

In France, health insurance is a branch of the social security system. It is funded by workers' salaries, by indirect taxes on alcohol and tobacco and by direct contribution based on income. More than 80% of French people have supplemental insurance, often provided by their employers. The poorest have free universal health care that is funded by general government revenues.

Medical malpractice environment

The French medical malpractice system incorporates elements of fault and no fault.

A fault system exists for injured parties when the physician cannot demonstrate that the injury was not caused by his or her doing. Injured parties have access to civil, criminal, administrative and professional tribunals and they may access one or more of these tribunals sequentially or concurrently.

A no fault system is in place for injuries resulting in invalidity of at least 25% when either no fault is declared or when the cause of the invalidity is a nosocomial infection. Claims are submitted to regional commissions that determine claim eligibility and fault. The National Office of Medical Compensation (Office National d'Indemnisation des Accidents Médicaux — ONIAM) takes responsibility for no fault payments. If the regional commission finds that there has been fault, the claimant must petition the practitioner's insurance for indemnification. Insurers can either accept the commission's findings or offer zero payment at which time the claimant can choose to enter the judicial system. While injured parties have access to the tort system for injuries regardless of the commission's ruling on fault, a victim's acceptance of an offer of compensation from the commission prevents them from making a claim through the courts.

Doctors within the public system have their premiums paid by their institution, while doctors in private practice must pay their own premiums.

Performance of the system

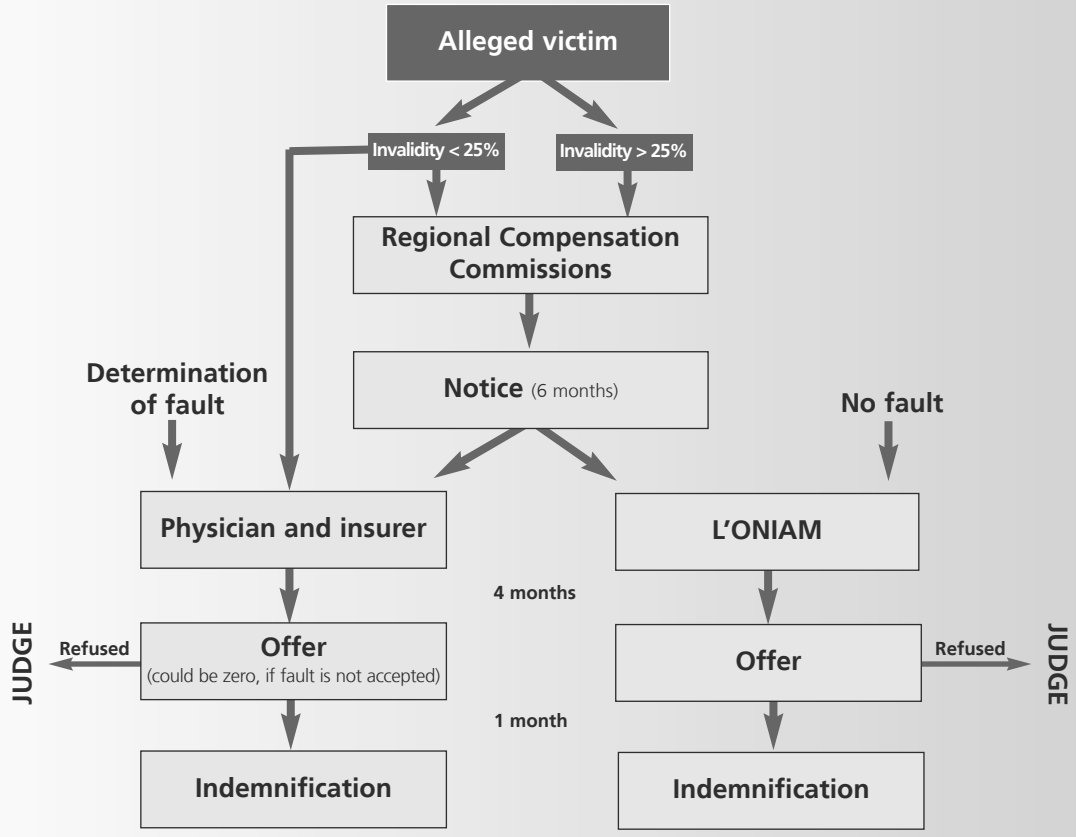
Recent changes have created uncertainty in France's medical malpractice system. The "Loi Kouchner" (2002) divided the system into the two streams of fault and no fault and made it mandatory for doctors to have insurance. The "Loi About" (2002) transferred the responsibility for hospital infections to ONIAM and changed the rules of timing for claim eligibility. These changes were implemented to attract insurers back into the marketplace. However, in the face of uncertainty, the exit of insurers has continued, driving up insurance costs to levels that have caused some specialists to manage their risks by reducing their practice, changing fields or retiring. These actions have affected the supply of medical treatment.

Despite the recent changes to the system, there remains an absence of structured risk management. This shortfall does not appear to be a priority for physicians, the Minister of Health or insurers. This is evidenced by the limited scope of the recently established Observatoire des Risques Médicaux whose role is to collect, clean and report information on accidents at an aggregated national level. The Observatoire des Risques Médicaux has no mandate to improve safety other than to share its information with hospitals and the Haute Autorité de Santé.

When an action is launched, it is the physician's or the institution's responsibility to demonstrate to the regional commission that there was no fault associated with the injury. Lacking a specific determination of fault, the state, through ONIAM, provides indemnification that results in the physician being less likely to be held accountable through professional sanctions. Unlike the other systems noted in this appendix, the French example puts the emphasis, from the outset, on the avoidance of accountability.

Exhibit 1 presents an overview of the indemnification process in France showing the paths for each of the fault and no fault based indemnification processes.

Exhibit 1
The indemnification process in France



NEW ZEALAND: ACCIDENT COMPENSATION PROGRAM

Health care system

New Zealand has a parallel system of public and private health services. Public health care is subsidized by the New Zealand Government while the individual pays for private health care. Individuals who can afford to pay for private health insurance do so while those who cannot, use the public health system.

In New Zealand, health problems are essentially divided into two categories: health problems that arise out of an accident and health problems that do not arise out of an accident. Health problems that arise out of an accident are subsidized by the Accident Compensation Corporation (ACC).

The medical misadventure component of the ACC, which deals with the indemnification of victims of medical treatment injuries, represents approximately 2% of the ACC's claim amounts. At inception of the ACC program, the injured party's right to sue was removed with "swift, scheduled payments" being provided in its stead.

Medical malpractice environment

Often referred to as a no fault system, New Zealand's accident compensation scheme consists of the ACC, a national insurance program that covers all bodily accidents caused by automobile, workplace, day-to-day life, medical treatment and exceptional incidents.

Under the medical misadventure component of the ACC, any victim of a medical treatment injury may apply for compensation. Claims must meet one of two conditions to be accepted: a medical error occurred and fault has been established by the ACC or, a medical mishap occurred and caused a "rare and severe" injury under an accepted treatment

For every 100 claims filed, 60 are rejected. Of the 40 approved, 15% are found to be the result of medical errors and 85% are found to be the result of medical mishaps causing a "rare and severe" injury. An appeal route exists for both sides.

Performance of the system

The annual cost for medical misadventures has risen recently. The total cost of $36 million (2003-2004) represents almost $10 per capita (15% higher than the per capita cost of the current tort-based system in Canada). Despite these high and rising costs, indemnity payments are comparatively low at, on average, between $2,000 and $5,000. When future claims liabilities are considered, the medical misadventures account is carrying $213 million reserve deficit (2003). The government is working to bring the account into a self-sustaining equilibrium by 2014.

The medical malpractice system in New Zealand was formally reviewed in 1982, 1992, 1998, 2001 and a new review was undertaken recently. The motivation for the reviews and their associated changes is twofold: to manage risks and to control costs. However, in some instances, the risk management and cost control objectives are in conflict.

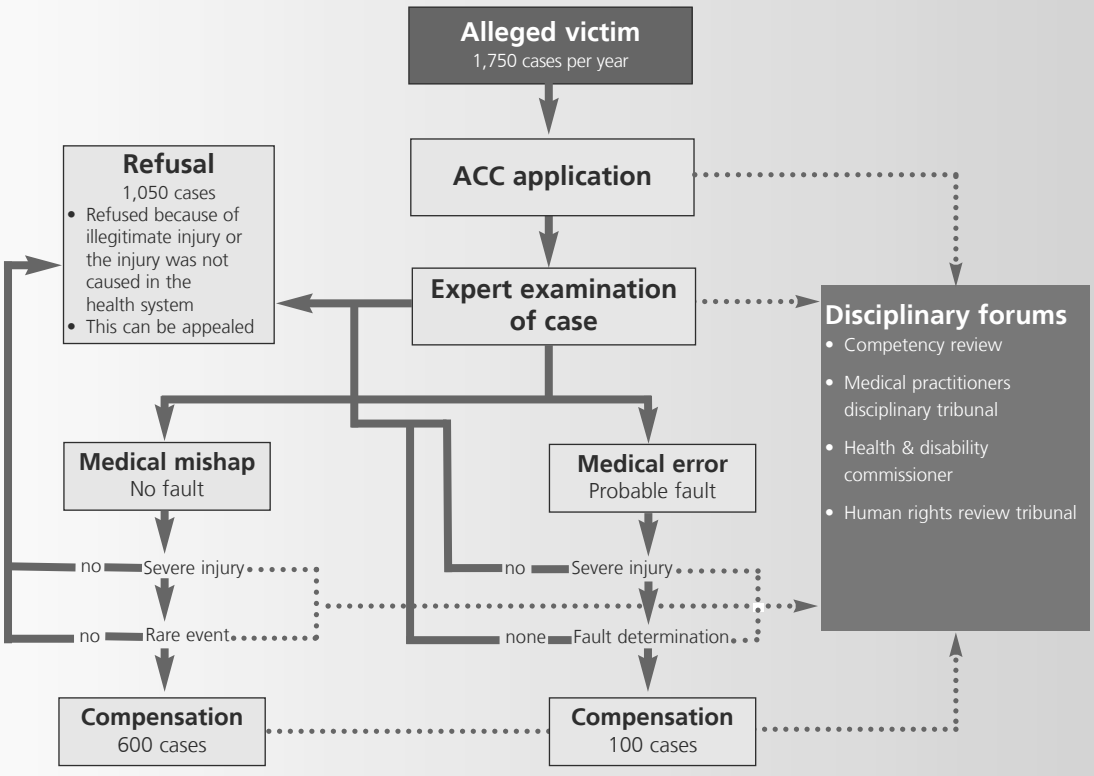
Patients' rights and physician accountability are managed by New Zealand's Health and Disability Commissioner (HDC). The HDC and several additional tribunals can all issue sanctions including suspension of license to practice and fines up to

$200,000. Since, by definition, "medical errors" involve an element of fault, there is pressure in the New Zealand system to find fault. While the ACC provides physicians medical malpractice insurance, once fault for a medical treatment injury is determined, physicians are open to professional, financial and legal sanctions. This creates conflict in the system as open participation can result in later sanctions.

An interesting aspect of recently proposed reform in New Zealand involves the separation of injury compensation from the determination of responsibility. This important separation may serve to encourage physicians to participate in the claims settlement process and thereby strengthen the patient safety aspect of the system. For this measure to truly have an effect on patient safety, not only should compensation and responsibility have a clear separation within the ACC, but also physicians must trust that determination of responsibility will not compromise their position in other forums like the HDC.

Exhibit 2 presents an overview of the indemnification process in New Zealand, showing the two paths, Medical Mishap and Medical Error and relationship to the Disciplinary Forums, together with approximate annual transaction volumes.

Exhibit 2
The indemnification process in New Zealand



Sources: interviews, ACC, Secor analysis

SWEDEN: COMPREHENSIVE NO-BLAME

Health care system

A fundamental principle of the Swedish health care system is that the provision and financing of health services for the entire population is a public sector responsibility. This responsibility rests primarily with the county councils. These councils operate almost all public services and levy taxes to finance them. As a consequence, health services in Sweden rest largely in the hands of local politicians in 21 geographical areas.

Health services account for almost 90% of the operations of the county councils. Approximately 70% of these operations are financed from tax revenues and the remaining 20% are financed by grants and payments received from central government finance for certain services. Patient fees amount to approximately 4% of county council revenue. To limit personal health care expense, there is a ceiling (approx. $150 CDN) on the amount of patient fees a patient can be charged in a twelve-month period. All medical treatment for children and young people under the age of 20 is free of charge.

Sweden has an extensive system of benefits for the sick that also includes compensation for participation in labour market rehabilitation schemes and benefits payable to expectant mothers who are unable to work during pregnancy.

The system's reliance on a comprehensive social net and a non-litigious culture limits the system's portability to only those jurisdictions in which these fundamental pillars exist.

Medical malpractice environment

In general, the medical malpractice system in Sweden is viewed very positively and it has now been replicated in Finland, Denmark and Norway. The key criterion that triggers compensation for a medical related injury in Sweden is that the accident must have been avoidable. This is determined through an evaluation of whether an experienced doctor would have had a different result. Health care providers actively participate in the claims process, with approximately 65% of all claims being made with the help of a social worker, physician or nurse.

Risk management is an important component of the system that is supported by a database of claims developed by the County Council and Region's Mutual Insurance Company available for each hospital. Sweden also works closely with other Nordic countries to develop risk prevention approaches. The various parties involved in risk management agree that most errors are caused by the system in place.

30

Performance of the system

One insurance company covers approximately 95% of the medical malpractice liability protection market. Compensation for injuries ranges widely from less than 1,000 euros up to 800,000 euros, with the total, in most cases, being less than 2,000 euros. Compensation is paid on a “top-up” basis, as the strong health care and social system pay most of the costs of indemnification.

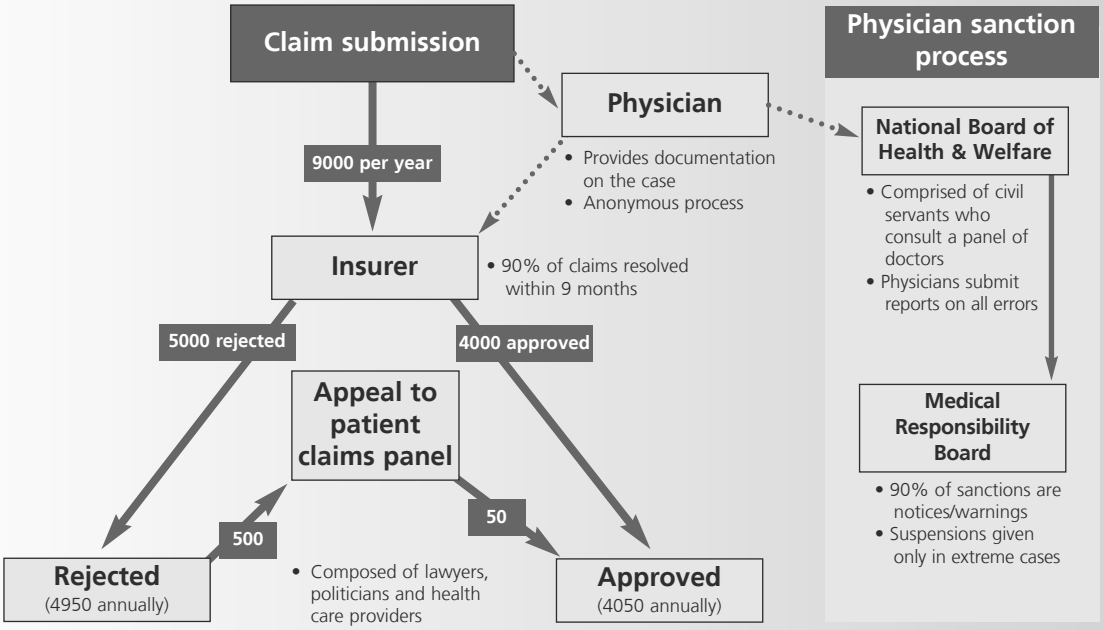
The insurer is responsible for reviewing claims, of which approximately 45% are approved. Even with the potential for moral hazard, the system seems to be functioning well, as only 10% of claims are appealed, and of those, only 10% are overturned.

In the Swedish system, the process through which physicians are held accountable is separate from the process through which compensation decisions are made. The information physicians provide to the insurer responsible for compensation decisions is provided anonymously. Physicians also submit reports on all errors to the National Board of Health and Welfare. As a result of this structure, physicians now play an important part in the claims process. However, it took approximately 10 years before physicians were comfortable participating at this level.

The most significant issue with this system is its portability. Payments in Sweden have always been low relative to other countries. The system's reliance on a comprehensive social net and a non-litigious culture limits the system's portability to only those jurisdictions where these fundamental pillars exist.

Exhibit 3 presents an overview of the claim processing system and relationship to the Physician Sanction Process in Sweden with approximate annual transaction volumes.

Exhibit 3
Claim processing system in Sweden



UNITED STATES — A SYSTEM IN CRISIS

Medical system

In the U.S., the majority of health care funding comes from the private sector, most notably through insurance provided at the workplace. Two government-run programs, Medicare and Medicaid, provide health insurance to people with low income and the elderly.

Medical malpractice environment

Multiple factors are stressing the U.S. medical malpractice system. Compensation awards have increased dramatically and the U.S. Health and Human Services has estimated that medical liability costs add $60-$108 billion to the total cost of health care each year. Multiple groups are pushing for reform. As of July 2005, the American Medical Association (AMA) considers 20 states as being in a full-blown medical liability crisis.

Florida case study

Over the last few years, the cost of medical malpractice insurance increased dramatically in the state of Florida and large loss ratios contributed to the exit of insurers from the state. In response to these conditions, in 2004 more than 5% of Florida's almost 50,000 physicians had adopted the drastic measure of "going bare," that is, not taking any insurance at all.

The Florida Birth-Related Neurological Injury Compensation Association (NICA) is a no fault compensation plan that was adopted in 1988 because tort claim costs in this area were particularly high, and because a no fault system limited to this area was feasible and would involve manageable costs. The program is limited to injuries that render the infant permanently and substantially mentally and physically impaired. Compensation for expenses is structured, including payment for "necessary and reasonable" expenses.

NICA is performing well financially. The program began with a one-time appropriation of $20 million and is financed on an ongoing basis by a combination of state funds, assessments on physicians and hospitals and participation fees.

Performance of the Florida NICA system

Some studies have shown that NICA has under-performed by compensating fewer claimants than expected and a substantial proportion of cases (7%) still go to the tort system. Compensation for expenses is paid over the lifetime of the child and includes necessary and reasonable care, services, drugs, equipment, facilities, and travel. Compensation may also include a one-time cash award, not to exceed $100,000, to the infant's parents or guardians, for funeral expenses and reasonable expenses for filing the claim, including attorney's fees.

In general, NICA is an efficient system, with approximately two-thirds of claims being completed within six months. The physician experts and the judge involved in NICA have participated in the program almost since its inception. These experienced experts are key to NICA's efficiency. While NICA is efficient and has slowed increases in premiums, it is not the complete solution. This is evidenced by the malpractice insurance premiums for OB/GYNs in Florida that are still among the highest in the nation.

Appendix 3 — Alternative Scenario Models

This appendix provides an overview of four possible alternative medical malpractice protection models, drawing on the understanding of international models and prospectively applied in the Canadian context. The analysis was completed by Secor Consulting through rigorous modelling of each scenario based on the elements of cost, accessibility and compensation[12] A discussion of the potential benefits, trade-offs and the predicted consequences of these trades-offs is presented for each scenario.

The following four scenarios were modelled and are described in the following pages:

- A pure, all in no fault compensation system
- A combination of tort and no fault (based on the Prichard recommendations)
- Government indemnification with tort-based filter (similar in principle to the NHSLA)
- A segregated compensation program for severely compromised infants (similar to the NICA program in Florida)

For comparative purposes, based on data from the past six years, average annual costs for the Canadian medical malpractice system are approximately $225 million, including indemnities of approximately $110 million (49%), and for administrative costs, legal and expert fees of approximately $115 million (51%). Hospitals carry separate property and casualty insurance and are excluded from these estimates. While the Canadian system is inexpensive in comparison to other models, accessibility to compensation is limited to cases in which either fault is proven or a settlement is made.

Observations: Alternative medical malpractice programs in Canada

In order to control costs, significant compromises would be required to any system that incorporates an element of no fault. An all in, no fault system would be a multi billion dollar investment. Even limiting the program to "unintended and avoidable" injuries, as is done today in Sweden, would involve potential costs of up to $1.7 billion per year. A government run litigation authority in Canada would commit the government to billions in future liabilities. This is supported not only by the quantitative analysis completed for this report but also by the NHSLA experience in the UK The introduction of a segregated compensation program for severely compromised infants would remove a controversial component from the current system, but in so doing, could more than double the cost of medical treatment injury indemnification while only benefiting a small percentage of cases.

While it is true that the three scenarios that incorporate elements of no fault improve accessibility, this accessibility comes at a cost. This cost would likely be borne in part by patients through access to lower indemnity payments, in part by physicians through increased protection fees and in large part by society through considerable increases in the cost of healthcare.

12 The full Secor Consulting report is available at www.cmpa-acpm.ca

The implications of this analysis on public policy are significant. None of the modelled scenarios result in reductions to Canada's medical treatment related injury indemnification costs. Rather, most appear to increase costs significantly and to potentially unsustainable levels, thereby presenting a serious threat to the quality of healthcare in Canada.

It appears that there are two potential paths that reform to Canada's medical treatment injury indemnification program could take. The first path involves a funnelling of significant health care dollars into victim compensation. The price tag of such a move is high with the benefits being limited to a small group. The second path involves maintaining the current indemnification program and funnelling efforts and dollars into patient safety initiatives. This path maintains current victim compensation levels and leads to the reduction of future injuries entering into the system.

The importance of patient safety initiatives has been recognized in Sweden where the various stakeholders are engaged in the risk management and patient safety initiatives and are working to address what all agree are the most significant source of medical errors, the medical system itself. Yet, the success of patient safety initiatives is not limited to the Nordic countries. The progress made by anaesthetists in the U.S.[13] provides a strong example of risk, injury and cost reduction related to a focused, committed and coordinated patient safety initiative.

While this review was based on primary research (including interviews with key stakeholders in each of the systems discussed), secondary research and rigorous quantitative modelling, it is important to note that medical treatment injury liability systems do not operate in a vacuum. Their performance is impacted by social, legal, cultural and historical factors. It is difficult, if not impossible, to evaluate the performance of a medical liability protection program without considering the environmental impacts. It would be, therefore, unwise to believe that a whole system or an even the key elements of a particular international model (such as no fault) would perform similarly if was it to be "exported" and overlaid on an existing system operating elsewhere.

13 Patient safety initiatives contributed to the reduction over the last two decades of anaesthesia related deaths from 1 death per 5,000 cases to 1 per 200,000 to 300,000. Premiums paid by anaesthetists have also reduced dramatically over this period.

A COMPREHENSIVE NO FAULT COMPENSATION SYSTEM

Description

A comprehensive no fault system would provide indemnification to all victims of medical treatment injuries. In the absence of a fault filter, approximately 410,000 cases would be eligible to enter the system. Under a pure no fault system, a "suitable" level of compensation would need be determined, likely through the creation of a standard indemnification table.

Results

The cost associated with admitting all medical treatment injuries is significant. Compensating injuries at even half of current compensation levels would drive the total annual program cost up from $225 million to $40 billion per year. This represents an approximate 150-fold increase over the current program's combined cost of awards, settlements, administration, legal and expert advice.

Discussion

For patients, this system would provide universal access to per case indemnities of, on average, approximately $235,000. However, at 150 times the cost of the current program, it is unclear how the medical community could finance this program or how the healthcare system could support an almost $40 billion dollar increase in healthcare costs. As such, the sustainability of this type of system appears to be questionable. It is also unclear how society would react to a $40 billion dollar increase to the cost of healthcare that is neither focused on improving the safety nor on improving the performance of the healthcare system.

If implemented, few options would be available to control the cost of such a system. Either compensation levels would have to be reduced dramatically or some form of filter would be needed to limit the number of claims entering the system. To maintain the current program costs of $225 million per year, average indemnity payments in a no fault system would need to be reduced from the current $235,000 to less than $1,000. Alternatively, the number of cases entering the system could be reduced by compensating only "unintended and avoidable" injuries, as is done currently in Sweden. It is estimated that 90% of injuries would not meet this criteria. However, even by applying this filter and reducing per case indemnities to 25% of today's level for smaller claims and to 50% of today's level for the few larger claims, the total cost of the program would rise to an estimated $2.6 billion per year.

Limits would be needed to control the costs of a no fault system. However, the reintroduction of fault negates the perceived benefits of removing blame from the system. Further, determining the correct criteria for payment and an appropriate compensation level would likely prove difficult. Even with these limits in place, it remains unclear how an additional $2.6 billion dollars in health care costs focused solely on injury indemnification would be viewed and paid for by the healthcare system's stakeholders.

A COMBINATION OF TORT AND NO FAULT

(based on the Prichard recommendations)

Description

The Prichard Report was commissioned by Canada's deputy health ministers in 1990 to review other medical liability systems, literature and legal precedent, Canadian malpractice claims trends and Canadian stakeholder opinion. Prichard's recommendation involved a no fault option for persons suffering "significant avoidable health care injuries." Access to the tort system would remain in place for those and all other victims. This change from the fault-based nature of the current system to "avoidable" would reduce the filter and would therefore allow more claims into the system.

Results

Based on Prichard's own assumptions, such a change would increase the number of claims flowing into the system. If the "significant" injuries were compensated through the no fault system at today's levels, leaving the smaller claims to access the tort system, the total cost of medical liability could rise from today's level of $225 million to $2.8 billion per year. A significant reduction in per case no fault payments could be expected to drive the "significant" claims back into the tort system. As such, per case no fault indemnities would have to be maintained at a level that is high enough to create an incentive for victims to use the no fault portion of the system. At that level of compensation, given the predicted increase in the number of claimants accessing the system, costs could be expected to rise to $1.7 billion per year.

Discussion

The limits set on per claim compensation for the no fault system would result in a transfer of liability between the no fault and fault streams. This give and take relationship could contribute to friction among different parties in the system and could create an incentive for either party to counsel the potential claimants to use the other option.

Applying the "avoidable" test is similar to the idea of a fault filter and would still involve the notion of blame. This neutralizes one of the more frequently heard arguments in favour of no fault systems, namely the removal of blame from the system.

As was highlighted in the discussion of the no fault system, it is not clear how an additional $1.5 to $2.5 billion dollars per year in health care costs focused solely on injury indemnification would be viewed and paid for by the healthcare system's stakeholders.

Government indemnification with tort-based filter

(similar in principle to the NHSLA)

Description

There are several compelling reasons to study the potential impacts of a government run indemnification program that applies a tort-based filter to limit the number of claims entering the system. First, this type of approach is in place in the UK and, by all accounts, is functioning well. Second, for the reasons cited in the discussion of the first two scenarios in previous pages, a significant reduction in indemnity payments is an unlikely solution to controlling the cost of a pure or restrictive no fault system.

This scenario, which follows the principles of the NHLSA system from the UK, presents a public indemnification scheme with a tort-based filter that limits the number of cases entering the system.

Results

The financial implications of such a system would depend largely on the objectives set by the government litigation authority. If the objective was to broaden access, within five years the total program liabilities[14] could be expected to top $10 billion per year. If the objective was to expand access but maintain costs, per case indemnities would need to be reduced in proportion to the increase in access. Even with this trade-off, yearly premiums required to maintain an actuarial balance would surpass today's level by year 7 before reaching $350 million per year by the 10th year of operation.

Discussion

The government taking on the role of self-insurer of its physician "employees" would represent a significant paradigm shift and create a relationship that neither group may accept. This shift would also transfer significant liabilities to the public sector.

This scenario could prove difficult to implement in the Canadian Federal-Provincial context. It could create issues related to territory and jurisdiction if run at the federal level and issues of efficiency and debt allocation if managed by the provinces.

14 The amount required to cover current and future claim liabilities

SEGREGATED COMPENSATION SYSTEM FOR COMPROMISED INFANTS

Description

This scenario explores two alternatives for managing birth-related neurological injury compensation. In the first alternative, all "severely compromised" infant cases would be compensated at the same level as the current tort system. In the second alternative, which would be more similar in its functioning to the NICA program in Florida, significantly compromised infant cases would be indemnified at a level that covers all reasonable expenses for the life of the victim. In both options, all cases not related to severely compromised infants would continue to flow through the tort-based system that is in place today.

Results

Indemnifying all severely compromised infants at current day levels, would add $383 million per year to the total cost of medical treatment injury indemnification, due to the increase in the number of cases that would be indemnified.

In the second alternative, by allowing all severely compromised infant cases to enter the system and compensating at a "fair and reasonable" level, the total cost of medical treatment injury indemnification would be expected to increase by $221 million to $446 million per year.

Discussion

A NICA-type program has the potential to reduce the "lottery effect" of a tort-based system for severely compromised infants. That being said, the selection criteria would be an important factor in the success of the program. While admitting all cases would be expected to add between $221 million and $383 million per year to the total cost of medical treatment injury indemnification, this option would take a controversial component out of the current tort system.

The Canadian Medical Protective Association

Who we are

As a mutual defence organization that provides education, advice, legal defence and indemnification to more than 66,000 member physicians across Canada, the Canadian Medical Protective Association draws on more than 100 years of expertise in managing risks in clinical practice to assist physicians in providing medical care to patients.

The CMPA is a not-for-profit medical mutual defence association founded in 1901 and incorporated by a 1913 Act of Parliament. As a mutual defence organization, the financial costs, savings and risks are shared amongst its physician members.

The original principles set out in its 1913 Act of Incorporation require the CMPA to:

- Support, maintain and protect the honour, character and interests of its members.
- Encourage the honourable practice of the medical profession.
- Give advice and assistance to and defend and assist in the defence of members of the Association in cases where proceedings of any kind are unjustly brought or threatened.
- Promote and support all measures likely to improve the practice of good medicine.

Vision

The Canadian Medical Protective Association will be recognized as a valued national resource committed to defending the professional integrity of doctors and will lead by promoting and supporting those medico-legal and practical measures likely to improve the practice of medicine.

Mission

The mission of the Canadian Medical Protective Association is to be a non-profit medical mutual defence organization whose raison d'être is to protect a member's professional integrity by providing services of the highest quality including legal defence, indemnification, risk management, educational programs and general advice.

The Canadian Medical Protective Association
L'Association canadienne de protection médicale

Cette publication est également disponible en français.

You can also access this document from our Web site at **www.cmpa-acpm.ca**

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Submitted by

Canadian Mental Health Association

CANADIAN MENTAL HEALTH ASSOCIATION
ASSOCIATION CANADIENNE POUR LA SANTÉ MENTALE

Submission to the Task Force on Adverse Health Events
By
The Newfoundland and Labrador Division of the Canadian Mental Health Association

Preamble:

The Newfoundland and Labrador Division of the Canadian Mental Health Association (CMHA-NL) is a non-profit charitable organization providing advocacy, public education and information and referral in relation to mental health and mental illness. CMHA-NL has been existence in this province since 1964.

CMHA-NL commends the provincial government for establishing the Task Force on managing adverse medical events in order to promote a culture of safety within the health care system and to minimize the impact of medical errors and adverse medical events.

The Executive Director and a Board Director of CMHA-NL attended the recent forum on managing adverse health events and were impressed with the quality of presentations and the approach taken to seeking input from groups and organizations involved in the broader health sector.

Following attendance at this forum and at the symposium hosted by the Cameron Inquiry (attended by the Executive Director) these recommendations are respectfully made.

Recommendations:

1. **Establish a Patient and Family Safety Council in each health care region. These councils should be comprised of residents from the region - some of the membership will have experienced medical errors while in the care of the related or other health region.**

   Councils will be tasked with providing advice to the Regional Integrated Health Authority on enhancing patient safety; hearing concerns from regional residents regarding medical safety issues and providing advice and recommendations on how to address these issues; and promote patient and

family involvement in safer medical care through whatever means is reasonable and appropriate.

2. **Establish patient advocate positions in each health region. These positions will focus on patient and family concerns in relation to health care provided, document the nature of the concern, steps taken to resolve the concern and provide a related monthly report to senior management of the RIHA and the Patient and Family Safety Council. The advocates will attend the meetings of Council to ensure two-way communication in relation to medical safety issues.**

3. **Each Regional Integrated Health Authority issue a semi-annual report to their regional residents on safety measures that have been adopted as a result of identifying a medical care issue/error and making the related improvements. Such a report will be released to local media and posted on the RIHA website. The patient advocates should be identified in these reports as RIHA contacts should members of the public or media have questions – this may promote more direct communication between the public and the RIHA.**

Respectfully prepared by:

Geoff Chaulk, MSW, RSW
Executive Director

Patrick Fleming, BSc.
Board Director

Submitted by

Canadian Patient Safety Institute

ADVERSE EVENT REPORTING AND LEARNING SYSTEMS:

A REVIEW OF THE RELEVANT LITERATURE
JUNE 25, 2007

PAPER PREPARED FOR CPSI BY:
Jennifer L. White, B.Sc. M.E.Des.

2007

CANADIAN PATIENT SAFETY INSTITUTE (CPSI)
INSTITUT CANADIEN POUR LA SÉCURITÉ DES PATIENTS (ICSP)

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INTRODUCTION

Background

The Canadian Patient Safety Institute (CPSI) determined that a literature review of key published articles in the area of medical error, adverse event and critical incident reporting would be a useful tool to further understanding and insight into reporting systems in health care.

This review draws information from the published literature on adverse event reporting and learning systems in health care and classifies the information according to the following seven themes:

1) Governance and legislative frameworks for national reporting systems
2) Taxonomy, classification, and vocabulary used in data reporting and analysis
3) Technical considerations including reporting system software design and development and user issues
4) Anonymous reporting systems and confidential (but identifiable) reporting systems
5) Reporting by physicians/nurses/allied health professionals as well as patients and family members
6) Financial implications of reporting systems
7) Feedback systems in use to produce safety information from the data and to improve the safety of health systems

Search Methodology

The Librarian/Information Specialist for CPSI completed searches in the electronic health databases Medline, the Cumulative Index for Nursing & Allied Health Literature (CINAHL) and Embase, as well as the multidisciplinary electronic database Web of Science, which searched literature in scientific disciplines other than medicine and health care. The searches were designed to retrieve records that specifically discussed the technology, implementation, learning, or classification of reporting adverse events. The initial search (methodology detailed in the Appendix), identified 220 unique records, which were then limited to 121 resources by CPSI staff. Large scale or very detailed resources considered most relevant to the subject area were included in the 121 selected articles and all works deemed to be irrelevant, editorial, or single case studies were eliminated.

The creation of the literature review included a detailed review of these 121 documents, which were then further reduced to a selection of articles believed to best represent the seven themes described above. Additional publications to include in the review were identified from cross-references in the selected articles and were retrieved. Criteria for excluding articles from the review included the following:

- Not directly relevant to the field of patient safety/adverse event reporting and learning systems.

- Relevant to the field of patient safety/adverse event reporting but did not contain adequate information on any one of the seven themes (above).
- Relevant to the field of patient safety but did not provide an adequate description of adverse event reporting systems.
- Relevant to the field adverse event reporting but did not provide an adequate description of patient safety.

Glossary of Terms

The following terms are used commonly in the description of reporting systems and are defined as follows for the purposes of this literature review (note that all definitions are those of the author unless otherwise stated).

Reporting System – a formal or informal process whereby verbal or written accounts of health care related adverse events are shared with others, either internally within a department/facility/organization or externally with other interested parties. The purpose of a reporting system is often to provide a medium for sharing lessons learned and opportunities for improvement, and to prevent recurrence of similar incidents in the future.

Voluntary Reporting System – a reporting system whereby accounts of health care related adverse events are shared freely and/or spontaneously without compulsion from external authorities.

Mandatory Reporting System – a reporting system whereby accounts of health care related adverse events are compelled by law, policy/regulation, or by any other formal means.

Anonymous Reporting System – a reporting system whereby verbal or written accounts of health care related adverse events are shared without the inclusion of any identifiable details of the patient and/or care providers involved. The information contained in anonymous reporting systems is often less complete than information contained in confidential reporting systems.

Confidential Reporting System – a reporting system whereby accounts of health care related adverse events are shared with the inclusion of identifiable details of the care provider/providers involved to allow for follow-up and/or clarification of the reported incident with the individual who supplied the report. Once it is determined that the details supplied in the report are sufficient and further contact with the reporter is not required, identifying details are stripped from the report. The information contained in confidential reporting systems is often more complete than information contained in anonymous reporting systems.

Adverse Event – the Canadian Patient Safety Dictionary defines adverse event in one of the following three ways: "1. An unexpected and undesired incident directly associated with the care or services provided to the patient; 2. An incident that occurs during the process of providing health care and results in patient injury or death; 3.

An adverse outcome for a patient, including an injury or complication" (Davies et al. 2003). This term is preferred to other commonly used phrases such as "medical error" which can be interpreted to imply blame or fault on the part of the care provider.

Critical Incident – the Canadian Patient Safety Dictionary defines critical incident as the following: "an incident resulting in serious harm (loss of life, limb, or vital organ) to the patient, or the significant risk thereof. Incidents are considered critical when there is an evident need for immediate investigation and response. The investigation is designed to identify contributing factors and the response includes actions to reduce the likelihood of recurrence" (Davies et al. 2003). It is important to note that not all adverse events are critical incidents. Critical incidents are the most serious subset of adverse events.

Revision History

November 14, 2006: version 1.0 submitted to CPSI
November 14 to December 1, 2006: document reviewed by CPSI staff
Paula Beard – Project Manager
Orvie Dingwall – Librarian/Information Specialist
Carolyn Hoffman – Director of Operations, Ontario to British Columbia
Dominique Yu – Website Coordinator
December 1, 2006: verbal comments provided to author for version 2.0
December 6, 2006: written comments provided to author for version 2.0
December 22, 2006: seventeen additional articles provided to author for consideration
January 31, 2007: version 2.0 submitted to CPSI
March 28, 2007: written comments provided to author for version 2.1
June 25, 2007: version 2.1 (final version) submitted to CPSI

1) GOVERNANCE & LEGISLATIVE FRAMEWORKS

Establishing a Need for Adverse Event Reporting and Learning Systems

"*…the value of history lies in the fact that we learn by it from the mistakes of others – learning from our own is a slow process*" (Sykes 1960)

Adverse event reporting and learning systems in health care have the potential to improve safety for all patients through the analysis of reported events, dissemination of recommendations for system improvements, and the local implementation of leading practices. This is achieved while maintaining a system-based emphasis on seeking and understanding the lessons that can be learned. The use of incident reporting in health care can be traced to a landmark 1978 study examining adverse events in the field of anaesthesia (Cooper et al. 1978). Although the impetus for the study was the rising cost of malpractice insurance, the result of the investigation was an improvement in safety practices (Wagner et al. 2005). Since that time, other specialties and sectors of health care have adopted diverse process improvement models, including adverse event reporting and learning systems.

In 1999, the Institute of Medicine challenged the health care system to begin the process of making major reforms in patient safety through the publication of the document *To Err is Human: Building a Safer Health System* (Corrigan et al. 2000). This report recommends the establishment of a U.S. national mandatory reporting system in hospitals, followed by expansion beyond the hospital setting to every site where patients receive care as the next steps toward improving the safety of the health system for all patients.

Although *To Err is Human* was prepared by an American organization, the same guiding principles for the promotion and delivery of safe health care can be applied universally. Studies providing estimates of actual rates of adverse events in health care have been completed in many countries worldwide, including in Canada with *The Canadian Adverse Events Study* (Baker et al. 2004). This study established an estimate of the national rate of adverse events occurring annually in Canada as 7.5% of medical/surgical admissions in acute care hospitals, based on 3,745 chart reviews conducted in five provinces from admissions in the year 2000 (Baker et al. 2004). Approximately thirty-seven percent of these adverse events were deemed to be preventable in nature, which emphasizes that a significant opportunity exists for Canadian health care providers to improve the safety of the care provided to patients on a daily basis (Baker et al. 2004).

Another national initiative to improve patient safety in Canada is the creation of the Canadian Patient Safety Institute (CPSI), an independent not-for-profit organization established in 2004. The mandate of CPSI is to provide national leadership on the improvement of the safety of the health care system for all Canadians through collaboration with health professionals and organizations, patients and members of the public, regulatory

bodies, as well as provincial and national governments (CPSI 2006). Three key areas of focus for CPSI are the following:

1. To promote innovative methods of improving patient safety
2. To empower patients and their families with information and support
3. To establish a funding environment for research/analysis encouraging exploration, exposure, and resolution of patient safety issues (CPSI 2006).

Incentives and Barriers to Reporting: Lessons from Other Industries

Following the release of *To Err is Human*, some organizations have been quick to implement reporting and learning systems for adverse events and critical incidents, while others find the barriers to implementation of a reporting system insurmountable (Beverly 2001). One author (Beverly 2001), who is a nurse, hospital administrator and patient safety advocate in the U.S., identified nine key areas on which to focus efforts when developing and introducing a reporting system:

- Reforming education
- Creating a blame free culture within the organization
- Enhancing communication
- Participating in reporting device design
- Redesigning staffing levels to meet the demands of reporting
- Fostering a continuous learning environment
- Designing reporting systems
- Involving the patient and family in care
- Examining regulatory and legal implications

The Federal Aviation Association in the U.S. has been collecting reports of safety concerns and actual and potential incidents for over 30 years, and manages the reports in a non-punitive culture with an emphasis on system-based learning (FAA 2006). As a result, the aviation industry is often used as an example of implementing a successful reporting scheme to track events and disseminate recommendations for improving the safety of the system as a whole (Billings 1998). A successful system is one in which reports of actual and potential events are submitted, evaluated for safety improvements, and recommendations to improve safety are disseminated to all stakeholders and implemented (Billings 1998). Following the development of the U.S. Aviation Safety Reporting System in 1976, it became clear that in order to achieve success in a reporting system there are two key principles that must be met:

1. There must be a demonstrated, widely agreed-upon and tangible need for more and better information.
2. There must be a highly respected body, independent of the influences of other stakeholders of the system, to conduct the collection and analysis of the data (Billings 1998).

Barach and Small (2000) conducted an in-depth review of 25 non-health care related adverse event reporting systems, including those in the nuclear power, aviation, petrochemical, and aeronautical industries. From the review, they developed a list of the individual, organizational, and societal barriers and incentives to incident reporting; they note that these

are characteristics that can be similarly attributed to the health care industry (Barach and Small 2000).

For an adverse event reporting system to succeed, they established that there must be perceived incentives for professionals to report events voluntarily, completely, confidentially, and objectively, and those incentives must outweigh any perceived barriers (Barach and Small 2000). A useful reporting and learning system is one in which accountability is balanced with transparency and protection for reporters, and the reporting community is actively involved with the oversight of the system as well as support and advocacy (Barach and Small 2000). A successful system must also show a demonstrated ability to prevent, detect, and minimize the effects of undesirable combinations of design, performance, and circumstance that lead to adverse events (Barach and Small 2000).

Table 1. Incentives and Barriers to Implementing Reporting Systems (Barach and Small 2000)

	Individual	Organizational	Societal
Legal			
Barrier	Fear of reprisals, lack of trust	Fear of litigation, costs, sanctions undermine trust, bad publicity	Legal impediments to peer review, confidentiality, and multi-institutional database
Incentive	Provide confidentiality and immunity	Provide confidentiality and immunity	Ensure accountability, enforce reporting statutes
Cultural (values, attitudes, beliefs)			
Barrier	Dependent on profession, code of silence, fear of colleagues in trouble, skepticism, extra work	Dependent on organization, pathological, bureaucratic, generative cultures, don't want to know	Wide public trend towards disclosure, lack of trust owing to highly publicized medical errors, concerns that professions are too privileged, lack of education about systems effects
Incentive	Professional values, philanthropic, integrity, educational, cathartic	Become a leader in safety and quality, good for business	Enhanced community relations, build trust, improve health care, transparency
Regulatory			
Barrier	Exposure to malpractice, premiums will go up, investigation and potential censure, license suspension and subsequent loss of income	It doesn't apply to us, we do our own internal analysis process, they can't understand our problems anyway	Need more effective regulations, resource intense
Incentive	Prophylactic, follow the rules	Fear of censure	Enhances regulatory trust, more public accountability
Financial			
Barrier	Loss of reputation, loss of job, extra work	Wasted resources, potential loss of revenue, patient care contracts, not cost effective	Cost more tax dollars to enforce, more bureaucracy
Incentive	Safety saves money	Publicity relations, improve reputation of quality and safety	Improves confidence in health care system

National Adverse Event Reporting and Learning Systems

A review of the relevant literature revealed that several countries, including the United States, the United Kingdom, and Japan have published information on national adverse event reporting systems, both mandatory and voluntary in nature, that are in place to improve patient safety. Mandatory and voluntary incident reporting systems have traditionally both played a role in improving system safety, with mandatory systems often designed to track more egregious errors and voluntary systems intended to collect information on less serious errors including potential hazards and near misses (Thompson 2001, Dunn 2003). Both mandatory and voluntary systems have an important role to play in patient safety adverse event reporting and learning systems.

National Reporting in the United Kingdom

The U.K. initiated a national program to improve patient safety in 2000, when the Chief Medical Officer's report *An Organisation with a Memory* was published and drew public attention to the statistic that approximately one in ten patients admitted to a National Health Service (NHS) hospital suffered unintentional harm (Donaldson 2000). The key criticism outlined in the report was that the presence of a culture of blame and the lack of a national system for sharing lessons learned were acting as barriers to the identification and reduction of patient safety incidents (Donaldson 2000). In response to these criticisms, the NHS established the National Patient Safety Agency, which was in turn given the mandate of developing a National Reporting and Learning System (NRLS) (Leigh 2006).

The expectation for incident reporting is built into all organizational clinical governance agreements with NHS facilities (Ashcroft et al. 2005). The NRLS is an Internet-based, anonymous mandatory reporting system used to identify actual and potential adverse events, collect safety information from other existing sources, and develop and distribute solutions and lessons learned based on all information collected (Ashcroft et al. 2005, Leigh 2006).

The vision for the NRLS is to develop a reporting system that becomes an integral aspect of NHS culture with the capacity to:

- Actively identify risk
- Accurately and objectively record and report adverse events
- Analyze events and trends
- Learn from adverse events and disseminate findings
- Implement change to limit future recurrence (Bird 2003).

While the NHS has clearly stated that making the National Health System safer for patients is the cornerstone of clinical governance, a committee reviewing the progress to date has found that insufficient progress has been made towards achieving the goal of improving the safety of the NHS for patients (Leigh 2006). As a result, a number of specific recommendations have been made to improve the efficacy of the NRLS in years to come (Leigh 2006).

National Reporting in the United States of America

In *To Err is Human (2000)*, the Institute of Medicine recommended development of both nationwide mandatory and voluntary incident reporting systems to begin to allow health care providers to identify and learn from adverse events (Corrigan et al. 2000). The Quality of Health Care in America Committee of the Institute of Medicine, the committee responsible for preparing *To Err is Human*, stipulated that American state governments implement mandatory reporting systems that collect standardized information about incidents resulting in death or serious harm (Corrigan et al. 2000). Voluntary reporting systems should also be developed to complement the mandatory systems and focus on collection of information about adverse events causing minimal harm or near misses (Corrigan et al. 2000). Despite this call to action, very few state-wide reporting systems have been developed with the ability to record, track and monitor adverse events and allow organizations to accurately measure their safety environments (Carroll-Solomon and Denny 2005, Joshi et al. 2002).

The U.S. House and Senate passed an Act called the Patient Safety and Quality Improvement Act (Public Law 109-41) in July 2005 (Fong 2005). The bill included the following requirements:

- Create a U.S. national voluntary database of non-identifiable patient safety data to track trends and identify systems-based causes of medical errors resulting in minor injuries or near misses
- Identify patient safety organizations to collect and assess the confidential safety data (including the Agency for Healthcare Quality and Research)
- Make patient safety data privileged to prohibit it from being used against care providers in litigation or administrative proceedings
- Develop standards for communication of health information using information technology (Bleich 2005, Fong 2005, U.S. Department of Health and Human Services 2006).

By September 2005, 25 American states had passed legislation and/or regulations related to the reporting of critical incidents and adverse events occurring in a hospital setting (NASHP 2006). There are 22 U.S. states with mandatory reporting systems actually in place (Bleich 2005). All of these systems are designed to protect collected data, although they are generally established in statute and not in regulation (Bleich 2005). Of these 22 states, seven release incident specific data from their reporting systems, and fourteen release (or plan to release) aggregate reports only, and one is undecided about what information will be shared. Five of the states releasing aggregate data will also include data with individual facilities identified (Bleich 2005).

The requirements for these mandatory reporting systems vary from state to state. Some states only require reporting of incidents causing serious harm to patients, while others mandate the reporting of near misses or incidents that reached the patient but did not cause harm. Some states will release the name or names of practitioners involved, but none of the states release the names of affected patients (Weissman et al. 2005).

Seventeen American statewide public-private partnership patient safety coalitions have been formed, which focus on dissemination of best practices, mandatory and voluntary event reporting, educating policymakers and consumers, developing information technology,

professional accountability, and systems improvement (Bleich 2005). The National Academy for State Health Policy (NASHP) has developed a resource called the Electronic Patient Safety Toolbox for states to provide regulators or policy-makers with common instruments that can be used throughout the development and implementation of new incident reporting systems, or the modification of existing systems (NASHP 2006). Some of the information provided includes tools for collection and analysis of data, as well as the interpretation of data, and appropriate distribution of feedback to maximize system safety improvements.

National Reporting in Japan

Following a highly publicized case in Japan in 1999 where a case of mistaken identity resulted in two patients receiving incorrect heart surgeries, the government mandated a series of requirements for all facilities in the country (Nakajima et al. 2005). All facilities in Japan are now required to have a patient safety policy, collect information related to actual and potential harm, form a committee for the prevention of adverse events, and conduct staff education on patient safety (Nakajima et al. 2005). Tertiary care hospitals are also required to establish a division of patient safety, to employ a full time clinical risk manager, and to open a patient complaint office (Nakajima et al. 2005).

While these requirements are uniformly applied nationwide, it is up to each hospital or facility to develop their own incident reporting process and system. In Japan, the Organization for Pharmaceutical Safety and Research have also created a national voluntary reporting program for medication-related incidents, and the authors of a study on the effects of the voluntary program (Furukawa et al. 2003) indicate that a national mandatory medication incident reporting program will be introduced by April 2004.

Common Themes in Reporting and Learning Systems

Each incident reporting system is unique in its design, maintenance, and operation, however many share common traits in their purpose. These commonalities include maintaining patient and care provider confidentiality as a priority, and focusing on the use of information technologies and deidentified data to recognize problems with the delivery of care and health system rather than to launch reprisals against staff involved with the events (Gillespie 2001).

The success of incident reporting in the aviation industry, including NASA's Aviation Safety Reporting System and the U.K. Confidential Human Factors Incident Reporting Program, has encouraged the development of many similar incident reporting initiatives in the field of health care (Johnson 2003). An aviation-styled incident reporting system moves the focus away from the analysis of low frequency and high consequence events to the analysis of the more frequently occurring near miss events (Johnson 2003). Information about potential events and how to mitigate their occurrence in the future is published frequently in safety alerts, news bulletins, and on Internet websites (Johnson 2003). Many health care reporting systems, however, are still focused on reporting only the critical incidents where harm comes to patients and the great benefit of learning from potential events is lost (Johnson 2003).

There are several characteristics of a successful health care adverse event reporting system, including the following:

- Data are analyzed by independent organizations composed of subject matter and safety experts
- Timely feedback is provided to system users
- Suggests systems-oriented solutions to reported problems
- Participant organizations are responsive to suggested changes
- Non-punitive
- Confidential (Karsh et al. 2006).

Some reporting systems include penalty clauses for failure to comply in the legislative or regulatory requirements for mandatory reporting. The state of Florida, for example, can fine hospitals up to $250,000 for violations of the mandatory reporting system when they fail to report required incidents (Williams et al. 2003). In Japan, hospitals that do not comply with the patient safety infrastructure requirements are penalized by a reduction in government funding of 100 yen (or approximately $1) per patient per day (Nakajima et al. 2005). It is believed that these punitive measures have been somewhat effective at improving compliance with reporting requirements (Williams et al. 2003, Nakajima et al. 2005).

In both mandatory and voluntary systems, timeliness of reporting is very important. Webb and colleagues (1993) examined data reported to the Australian Patient Safety Foundation AIMS system (Australian Incident Monitoring Study), which collects anonymous and voluntarily submitted anaesthesia patient safety data. They determined that the longer the time lapse between when the incident occurred and when the report was filed, the more likely there was a selective loss in report of more minor incidents with less harm or no harm to patients (Webb et al. 1993). This means that there is a correlation between slow reporting timeframes and fewer reports of minor incidents (Webb et al. 1993). It is therefore important that report forms or online systems are immediately available to care providers following adverse events and that the importance of timeliness of report is stressed to frontline staff so that the maximum number of incidents, including those more minor in nature, can be reported (Webb et al. 1993).

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is the U.S. body responsible for accreditation of health care facilities. Every JCAHO-accredited facility is required to perform an in depth (root cause analysis) review following a serious care-related event; however, the details of the incident and the outcome of the review are reported to JCAHO on a voluntary basis (Williams et al. 2003). A study of U.S. states with mandatory reporting systems showed that very few incidents reported to the statewide system were also reported to JCAHO (Williams et al. 2003). For example, in 1999 there were 204 events with an outcome of patient death reported to the state mandatory reporting system in Florida, while only 1 comparable event was reported to JCAHO (Williams et al. 2003).

One disincentive to the JCAHO voluntary reporting system may be that information reported to JCAHO is not clearly protected from legal discovery during trial (Williams et al. 2003). Discovery is a pre-trial stage in a lawsuit where each party is able to request documents and other evidence through the use of subpoena, depositions, and requests for production (Williams et al. 2003). Another important point for consideration is that all incident

reporting is essentially voluntary, because regardless of the legislative or regulatory requirements, it is up to the individual care provider or facility to determine whether or not to comply with those requirements and report (Williams et al. 2003).

Charles Billings, former Chief Scientist at NASA Ames Research Center, reminds us to question the purpose for creating a new adverse event reporting system:

> "…there are enough reports of mishaps with potassium chloride, lidocaine, vincristine, and other drugs and devices to have made it very clear that a problem with these exists. The information that these events occur is already present. We may well ask what it is that keeps us from making progress on safety, given that we already know about the existence of these problems. What is added by more formal, elaborate (and expensive) incident reporting?" (Johnson 2003)

Adverse event reporting and learning systems are capable of yielding good insights into local problems and in ideal circumstances can identify regional or national patterns of failure, however, the users of the system need to be receptive of the information as feedback is provided and implement the necessary changes to make the health care system safer for all (Johnson 2003). Without this, reporting systems become merely tools for the collection of statistics (Leigh 2006).

2) TAXONOMY AND CLASSIFICATION SYSTEMS

Reporting adverse events to a national learning system will require a standardized taxonomy for coding and classification of events to ensure the reported data is appropriately categorized and prepared for analysis. Health care adverse event reporting systems differ among organizations and facilities in how they define, count, and track events as well as how information is coded and analyzed, which makes comparisons between systems complicated and sometimes impossible (Loeb and Chang 2003). Inconsistency in the definition, classification, and measurement of adverse events has been shown in the past to hamper the establishment of effective voluntary and mandatory reporting systems (Thompson 2001).

Individuals given the task of developing a new reporting system often find the lack of a standardized taxonomy and clear definition of reportable events to be difficult to overcome (Kivlahan et al. 2002). The more generic and widely accepted definitions of adverse events and/or critical incidents are not specific enough to guide the daily practice of health care workers in deciding when to provide a report (Kivlahan et al. 2002). For a patient safety classification system to be truly effective, the data collected and analyzed must be used to inform the development of strategies for reducing the occurrence of adverse events, or to minimize the harm to patients if they do occur (Loeb and Chang 2003)

When developing the National Reporting and Learning System (NRLS) in the U.K. in 2002, system administrators at the National Patient Safety Agency (NPSA) learned that there was not a single agreed-upon national taxonomy for collecting and organizing patient safety data that covered all care settings in existence in any country (Williams and Osborn 2006). The NPSA reviewed what was available and brought together a team of 300 clinicians and managers to create a new taxonomy suitable for the U.K. context (Williams and Osborn 2006).

Any organization developing an adverse event reporting and learning system might choose to take advantage of a previously existing classification system, such as the World Health Organization International Classification of Diseases codes (ICD), however this has proven complicated because this coding scheme was designed for economic purposes rather than patient safety and it has been difficult to retrofit the ICD coding to suit the purposes of a newly developed incident reporting system (Young 2001).

The World Health Organization (WHO) has recently recognized that the ability to classify, aggregate, and compare patient safety information across differing data collection systems would be of significant benefit to improving patient safety internationally (Lewalle 2006). In order to facilitate these comparisons, an internationally agreed upon classification system for adverse events and near misses needs to be developed. The WHO has initiated the process of development of an international patient safety taxonomy, called the IPSEC (International Patient Safety Event Classification), which will define, harmonize, and group patient safety concepts into an agreed upon classification in such a way as to promote learning and improving patient safety across systems (Lewalle 2006). The IPSEC, currently in the

preliminary stages of development, is intended to be adaptable across cultures and languages and yet consistent throughout the entire spectrum of health care (Lewalle 2006).

Subjectivity in Reporting Systems

System administrators in Missouri deliberately decided to not constrain what patient safety events could be reported with the inclusion of stringent definitions, and instead chose to allow the event reporter to define both the event and harm level, after which the department managers would determine an appropriate level response for the event (Kivlahan et al. 2002). However, the potential workload involved with categorizing these subjective reports would make this style of reporting highly unsuitable for any large scale reporting system (Kivlahan et al. 2002).

Even reporting systems with more complete classification schemes are open to subjectivity in reporting. A medication error reporting system at Johns Hopkins Children's Center in Baltimore found that despite a full complement of descriptive categories of events, almost 60% of the time reporters chose the non-descript "other" category on the reporting tool (Miller et al. 2006). In order to maximize the opportunities for system improvements, it is important to have incidents commonly classified for investigation, analysis and feedback (Lewalle 2006). While an "other" category may be necessary, and indeed desirable, to ensure that all appropriate incidents are reported, it is in the best interests of system administrators that as many incidents as possible are classified into specific categories to allow for improved analysis and detection of potential system improvements.

In the U.K., the requirements for clinical risk management are nationally guided, although the incident reporting systems are locally established (Tighe et al. 2006). Staff members in one emergency department are asked to report on any incident that concerns them or that might endanger a patient (Tighe et al. 2006). A more sophisticated system may include a designated list of incidents that trigger a report, although employees are still able to report on other issues that do not fall into these defined categories (Tighe et al. 2006).

Examples of Classification Models

Eindhoven Classification Model

The Eindhoven Classification Model (Van der Schaaf 1992), was originally developed for the chemical processing industry and has been adapted for use in health care incident reporting frameworks (Battles et al. 1998). The classification model describes adverse events in two distinct categories: those involving latent errors, and those involving active error (Battles et al. 1998). A latent error is one that results from an underlying failure in the system, whereas an active error or human error is one that is precipitated by a human behaviour (Battles et al. 1998).

Table 2. Classification of Latent and Active Errors
(Battles et al. 1998)

Category	Description
Latent errors **Errors that result from underlying system failures**	
Technical Refers to physical items, such as equipment, physical installations, software, materials, labels, and forms	
External	Technical failures beyond the control and responsibility of the investigating organization
Design	Failure due to poor design of equipment, software, labels, or forms
Construction	Correct design was not followed accurately during construction
Materials	Material defects not classified under design or construction
Organizational	
External	Failures at an organizational level beyond the control and responsibility of the investigating organization
Transfer of knowledge	Failures resulting from inadequate measures taken to ensure that situational or domain-specific knowledge or information is transferred to all new or inexperienced staff
Protocols/procedures	Failures related to the quality and availability of the protocols within the department (too complicated, inaccurate, unrealistic, absent, or poorly presented)
Management priorities	Internal management decision in which safety is relegated to an inferior position in the face of conflicting demands or objectives. This is a conflict between production needs and safety (e.g. decision about staffing levels)
Culture	Failures resulting from collective approach to risk and attendant modes of behaviour in the investigating organization
Active errors (human) **Errors or failures resulting from human behaviour**	
External	Human failures originating beyond the control and responsibility of the investigating organization
Knowledge-based behaviours	
Knowledge-based errors	The inability of an individual to apply existing knowledge to a novel situation
Rule-based behaviours	
Qualifications	Incorrect fit between an individual's qualifications, training, or education and a particular task
Coordination	Lack of task coordination within a health care team in an organization
Verification	Failures in the correct and complete assessment of a situation, including relevant conditions of the patient and materials to be used, before starting the intervention
Intervention	Failures that result from faulty task planning (selecting the wrong protocol) and/or execution (selecting the right protocol but carrying it out incorrectly)
Monitoring	Failures during monitoring of process or patient status during or after intervention
Skill-based behaviours	
Slips	Failures in performance of fine motor skills
Tripping	Failures in whole-body movements
Other	
Patient-related factor	Failures related to patient characteristics or conditions that influence treatment and are beyond the control of staff
Unclassifiable	Failures that cannot be classified in any other category

Victoroff Multiaxial Taxonomy

The Victoroff (2006) multiaxial taxonomy of medical errors was used by Fernald and associates (2004) when developing the Applied Strategies for Improving Patient Safety (ASIPS) primary care reporting system. The ASIPS multiaxial classification system consists of five domains and ten axes (Table 3) (Fernald et al. 2004). Each event report must include an applied code for each axis, although multiple codes may be used within any single domain (Fernald et al. 2004). The taxonomy includes a detailed description of the following domains: outcome, course of the event, participants, and event discoverer; a fifth domain, patient information, was collected, however the data is not used for the purposes of analysis (Fernald et al. 2004).

Table 3. ASIPS Multiaxial Taxonomy
(Fernald et al. 2004)

Domain	Axis
Patient information	
Outcome	Harm
	Resultant interventions as result of error
Course of event	Type of event (can never be 'unknown')
	Location
	Intent
	Event process (can never be 'unknown')
	Cause
	System
Participants	Participants
	Contribution
Discovered by	

Other Classification Models

The Joint Commission for the Accreditation of Healthcare Organizations in the U.S. developed a patient safety taxonomy that integrates several existing patient safety event classification systems and is intended to be broadly applicable to any incident resulting from patient care regardless of setting or type of event (Chang et al. 2005). The taxonomy has four root nodes (impact, type of event, causes, and domain) which are broken down into a further 14 secondary classifications that again branch into 140 coded categories with the flexibility to include free-text in addition to the coded responses (Chang et al. 2005).

One example of how many varied classification systems are currently in use can be seen by examining the coding for harm or the level of impact an event has on the patient involved. Carroll-Solomon and Denny (2005) use 11 categories to classify incidents according to the level of impact on patients, while Jones and associates (2004) describe nine categories of harm (Jones et al. 2004), and Fernald and colleagues (2004) use five. The review of relevant literature highlights that a trade-off exists between quality of data and ease of use of the system: to have eleven ways to classifying severity of an incident allows for a more complete understanding of the harm that did or did not occur. The more categories a system contains, however, the more complicated it becomes for users and the more elaborate the requirements are for data analysis.

Table 4. Examples of Severity Categories in Incident Report Systems (Carroll-Solomon and Denny 2005, Jones et al. 2004, Fernald et al. 2004)

Carroll-Solomon and Denny	Jones et al.	Fernald et al.
Unknown	Circumstances have the capacity to cause error	No known harm (a combination of no reported harm and unknown)
Safety environment	An error occurred, but the error did not reach the patient	Unstable (too early to ascertain harm)
Near miss	An error occurred that reached the patient but did not cause harm	Nonclinical harm
No harm – no increased monitoring	An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm	Future risk of clinical harm
No harm – increased monitoring	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention	Clinical harm
Temporary harm – no treatment	An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization	
Temporary harm – minor treatment	An error occurred that may have contributed to or resulted in permanent patient harm	
Temporary harm – major treatment	An error occurred that required intervention necessary to sustain life	
Permanent harm	An error occurred that may have contributed to or resulted in patient death	
Near death		
Death		

Relational Databases

Most large-scale reporting systems use a relational database for the storage of reported information (Johnson 2003). A relational database is one that consists of a collection of relations, or tables, where data is organized into rows and columns of information with the same attributes (Johnson 2003). This type of database is unique in that all data stored within a given column should be in the same domain and consist of the same data type, while neither the rows nor the columns should have an order to them (Johnson 2003).

Relational databases store incident data according to the classification of the incident as entered by the individual who filed the report, however problems will occur when the taxonomy changes (Johnson 2003). Change in taxonomy is seen as inevitable over time as our health systems transform and as the involvement of human factors is altered to represent changing provider roles in health care (Johnson 2003). "The net effect is that, in 10 years time, we may have to go back into our electronic databases and manually reclassify many hundreds of thousands of reports to reflect a revised taxonomy." (Johnson 2003) The effort and necessary expense associated with transforming a dataset in the future as demonstrated by Johnson (2003) highlights the importance of creating as complete a taxonomy as possible from the outset so as to minimize the need for future changes in the short- or medium-term.

3) TECHNICAL / DESIGN CONSIDERATIONS & USER ISSUES

Application and User Interface Design

Developing a new incident reporting system, whether it involves paper or electronic forms, should include extensive consultation with future users to ensure that the design of the system meets the needs and expectations of the users entering reports, as well as the users extracting data from the reporting system for the purposes of improving patient safety. For example, when creating a community pharmacy patient safety reporting initiative in the United Kingdom as part of the National Reporting and Learning System, extensive focus group testing was conducted prior to implementation to determine user preferences as well as comprehensiveness, validity, feasibility and sensitivity of the report form (Ashcroft et al. 2005). In this system, users exhibited a strong preference for report forms and systems that are easy to use, allow for anonymity, and complement existing working practices in the community pharmacy (Ashcroft et al. 2005).

Prior to the creation of a Wisconsin statewide patient safety incident reporting system, Karsh and colleagues (2006) conducted an extensive study exploring barriers and facilitators to the development of the reporting system and created theories of technology acceptance, adoption, and implementation associated with the process. In order to make users of this new incident reporting system comfortable with the process, they determined instructions should be provided that clearly stated the goals, mechanics, limitations and protections of the system (Karsh et al. 2006). Consultation with participants identified a preferred optimal time frame of approximately two minutes to complete a report, and that in no circumstances should it require more than five minutes to file (Karsh et al. 2006).

There were varying opinions on whether reports should be filed immediately following the occurrence of the incident, or whether users should be able to report at any time following the event (Karsh et al. 2006). Participants indicated a preference for a pluralistic system, that is, a system in which there are varying mediums available for reporting, such as electronic, telephone, or paper forms (Karsh et al. 2006). These requirements are suitable to diverse work environments for multiple professions as well as personal comfort level with varying reporting methods. The key component to reporting is that regardless of the mode of report, it be consistently available and provide all individuals within the organization an equal opportunity to report (Karsh et al. 2006).

Paper forms are often not considered ideal choices for reporting incidents based on the following reasons:

- Legibility/interpretation of hand-written comments
- Lost time while forms are passed through appropriate hands/sitting on desks prior to resolution of incident
- Loss of confidentiality if form is seen by others on a desk or in an inbox
- Lack of space to adequately describe event information on one form (Maass and Cortezzo 2000).

For reasons such as these, many patient safety experts consider paper-based reporting systems to be ineffective (Atherton 2002). Staff can be confused about which form to use, how to fill them out, where to send them once completed, and who is responsible for follow up (Atherton 2002). Error is also introduced with the flow of paper from desk to desk, where there exist multiple opportunities for misplacement or misdirection (Atherton 2002). The time required to track incidents and implement system improvements can be reduced by 25-50% when moving from paper reporting to electronic reporting that allows incident reports to be immediately viewed online by managers or other individuals responsible for investigating reports and instituting system-based improvements (Atherton 2002). An electronic reporting system can also ensure the comprehensiveness of data reported by eliminating the need to choose the correct form. As well, all appropriate information fields necessary can be selected automatically and completed with the use of automated prompting for further information given the unique circumstances of each event, as well as directing completed reports to suitable personnel for evaluation of risk and design and implementation of improvement initiatives (Atherton 2002).

Using an electronic incident reporting system has been found to support an organization's ability to have immediate access to descriptive data about adverse events and near misses, and subsequently facilitates the implementation of system improvements and interventions to improve safety overall (Avery et al. 2005). An electronic incident reporting system allows for trending and analysis of data to be performed at the level of the unit, facility, system, or organization, which meets the needs for both process improvement and risk management (Dixon 2002). Electronic forms are considered to be a more secure, confidential, and accurate method of reporting patient safety incidents than the paper forms previously used (Dixon 2002). Developing a new electronic system for the purpose of reporting adverse events can also be seen as an opportunity to do the following:

- Update current data sets and standardize them across the health care system
- Create a risk stratification model with an associated alert mechanism
- Serve as a tool for researching trends and setting benchmarks
- Increase the efficiency, effectiveness, and accuracy of current processes for capturing patient safety data
- Make real-time individual and aggregate data available to facility administration and management
- Comply with external regulatory guidelines and standards (Dixon 2002).

A further six benefits of utilizing an electronic adverse event reporting system have been described as follows:

- Simplifying the reporting process for frontline employees
- Eliminating multiple forms required to report critical incidents
- Increasing the quantity and quality of occurrence reporting data
- Improving response time by linking reports to department leadership and key personnel
- Improving evaluation and follow-up through a structured framework
- Enhancing the quality and safety of patient care and the employee work environment (Avery et al. 2005).

Battles et al. (1998) used a three round Delphi consensus process with a panel of 23 experts in three countries to establish ideal design parameters and functions for a prototype system to capture actual and potential critical incidents in the area of transfusion medicine. The Delphi methodology uses a skilled third-party facilitator who analyzes an expert panel's responses to anonymous questionnaires and uses structured feedback to lead the group through the process of consensus-building (Battles et al. 1998). The expert panel arrived at the following 25 parameters or system characteristics to be included when designing adverse event reporting system software:

Table 5. Ideal Parameters for Reporting System Design (Battles et al. 1998)

System Characteristics
Overall
Collect and analyze reports of errors and interpret results
Nonreprisal system, no adverse consequences are attributed to the reporter
Report all errors, including no harm and near miss
Solicit input from anyone with firsthand information about an error or event
Solicit input from all those involved in the error or event
System Input
Have the ability to track back from the reported error to the root cause
Identify the specific procedures involved
Indicate whether there was misidentification of patient, or product
Indicate the location of the error in the process
Identify any equipment malfunctions involved in the event or error
Data Collection
Allow further contact with reporters for data clarification while maintaining confidentiality
Make blank report forms available to all who might wish to report errors or events
Emphasize narrative descriptions of events (usefulness of reports resides in the narrative)
Use adaptable, online interactive computer system for easy reporting
Have a trained system operator with knowledge of domain to receive reports
Analytical Process
Look beyond a single error to the entire system
Categorize errors as to where they occurred in the process
Identify links between active human errors and latent system failures
Categorize errors as slips, mistakes, or system design errors
Identify common problems across institutions
Intervention
Find underlying system failures by analysis of all errors
Make recommendations based upon error analysis to appropriate levels of decision makers
Target problem areas prone to error for additional study
Track implemented corrective actions to determine their effectiveness
Develop intervention strategies by multidisciplinary groups

Use of Information Technology

Changes in the availability and the widespread use of new information technologies have the ability to impact an adverse event reporting and learning system. The use of personal digital assistants (PDAs) by physicians at patient bedside has grown in recent years. Pilot studies in the field of anaesthesia medicine explored the use of PDAs for recording cases and complications, and found adoption of this new method of data gathering to be acceptable by the professional community (Bent et al. 2002, Bolsin et al. 2004, Bolsin et al. 2005). A

cancer treatment center in Nashville, Tennessee, has implemented the use of wireless computer technology to allow point-of-care incident reporting as well as to allow the on-demand retrieval of patient support information to permit the team to better care for immediate patient needs at the time of the event (France and Cartwright 2003). While there may be support for using PDAs as one mode of submitting incident reports, the expense associated with providing PDAs to all frontline staff for the purpose of reporting events may be seen as a deterrent to implementation of a broad event reporting and learning system. One option is to design an electronic reporting system with the ability to be accessed from either a PDA or a computer terminal. In this way, multiple front line staff members who do not have PDA technology would be able to use shared access to a computer workstation to utilize the event reporting system.

The Risk Prevention and Management computer system developed by Baylor Health Care in Dallas, Texas includes an interactive education program as a component of the incident reporting software (Joshi et al. 2002). The system also features three reporting modules (anonymous, confidential, and near miss) and a virtual classroom that provides interactive education, as well as links to patient safety educational resources, together with a real-time risk analyzer (Joshi et al. 2002).

Over 300 organizations in the U.S. are using an electronic, Internet-based medication safety event reporting program developed by U.S. Pharmacopeia called Medmarx® (Gillespie 2001). The Medmarx system uses standardized medication error report forms to collect data on actual and potential events, which are then submitted to a national reporting center (U.S. Pharmacopeia 2006). The company then shares information on the quality of health care provided and compliance with technology standards with their member organizations (Gillespie 2001). Access to the Medmarx system is by paid subscription, and permits the sharing of knowledge and experiences among all participating health care facilities and organizations, regardless of connectedness or affiliation (U.S. Pharmacopeia 2006).

Using information technology resources as a method for the collection and transmission of patient safety data highlights the importance of ensuring that data is collected and stored securely. For example, the Medmarx system requires user names and passwords, as well as a unique facility identification code, in order to report an incident. The facility identification code is a random number generated by the Medmarx database and the company responsible for the program, U.S. Pharmacopeia, does not know which facility is assigned each identification number (Gillespie 2001). As well, the Medmarx system uses secure socket layer encryption technology (a security feature using endpoint authentication and cryptography to ensure the privacy of communications over the Internet) to protect the data during transmission to the central database (Gillespie 2001).

Administrators at Dartmouth-Hitchcock Medical Center in New Hampshire created an online Event Reporting Management System (ERMS) that utilizes several nationally-accepted taxonomies for the classification and grouping of each type of event (Avery et al. 2005). The electronic form uses branching logic, where the response to a particular question drives the appearance of the subsequent follow-up questions to be answered while completing the online data entry of information. Once a report is submitted, designated department personnel (such as risk managers or directors of quality and safety) receive immediate email

notification of the occurrence, and the system simultaneously sends email notification to the incident manager responsible for the type of occurrence reported. The incident manager follows up by reviewing the reported event and implementing changes.

The ERMS facilitates analysis of incidents, including graphic displays and comparison of information within the organization (Avery et al. 2005). The system has been credited with the following improvements to patient safety for their organization:

- Simplifying the reporting process for frontline staff
- Eliminating multiple forms used to report adverse events
- Increasing the quality and quantity of occurrence data
- Improving response time by linking reports to department leadership and key personnel
- Improving evaluation and follow-up through a structured framework
- Enhancing the quality and safety of patient care and the employee work environment (Avery et al. 2005).

Common Themes in the Design of Reporting and Learning Systems

Regardless of the specific nature and unique attributes of an adverse event reporting and learning system, there are several categories of pertinent details that should be included in all patient safety databases. When planning for the U.K. National Patient Safety Agency incident reporting system, the minimum data set was determined at the outset to contain the following information:

- What happened (description, severity of actual or potential harm, people and equipment involved)
- Where it happened (location/specialty)
- When it happened (date/time)
- How it happened (immediate causes)
- Why it happened (underlying causes)
- What action taken or proposed (immediate and longer term)
- Impact of event (harm to the organization, patient, other)
- Factors that did, or could have, minimized impact (Lipley 2001)

Other Considerations

When developing an electronic incident reporting tool, one important consideration is whether to allow users to enter free text data (i.e. fields that allow users to describe incidents in their own words) or to allow only structured data (i.e. check boxes or pre-determined selections from a drop down menu). While structured data can be entered more quickly and is easier to analyze, users of one incident reporting database have expressed a preference for a system with free text data fields because it allows them to provide context for the incident and to give a more rich account of what occurred (Holzmueller et al. 2005).

An advantage of the 'point and click' nature of a menu-driven electronic incident reporting system is that it provides structure and consistency for the content of reports. The

advantages of these reports versus unstructured or free text reports include a reduction in documentation time, improved quality of the data elements collected, and more efficient methods are available to analyze the data reported so system improvements can be enacted more rapidly (Wagner et al. 2005).

There exists a widespread but mistaken belief that computer-driven incident reporting systems are low cost and simple to operate (Johnson 2003). In fact, there are many complicating factors that need to be considered when developing an electronic incident reporting database and user interface. Johnson (2003) points out that many existing electronic reporting systems are deeply flawed in their design, which severely limits their usability. One example is when a user logs on to the system to report an incident, and the entry screen of the computer program features a logo that is easily visible and widely recognizable (Johnson 2003). The confidentiality of the report is then jeopardized because many health care workers are using shared computer workstations within visibility of coworkers, patients, and family members and it can also serve to discourage reporting altogether (Johnson 2003). User acceptance testing following the initial design phase can identify this type of problem prior to the system being widely implemented (Johnson 2003).

Another complicating flaw in design is the ability of the computer program to recognize the distinct nature of the incidents that will be reported. One system forced the user to identify the day, month, and year of the incident as well as the time the incident occurred. However many adverse events happen over a period of minutes, hours, or days, and may include multiple components, thus making accurate entry of the incident impossible (Johnson 2003). Again, this flawed design could be avoided through user acceptability testing of the system prior to implementation, or by utilizing design staff with a familiarity in the area and the ability to predict this type of problem prior to implementation (Johnson 2003).

When developing an adverse event reporting database it is essential to recruit user interface designers who are able to assist frontline staff through acceptance testing to accurately enter information about complex critical incidents into the database (Johnson 2003). It is also of critical importance to recruit specialists with expertise in the storage and retrieval of large datasets, and to explore alternatives to relational databases such as the use of free text retrieval, which will allow greater flexibility as taxonomies change over time (Johnson 2003).

Users of adverse event reporting systems need to be able to search through existing records in a timely and efficient manner. When software engineers are developing a reporting system, the balance of precision and recall of the system's querying capabilities needs to be appropriate for the specific use of each system (Johnson 2003). For example, a high recall query will return greater volumes of records including a large number that upon examination will be deemed irrelevant. A high precision query will return a small volume of records that are highly appropriate for the user's purposes but other relevant documents may be missed. There are important safety implications to consider for each type of system: a low recall system can defeat the purpose of compiling reports by failing to identify potentially similar incidents, while a low precision system can increase the burden for the user who is required to manually sort the relevant reports from those that are not appropriate (Johnson 2003).

One incident reporting system in a radiology department in France included a management verification step in the report submission process (LeDuff et al. 2005). After a user enters a report, the appropriate manager receives an automatic system-generated email notifying of the incident, and the manager must review the incident and accept it as 'valid' before it is sent to the facility risk manager (LeDuff et al. 2005). This may lead to employees who are intimidated at the prospect of their manager's review of the incident details and choose to not report (LeDuff et al. 2005).

When deidentified information is reported to a national incident reporting system, it is important to make certain that the information is given legal protection (Pace et al. 2003). If legal protection cannot be ensured, then it is important to make certain that the information is not "re-identifiable," that is, that it is not possible to identify an individual incident in a specific facility based on the information provided (Pace et al. 2003). For example, the date and time the incident occurred may allow the linking of an incident report to a known event. In this way, a database created for the purposes of incident reporting will need to meet specific requirements pertaining to date/time relationships, including the ability to link all information pertaining to a single event in a manner that does not identify the time (absolute or relative) the event was reported or the place it occurred without losing any internal event chronology and to manage the data collection without time/date markers (Pace et al. 2003).

While the discussion in this section clearly indicates a trend to move toward the online reporting of patient safety incidents, a recent study of voluntary reporting in a surgical intensive care unit in Missouri found that moving from an online reporting system to a paper form (a brief card with checkboxes and text fields to be completed by hand) increased physician reporting nineteen-fold (Schuerer et al. 2006). In order to encourage participation from all user groups, the forms provided and the technology used must be appropriate and acceptable to the targeted populations. User acceptance testing during pilot phases will help make this determination.

It is important to remember that technology alone can neither guarantee nor drive incident reporting volumes; the computerization of incident reporting systems should instead be seen as a tool to assist in data collection where reporting remains the responsibility of individuals and is dependent on both the culture and values of the organization in which individuals work (Dixon 2002).

4) ANONYMOUS AND CONFIDENTIAL REPORTING SYSTEMS

Ensuring the confidentiality of both the adverse event data and the person who provides the report is of utmost importance when designing reporting and learning systems. The most obvious method of ensuring confidentiality of the reporter is to have incident reports filed anonymously. However, anonymity is not always possible and is also not always the desirable choice in reporting critical incidents because analysts are unable to contact the individual who filed the report if further information or clarification is required (Barach and Small 2000). It has also been suggested that anonymous reports may be less reliable than their confidential counterparts (Barach and Small 2000). Barach and Small suggest that although an anonymous system may be criticized for its lack of accountability and transparency, it may be important to provide anonymity early in the evolution of an adverse event reporting system until trust is developed and frontline staff are able to see practical results and believe they will not be professionally disadvantaged for reporting incidents, at which time confidential reporting can be introduced (Barach and Small 2003).

A demonstration project involving the development of a primary care safety reporting system in Colorado allowed care providers the freedom to choose whether to submit event reports using an anonymous form (which contained no identifying details of the care provider or providers involved, or of the individual who provided the report) or a confidential form (which contained identifying information for the sole purpose of allowing further contact with the reporter if the information provided was incomplete or further clarification of the issue was required) (Fernald et al. 2004). After two years of operation of this dual reporting system, they found that the confidential reporting process was used for reports two-thirds of the time (Fernald et al. 2004). These confidential reports were also significantly more likely to contain codeable data than their anonymous counterparts (Fernald et al. 2004). The level of harm reported did not vary significantly between either the confidential or anonymous system, however clinicians were more likely to use the anonymous system when filing reports and administrative staff were more apt to use the confidential system (Fernald et al. 2004).

The U.S. Agency for Healthcare Research and Quality has funded the development of a voluntary patient safety reporting system and database that captures both anonymous and confidential reports of both actual and potential adverse events and critical incidents in a primary care practices in Colorado (Pace et al. 2003). Incidents can be reported electronically on the Internet, through completion of a paper form, or by an automated telephone hotline; users are given the choice of reporting confidentially (which includes identifiable information such as name and phone number that is held in confidence) or anonymously (Pace et al. 2003).

Some reporting systems utilize confidential reports that are quickly stripped of all identifiable information once the completeness of the data is verified (Pace et al. 2003). These confidential reports have been shown to provide better detail than anonymous reports, however concerns exist about whether the confidentiality of these reports can be maintained should the database be subjected to legal discovery or another security breach (Pace et al.

2003). As well, standard dataset elements such as date, time, or location could allow outside sources to link a reported incident to a specific event (Pace et al. 2003).

Anonymous reports do not allow the opportunity for follow-up questions and as such typically provide less detail than confidential reports. As a result, they do not usually contain sufficient information to understand the root causes of the adverse event (Pace et al. 2003). In the Colorado patient safety reporting system, the confidential report is briefer, and is followed by a telephone interview where the reporter is prompted to answer a series of more specific questions on the incident and further detail is elicited. Users of this system exhibit a preference for the confidential reporting system because of the shorter time required to complete the form, and system administrators prefer the confidential reporting system because of the higher quality data they are able to elicit through the telephone interview (Pace et al. 2003).

If the primary reason for collecting and analyzing reports of adverse events is to develop systems for error reduction or mitigation, then confidential reports have been shown to be the preferable choice when compared to anonymous reports (Pace et al. 2003). This choice is supported by the experience of the U.S. Federal Aviation Administration safety reporting system whose developers felt so strongly that confidential reports provide superior information that their systems will no longer accept anonymous reports (Pace et al. 2003).

If an organizations is shifting from an anonymous system to a confidential adverse event reporting program, studies have shown that any apprehension on the part of care providers can be reduced or alleviated if they can be reassured that organizational processes related to the critical events reported will actually change (Mekhjian et al. 2004). As with all reporting and learning systems, it is extremely important for continued reporting that the safety culture is well established and that individuals who report incidents under a confidential system are not disciplined or in any way professionally disadvantaged for providing their report.

5) REPORTING BY PROFESSIONALS AND/OR PATIENTS

Overcoming Barriers to Reporting by Professionals

Barriers to implementation of effective reporting systems include the need to remove the culture of blame and fear of reprisals, as well as a lack of awareness as to the extent of adverse events and critical incidents and a poor understanding of their causes (Thompson 2001). Finally, we need to design adverse event reporting systems that are also effective learning systems for those who report incidents (Thompson 2001).

Despite legislation, regulations or policies requiring the report of adverse events in a mandatory system, it has been noted that all incident reporting systems are essentially voluntary in that they require the cooperation of care providers to bring the information forward (Billings 1998). Underreporting remains a significant concern for any event reporting system (Billings 1998). In the opinion of the author, underreporting can occur in one of three ways:

1. The care provider is not aware the event occurred.
2. The care provider is aware the incident occurred, but is not aware of requirement to report.
3. The care provider is aware the incident occurred and reporting requirements, but chooses to not report.

A successful adverse event reporting and learning system must be designed in conjunction with appropriate educational programs to encourage care provider awareness of requirements to report. Additionally, the environment surrounding incident reporting should be that of a culture of safety, where reporters are not at risk of professional reprisal for reporting incidents.

In order to overcome existing barriers to incident reporting, it will be necessary to introduce a learning and non-punitive culture of safety; this will be ideally facilitated from the beginning of study in professional schools and graduate training programs and supported on an ongoing basis during professional practice by regulators, consumers, patient advocacy groups, and accreditors (Barach and Small 2000). As well, legal protection for those reporting incidents needs to be continually reinforced, as has been done successfully in Australia and New Zealand where adverse event reporting systems in health care have gained widespread acceptance and credibility (Barach and Small 2000).

A study of a medication event reporting system in Northern Ireland identified that the major factor contributing to low reports of critical incidents was lack of staff awareness of what constituted a reportable incident (Medicines Governance 2003). This was addressed through the introduction of a uniform reporting process, making personal contacts between frontline staff and those responsible for the incident reporting system, publication/distribution of safety memos and a quarterly newsletter, and development of an informational safety website

(Medicines Governance 2003). Following the implementation of these changes, a ninefold increase in reported incidents occurred (Medicines Governance 2003).

Some facilities, for example the Baylor Medical Center at Grapevine, have found success at initiating culture change and encouraging reporting through development and implementation of an incentive program. Individuals and teams that report more adverse events receive free lunches and movie coupons, as well as buttons and other forms of visible recognition for participation in the reporting and improvement process (Atherton 2002). Similar to the Baylor "I Plant Flags" campaign, a community hospital in Geneva, Illinois launched a "LifeSavers" safety program with a highly identifiable visual identity which helped increase the volume of medication event incident reporting in their facility (Force et al. 2006).

While studies show all groups of health care professionals have similar attitudes and beliefs regarding the purpose and importance of adverse event reporting, their response to and compliance with mandatory incident reporting systems in the U.S. is varied (Escoto et al. 2006). One study of physicians and their supporting staff (including nurses and medical assistants) found the following differences in preferences for reporting systems according to professional group:

Table 6. Physician versus Nurse Preferences for Reporting Systems
(adapted from Escoto et al. 2006)

Issue	Physician Preferences	Nurse Preferences
Rules and Regulations	Voluntary system	Mandatory system to ensure participation
Reportable Events	Both adverse event and near-miss reporting	Adverse event reporting only to reduce workload
Reporting Medium	Flexible (paper, phone, electronic) but strong preference for electronic	Flexible (paper, phone, electronic) but less preference for electronic
Duplicate Reporting (e.g. organizational and regional)	Did not view negatively	Viewed negatively because of workload

The implementation and daily operation of incident reporting systems can be complicated by participation bias in the collection of reports from staff (Johnson 2003). Past studies have shown nurses submit the vast majority of reports, and consequently the types of incidents reported, as well as the safety solutions proposed as a result of the reports, are not fully representative of the entire system of health care delivery (Johnson 2003).

An Australian study found that physician and nursing groups are equal in their beliefs that incidents should be reported under the national critical incident reporting system, however nurses are more likely to report incidents than are physicians (Evans et al. 2006). The major barrier to reporting for both groups was a lack of feedback following submission of the report. The time it takes to complete the report, as well as a belief that the incident was too trivial to report were other reasons frequently cited for not reporting events, harm to patients, or near misses (Evans et al. 2006). Senior physicians were less likely to submit reports of

incidents than their more junior counterparts, including interns and residents. The alternative is true for nurses: more senior nurses, including nurse managers and unit supervisors are more likely to submit reports of incidents than their subordinates (Evans et al. 2006). This important discrepancy will need to be addressed by any organization looking to develop and successfully implement an adverse event reporting and learning system.

An opinion poll of Canadian physicians in 2003 found that almost one-half oppose mandatory reporting of drug- and device-related incidents and view it as a burden (Lexchin 2006). This statistic casts doubt as to whether making reporting mandatory as opposed to voluntary will contribute to improved volume and/or quality of reports from physician groups (Lexchin 2006). However, there are several proven methods of encouraging physicians to report incidents: payment, education on the need to report, familiarizing them with the reporting system and its associated forms and guidelines, and providing them with follow-up about reports they have filed (Lexchin 2006).

Some incident reporting programs have tried to encourage participation through monetary incentives to report. A program designed to increase reporting of medication-related adverse events in a Vermont hospital in the early 1990s chose to pay a stipend of $5 to physicians for each incident they reported. All respondents to an informal survey of the program stated that they were initially attracted to the program because there was a stipend offered (Gilroy et al. 1990). The authors note that this is likely not a long-term solution, in part because of limited financial resources and in part because other groups of care providers, including nurses and pharmacists would also expect compensation for their participation in the incident reporting system (Gilroy et al. 1990).

When trying to address incident reporting by the physician and nursing professions, it is important to understand that there are vast differences not only in awareness and use of reporting systems but also in the underlying motivators for reporting (Wild and Bradley 2005). In a survey of conditions influencing decisions to report incident by physicians and nurses in Connecticut, the following differences in response were noted:

Table 7. Conditions Influencing Incident Reporting by Physicians and Nurses (Wild and Bradley 2005)

"I would be more likely to report an error if..."	Residents	Nurses	Significant Difference?
...if it were my own error	54%	91%	yes
...if a resident committed the error	4%	43%	yes
...if a nurse committed the error	38%	42%	no
...if I don't like the person who committed the error	25%	1%	yes
...if the patient was young and healthy	33%	19%	no
...if the patient had an intact mental status	29%	14%	no
...if the error had serious consequences	67%	72%	no

When consulted during the development of a statewide incident reporting system in Wisconsin, participants (including physicians and nurses) indicated that a mandatory reporting system would provide motivation to participate whereas voluntary reports would be a lower priority when considered against other scheduled activities (Karsh et al. 2006).

Participants also identified that voluntary reporting may lead to biased reporting in that only those with a keen interest in change would report (Karsh et al. 2006). There was concern expressed about when it was appropriate to report an incident, and participants felt that clear directives on what constitutes a reportable incident should be an integral part of training and instruction provided (Karsh et al. 2006). A 'laundry list' of specific reportable events may make the reporting process simpler but was thought to be difficult to develop (Karsh et al. 2006).

While many studies emphasize the importance of a culture of safety in eliciting reports of harm or near harm to patients, even employees who work with fear of reprisal or being professionally disadvantaged for the act of reporting have been shown to still actively report incidents in certain areas where there can be no direct action taken personally (Kaplan and Fastman 2003). These reports are most commonly found to involve equipment failures or device malfunctions (Kaplan and Fastman 2003). The next most frequent area for report is incidents that were caused by individuals in another department or area (Kaplan and Fastman 2003).

Including Patients in Reporting and Learning Systems

A survey of a Missouri health care center in 2000 found at least six current and separate data systems existed for reporting adverse events, each with their own paper reports to be completed and each with multiple staff members with roles to play in the review, analysis and intervention following report (Kivlahan et al. 2002). The disparate nature of these systems combined with their inability to be linked lead to confusion, duplication of efforts, and an incomplete understanding of safety issues in place in the facility, and prompted very few system-wide safety improvements to be implemented (Kivlahan et al. 2002). In response, a single new online reporting system was created to replace all previous processes (Kivlahan et al. 2002). Standalone computer terminals were provided throughout the hospital facility for staff, patients, and family or visitors to use to report comments , near misses, adverse events, or critical incidents from any computer in the hospital or from home via the Internet (Kivlahan et al. 2002). Staff members are given the option to report anonymously for near-miss events, although not for actual occurrences (Kivlahan et al. 2002).

Other incident reporting systems have acknowledged the important role patients and their family members can play in the safety improvement process and as such encourage them to identify perceived errors and/or elicit their feedback into incident reporting systems. For example, patients and their family members were found to have identified over 90% of pharmacy related adverse events in a Japanese national voluntary medication error reporting program (Furukawa et al. 2003). A national medical device incident reporting database in the U.K. also allows reports from patients and family members (Jefferys 2005). The responses from patients has been low to date, with only a few patient reports included in the approximately 8,500 total reports received annually (Jefferys 2005).

The Institute of Medicine recommended in *To Err is Human* that patients be involved in their own safety by understanding what medications they are taking and notifying their doctors

about side effects they are experiencing (Bleich 2005). However, the report stopped short of recommending that patients be allowed to submit reports of actual or potential adverse events they become aware of or that they experience directly.

6) FINANCIAL IMPLICATIONS

There are financial resource requirements associated with the development and operation of any adverse event reporting and learning system. Adverse events in health care bring with them associated expenses, not the least of which include increased hospital stays, the need for further interventions or treatments, and litigation costs. To date, very little information has been published about the specific costs associated with the development, implementation, and maintenance of incident reporting databases. The Institute of Medicine estimates that preventable adverse events in the U.S. alone have an associated cost of $17 to 29 billion dollars each year (Bleich 2005).

The National Health Service believes that incident reporting and subsequent system-wide safety improvements can reduce hospital admissions and extended stays and have the potential to save the organization £2 billion each year (Payne 2000), as well as to recover an additional approximately £400 million annually in settled negligence claims (Leigh 2006). The NHS has disclosed the costs associated with development and operation of the NRLS database as an estimated £5 million for the first three years since inception (Williams and Osborn 2006).

Costs associated with ongoing data collection, analysis and management of one online incident reporting system were assessed at $25,000 to $35,000 annually per facility (2002 U.S. dollars), or the equivalent of a 0.5-0.75FTE professional in a mid-sized community hospital (Atherton 2002). These costs do not include the expenses associated with system development and implementation (Atherton 2002). Another similar-sized facility noted that when moving from a paper-based reporting system to an online reporting system, cost savings of data entry personnel time were approximately $30,000 per year per facility (Joshi et al. 2002).

The U.S. Aviation Safety Reporting System has a dedicated team of coders who analyze each incident submitted to the system (Johnson 2003). These coders are trained and monitored to ensure consistency in application of coding to the reported incidents, at a cost of $3 million per year or approximately $100 per reported incident (Johnson 2003). However, a national health care adverse event reporting and learning system would likely not have the financial resources available to have a dedicated team of professionals to code incidents. In the U.K. alone, it would cost an estimated £50 billion to have a similar level of analysis to the adverse events that are believed to occur within the National Health Service each year (Johnson 2003).

Adverse event reporting and learning systems will require a sufficient financial commitment to recruit and retain the necessary expertise to evaluate submitted reports (Billings 1998). In the words of Dr. Billings (1998): “these systems cannot be run with a couple of clerks and a keypunch operator.” Just as the reported events are provided by experts providing direct patient care, there must be equivalent experts responsible for the evaluation of the reports and the determination of lessons learned to be disseminated (Billings 1998).

Studies have suggested that in the long term, a well-targeted safety intervention is likely to be cost effective, meaning that the cost of the system improvements are less than or equal to the potential savings from elimination of future incidents (Webster and Anderson 2002). Even if the improvement is not cost effective, organization administration may consider a net loss as acceptable if a significant reduction in patient harm can be demonstrated (Webster and Anderson 2002).

In the opinion of this author, in order to properly prepare for the financial implications of an adverse event reporting and learning system, the following areas and their associated costs that should be taken into consideration:

- Feasibility testing
- Legal advice
- Computer form design
- Hardware – database storage, data warehouse, backups
- Software – purchase and licensing or develop in-house
- Development of taxonomy/classification system
- User education
- User awareness
- User acceptance testing
- Data coding
- Data analysis
- Feedback reporting
- Promotion of system externally
- Incentive program

In order to develop an appropriate budget, the author recommends that in the early stages of planning an adverse event reporting and learning system that a more complete prediction of associated expenses be developed. As a result of the lack of details available in the published literature, these will most likely need to be obtained through structured interviews or personal communications with developers of similar programs.

7) FEEDBACK SYSTEMS TO IMPROVE SAFETY

> "Learning is more than the analysis of an adverse incident – it is about ensuring there is change based on well-designed action plans. These must be realistic, achievable and sustainable, with all stakeholders involved in their development." (Bird and Milligan 2003)

The key to effectively managing clinical risks and the ultimate purpose of event reporting systems is to learn from investigations into reported events and to share those lessons learned to other facilities and organizations that would be similarly vulnerable to that type of event occurring (Bird and Milligan 2003). One major barrier to incident reporting is perceived futility: users experience frustration when they take the time to complete a incident report and then never know what, if anything, changed as a result of those efforts (Khare et al. 2005). In order in encourage reporting, feedback needs to be frequent and staff involved in an incident should be made aware of any changes made to improve system safety. Improving feedback led to an increase in incident reporting in a community hospital in Illinois (Force et al. 2006).

A review of several studies of incident reporting in intensive care units found that information shared in published journal articles is primarily about the collection and analysis of events, and very little information is included about the implementation of any changes following reporting of the adverse event, and whether patient safety has been improved as the end result (Frey et al. 2002). Similarly, there are very few references in the published literature that address the specific methods for information sharing and safety improvements in multiple organizations once a reported event is determined to have system safety implications.

One of the major challenges when developing an incident reporting system is to find a means of providing users as well as stakeholders with access to meaningful data following reporting. It is important to determine what data sets are appropriate to share, as well as to create user-friendly formats for disseminating the information, targeting the appropriate audience, and establishing the most useful means for disseminating information in order to reach the intended audience (NASHP 2006).

Database users identify a lack of data feedback from the reporting system to be a disincentive to ongoing reporting (NASHP 2006). In this way, the timely dissemination of specific information about progress made and system improvements implemented following the report can act as a motivator and encourage increased participation in an incident reporting system (Karsh et al. 2006). Organizations participating in reporting systems have also suggested they would like to receive feedback in the form of quarterly or yearly summaries that highlight the most frequently reported types of safety events as well as process solutions for addressing certain types of incidents (Karsh et al. 2006).

The National Reporting and Learning System in the U.K. uses information distilled from reports of incidents and near misses to publish regular alerts and bulletins on safety issues through a series of reports called the Patient Safety Observatory (Williams and Osborn 2006). The data can also be used to inform the development of educational curriculum, as well as for performance assessment and standards development, for risk assessments both nationally and locally, and to improve the quality of care provided throughout the National Health Service (Williams and Osborn 2006). Health trusts are required to take action on all patient safety alerts issued by the NRLS, and must certify their compliance with the recommended actions within a predetermined timeframe (Leigh 2006).

A criticism of the NRLS is that although the system receives approximately 60,000 reported incidents each month, a relatively small number of safety alerts have been published to date (Leigh 2006). The committee evaluating the success of the system commented that the Agency responsible for the NRLS: "has yet to demonstrate that it is using this information and knowledge effectively to change health care practices rather than simply collecting statistics" (Leigh 2006). The committee recommended that patient safety feedback reports be produced and distributed to health trusts at least four times per year (Leigh 2006).

"For an organization to adopt event reporting rather than to simply comply with its requirement, there must be timely and effective feedback and demonstrable local usefulness" (Kaplan and Fastman 2003).

The challenge to all organizations implementing an adverse event reporting and learning system is to determine what type of information to disseminate, as well as how frequently and in what format. Keeping frontline care providers engaged in the process and aware of the outcome of investigations and system safety improvements will ultimately encourage continued participation in the event reporting system, driving the chain reaction of awareness of adverse events and their underlying causes to further patient safety initiatives in the future.

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APPENDIX: ELECTRONIC DATABASE SEARCH CRITERIA

Search Results

Database	Initial Search	After De-Dup
Medline	156	140
CINAHL	36	17
Embase	101	49
Web of Science	56	14
Total		**220**

Medline Search

#	Search History	Results
1	adverse drug reaction reporting systems/	2963
2	mandatory reporting/	1141
3	(mandator$ adj3 report$).tw.	449
4	(incident$2 adj4 report$).tw.	1805
5	national$ report$.tw.	250
6	event$ report$.tw.	1500
7	data collection/	51342
8	hospital information systems/	7857
9	information systems/	15832
10	information services/	13558
11	or/1-10	92862
12	exp medical errors/	52202
13	(medica$ adj3 error$).mp.	12314
14	(adverse$ adj3 event$).mp.	30671
15	(adverse$ adj3 effect$).mp.	64439
16	(health care adj3 error$).mp.	124
17	(healthcare adj3 error$).mp.	37
18	(sentinel adj3 event$).mp.	350
19	(diagnos$ adj3 error$).mp.	24899
20	(nurs$ adj3 error$).mp.	210
21	(physician$ adj3 error$).mp.	247
22	(patient care adj3 error$).mp.	43
23	(surg$ adj3 error$).mp.	557
24	near$ miss$2.mp.	596
25	(critical$ adj3 incident$).mp.	891
26	(critical$ adj3 outcome$).mp.	1174
27	(adverse$ adj3 outcome$).mp.	10260
28	(unanticipated adj4 outcome$).mp.	48
29	iatrogenic disease/	9274
30	or/12-29	166832
31	11 and 30	4117
32	limit 31 to english language	3822

33	report$.ti.	255456
34	32 and 33	651
35	classification/	4407
36	classificat$.tw.	
37	taxonom$.tw.	14329
38	computers/	45474
39	comput$.tw.	281541
40	technology/	4774
41	technolog$.tw.	107885
42	implement$.tw.	92559
43	exp systems analysis/	18981
44	data interpretation, statistical/	23610
45	information dissemination/	3378
46	govern$.tw.	56392
47	or/35-46	
48	34 and 47	134

Also considered:

Legal$.tw. -nothing relevant was added. Mostly articles about reporting mental health cases/situations, reporting abuse cases, etc.

Infrastructure$.tw. –nothing relevant was added. (e.g. "Staffing and infrastructure of the recovery room…" and "Clinical research infrastructures and networks in France: report on the French ECRIN workshop"

Cumulative Index for Nursing & Allied Health Literature (CINAHL) Search

#	Search History	Results
1	mandatory reporting/	1652
2	incident reporting/	1037
3	(mandator$ adj3 report$).tw.	136
4	(incident$2 adj4 report$).tw.	545
5	national$ report$.tw.	60
6	event$ report$.tw.	253
7	data collection/	3167
8	exp health information systems/	9108
9	exp information systems/	25470
10	information services/	1892
11	or/1-10	32802
12	medication errors/	3755
13	(medica$ adj3 error$).mp.	4837
14	(adverse$ adj3 event$).mp.	4669
15	(adverse$ adj3 effect$).mp.	4900
16	(health care adj3 error$).mp.	1499
17	(healthcare adj3 error$).mp.	488
18	(sentinel adj3 event$).mp.	342
19	(diagnos$ adj3 error$).mp.	2184
20	(nurs$ adj3 error$).mp.	1862
21	(physician$ adj3 error$).mp.	621
22	(patient care adj3 error$).mp.	999
23	(surg$ adj3 error$).mp.	604
24	near$ miss$2.mp.	137
25	(critical$ adj3 incident$).mp.	874
26	(critical$ adj3 outcome$).mp.	1565
27	(adverse$ adj3 outcome$).mp.	1551
28	(unanticipated adj4 outcome$).mp.	24
29	iatrogenic disease/	526
30	or/12-29	21397
31	11 and 30	1665

32	limit 31 to english language	1644
33	report$.ti.	24428
34	32 and 33	296
35	classification/	671
36	classificat$.tw.	8099
37	taxonom$.tw.	719
38	"computers and computerization"/	3476
39	comput$.tw.	18279
40	exp technology/	8794
41	implement$.tw.	24937
42	exp systems analysis/	725
43	clinical governance/	459
44	govern$.tw.	11454
45	or/35-42	70533
46	34 and 45	45

Embase Search

#	Search History	Results
1	mandatory reporting/	165
2	voluntary reporting/	30
3	(mandator$ adj3 report$).tw.	279
4	(incident$2 adj4 report$).tw.	1291
5	national$ report$.tw.	572
6	event$ report$.tw.	1413
7	information processing/	39409
8	exp information system/	23618
9	information service/	1566
10	or/1-9	64405
11	exp medical error/	18459
12	(medica$ adj3 error$).mp.	5050
13	(therap$ adj3 error$).mp.	462
14	(adverse$ adj3 event$).mp.	30363
15	(adverse$ adj3 effect$).mp.	52371
16	(health care adj3 error$).mp.	123
17	(healthcare adj3 error$).mp.	19
18	(sentinel adj3 event$).mp.	178
19	(diagnos$ adj3 error$).mp.	15806
20	(false$ adj3 result$).mp.	8858
21	(nurs$ adj3 error$).mp.	187
22	(physician$ adj3 error$).mp.	337
23	(patient care adj3 error$).mp.	218
24	(surg$ adj3 error$).mp.	706
25	near$ miss$2.mp.	352
26	(critical$ adj3 incident$).mp.	542
27	(critical$ adj3 outcome$).mp.	1421
28	(adverse$ adj3 outcome$).mp.	9119
29	(unanticipated adj4 outcome$).mp.	23
30	exp iatrogenic disease/	140023
31	or/11-30	241427
32	10 and 31	3814

33	limit 32 to english language	3552
34	report$.ti.	140879
35	33 and 34	449
36	exp classification/	240606
37	classification$.tw.	70183
38	taxonom$.tw.	8419
39	computer/	10637
40	comput$.tw.	193342
41	technolog$.tw.	82116
42	implement$.tw.	67502
43	system analysis/	5346
44	information dissemination/	1636
45	govern$.tw.	38911
46	or/36-45	633133
47	35 and 46	101

Web of Science

#42	56	#34 AND #41
#41	>100,000	#40 OR #39 OR #38 OR #37 OR #36 OR #35
#40	>100,000	TS=govern*
#39	>100,000	TS=implement*
#38	>100,000	TS=technolo*
#37	>100,000	TS=comput*
#36	51,110	TS=taxonom*
#35	>100,000	TS=classificat*
#34	363	#32 AND #33
#33	>100,000	TI="report*"
#32	2,591	#31Language=English
#31	2,668	#13 AND #30
#30	88,603	#29 OR #28 OR #27 OR #26 OR #25 OR #24 OR #23 OR #22 OR #21 OR #20 OR #19 OR #18 OR #17 OR #16 OR #15 OR #14
#29	416	TS="iatrogenic disease*" OR TS="iatrogenic AND disease*"
#28	32	TS="unanticipated outcome*" OR TS="unanticipated AND outcome*"
#27	7,977	TS="adverse* outcome*" OR TS="adverse* AND outcome*"
#26	117	TS="critical* outcome*" OR TS="critical* AND outcome*"
#25	1,121	TS="critical* incident*" OR TS="critical* AND incident*"
#24	6	TS="near* miss*" OR TS="near* AND miss*"
#23	125	TS="surg* error*" OR TS="surg* AND error*"
#22	2	TS="patient care error*" OR TS="patient AND care AND error*"
#21	62	TS="physician* error*" OR TS="physician* AND error*"
#20	23	TS="nurs* error*" OR TS="nurs* AND error*"
#19	969	TS="diagnos* error*" OR TS="diagnos* AND error*"
#18	164	TS="sentinel* event*" OR TS="sentinel* AND event*"

#17	17	TS="health care error*" OR TS="health care AND error*" OR TS="healthcare error*" OR TS="healthcare AND error*"
#16	50,334	TS="adverse* effect*" OR TS="adverse* AND effect*"
#15	28,567	TS="adverse* event*" OR TS="adverse* AND event*"
#14	2,083	TS="medica* error*" OR TS="medica* AND error*"
#13	41,830	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12
#12	686	TS="informat* AND service*"
#11	4,619	TS="informat* service*"
#10	4,245	TS="informat* AND system*"
#9	28,536	TS="informat* system*"
#8	1,539	TS="event* AND report*"
#7	1,549	TS="event* report*"
#6	246	TS="national* AND report*"
#5	267	TS="national* report*"
#4	143	TS="incident* AND report*"
#3	642	TS="incident* report*"
#2	56	TS="mandator* AND report*"
#1	234	TS="mandator* report*"

Review of Provincial, Territorial and Federal Legislation and Policy Related to the Reporting and Review of Adverse Events in Healthcare in Canada

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November 15, 2007

EXECUTIVE SUMMARY

The reporting of patient safety events including Adverse Events, Critical Incidents, Sentinel Events and Near Misses (each such term is hereinafter defined), both within the healthcare organizations that discover them and beyond, is an important means to improve the safety of healthcare systems. Such reporting is consistent with the vision of the National Steering Committee on Patient Safety in their 2002 Report[1] and has been a part of patient safety efforts in the United States, the United Kingdom and elsewhere. However, such reporting raises important issues about protecting the privacy of individuals and creating processes that are consistent with varying legislative and policy requirements that influence the collection, analysis and dissemination of such information.

In this report, we analyze key enablers and barriers for the reporting and review of Incidents (hereinafter defined) on a national scale ("**Pan-Canadian Reporting**"). We report on the following: (a) an analysis of the application of provincial and federal legislation; (b) a review of policies at provincial and regional levels; (c) surveys of healthcare regions, hospitals and other health delivery organizations; and (d) interviews with experts and key stakeholders interested in the reporting of Incidents.

Our review of evidence legislation, general and health-specific privacy laws and related legislation indicates that most jurisdictions provide legislative protections for the privacy of personal health information while enabling a healthcare organization to gather and analyze information to improve quality and safety within such organization. Even so, there remains considerable variation in these approaches. For example, some provinces (Saskatchewan, Manitoba and Quebec) have developed legislation that mandates reporting both within the healthcare institution that discovered the Incident and to the provincial Ministry. Other provinces have not developed mandatory reporting legislation such that reporting of Incidents may only occur at an institutional level, if at all. Moreover, our legislative review also indicates that most jurisdictions prohibit the sharing of patient safety information both within and outside of the province, thereby acting as a barrier to Pan-Canadian Reporting.

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1 National Steering Committee on Patient Safety, "*Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care*" (September 2002). The Report can be found at http://rcpsc.medical.org/publications/buildingasafersysteme.pdf.

A review of federal, provincial and territorial policies on the reporting of Incidents, along with interviews with key policy makers, indicates that there is a lack of a common approach, shared definitions and other elements needed to collect and compare data on a provincial basis, let alone on a Pan-Canadian basis. In addition, policies in many jurisdictions are underdeveloped in terms of reporting mechanisms, accountability and evaluation criteria and standards.

Our survey of health regions and health delivery organizations reveals a similar pattern of varying policies and incomplete implementation of systems to collect, analyze and learn from Incidents. While some regions and organizations are well advanced in these areas, others are still developing such systems. Based on this information, we interviewed international and national experts on the critical barriers and enablers and potential solutions to advance Pan-Canadian Reporting and sharing of lessons learned.

An effective strategy to improve reporting and learning from Incidents will include both local reporting and analysis, and sharing of lessons learned at a provincial and Pan-Canadian level. Our recommendations urge the development of local capabilities to collect and analyse reports within organizations and regions. Additional funding from the federal government or other sources would help to encourage participation and speed the development of such capabilities.

We also recommend that mechanisms be established to enable the transfer of useful information within each province and beyond. A review of current legislative provisions in most provinces suggests potential barriers to the transfer of such useful information, particularly on a personally identifiable basis. In our view, based on a review of privacy legislation and the privacy provisions of evidence and quality assurance legislation (where applicable), the political capital required to effect the statutory amendments necessary to achieve the Pan-Canadian Reporting of personal health information ("**PHI**") would be immense. We would therefore recommend an alternative approach; modelled on the approach in Alberta, Saskatchewan or Manitoba that would establish a provincial body responsible for reporting in each province (which body could include the Minister, as is the case in Manitoba, or a separate organization, as is the case in the other named provinces). This provincial body could coordinate reporting by healthcare institutions and healthcare professionals in that province in compliance with provincial law. The provincial body would also be responsible for sharing de-identified information with a Pan-Canadian body capable of disseminating information and warnings on a national basis.

In order to obtain useful information, a Pan-Canadian body would work with provincial bodies to develop a framework for the classification of Incidents across the country. By standardizing each province's approach to reporting and to de-identification, Pan-Canadian Reporting can draw from the lessons learned across the country on a consistent basis.

Finally, although we are of the view that federal legislation is not required for the development of Pan-Canadian Reporting and sharing at this point in time, federal legislation could be developed for the purpose of setting out the objectives of the Pan-Canadian model and to provide additional funding to support those objectives. Such legislation would not override provincial legislation but it would likely demonstrate to Canadians the importance of patient safety to the federal government and foster cooperation among the provinces and territories.

DEFINITIONS

In this report the following terms have the meanings set out below:

"**Adverse Events**" are unintended injuries or complications that are caused by healthcare management, rather than the patient's underlying disease and that lead to death or disability or require additional use of hospital or other healthcare organizational resources, such as prolonged hospital stay, additional testing or interventions.

"**Classification System**" is the grouping of information about an event to be deconstructed and translated into a common (coded) language and to create an electronic record that can be compared with other records and analyzed as part of a larger set of data.[2] [3]

"**Critical Incidents**" are incidents resulting in serious harm (loss of life, limb, or vital organ) to the patient/client/resident, or the significant risk thereof, i.e., incidents are considered critical when there is an evident need for immediate investigation and response.

"**Disclosure**" means the communication of information to the patient and open discussion with the patient, by healthcare providers, about an Incident that results in unintended harm to the patient while receiving healthcare and the associated investigation and recommendations for improvement.[4]

"**Government**" means any federal or provincial government or government agency or government funded organization dealing with patient safety.

"**Incidents**" means patient safety events including Adverse Events, Critical Incidents, Sentinel Events and Near Misses; and "**Incident**" means any one of them.

"**including**" means including without limitation and "**includes**" means includes without limitation and neither "**including**" nor "**includes**" shall be construed to limit any general statement which they follow to the specific or similar items or matters immediately following them.

"**Major and Enduring Loss of Function**" is sensory, motor, physiological, or psychological impairment not present at the time services were sought or began. The impairment lasts for a minimum period of two weeks and is not related to an underlying condition.

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[2] WHO, World Alliance for Patient Safety (2005, October) "*Project to Develop the International Patient Safety Event Taxonomy*": Report of the World Alliance for Patient Safety Drafting Group.

[3] Runciman WB, "*Shared Meanings: Preferred Terms and Definitions for Safety and Quality Concepts*". MJA 2006 184;10: S41-S43.

[4] Health Quality Council of Alberta, Disclosure of Harm to Patients and Families Provincial Framework and Australian Council for Safety and Quality in Health Care. "*Open disclosure standard: a national standard for open communication in public and private hospitals, following an adverse event in health care*" (2003). Commonwealth of Australia.

"**Near Misses**" are occurrences that could have caused harm to the patient but ultimately did not as a result of chance or prevention, or mitigation through a planned or unplanned recovery process.

"**RCA**" means root cause analysis of an Incident to determine how the Incident occurred.

"**Reporting/Reported/Report**" means the reporting of an Incident, or the making of a report about an Incident, within the healthcare organization in which the Incident occurred including management, the board and the committee that has as its primary purpose the carrying out of quality assurance activities and to the Government of the province where the Incident occurred.

"**Sentinel Events**" means an unexpected Incident, related to system or process deficiencies and/or human error, which leads to death or Major and Enduring Loss of Function for a recipient of healthcare services.

"**Sharing/Shared/Share**" means the disclosure of an Incident to a person outside of the healthcare organization in which the Incident occurred.

"**Taxonomy**" is a delineation of terms or relationship among terms that provides a structured representation of part of the domain of the knowledge about safety.[5]

INTRODUCTION

We were engaged by the Canadian Patient Safety Institute ("**CPSI**") to conduct a comprehensive review of legislation (Part One) and policy (Part Two) related to the Reporting and review of Incidents in Canadian healthcare, as further described below. Our mandate also included: (a) developing and implementing a survey of health regions and health delivery organizations throughout Canada with respect to their experience with Reporting; and (b) interviewing 15 key informants on this subject (Part Three).

Based on the reviews, surveys and interviews, we were able to identify key barriers and enablers to Reporting. We have developed a set of recommendations for consideration by CPSI when addressing these barriers and promoting Reporting (Part Four).

For clarity, the scope of our work was limited to Reporting. It was not part of our mandate to consider the issue of Disclosure. Accordingly, we have not considered the Draft National Guidelines for the Disclosure of Adverse Events as part of our review. Nonetheless, many institutional policies and academic commentary on Incidents often deal with both Reporting and Disclosure as one topic and may not distinguish between the two. Accordingly, we may at some point throughout this report use the terms "reporting" and "disclosure" interchangeably where it has been done in a particular piece of legislation, policy or by academic commentators and other key stakeholders.

Also, it was not part of our initial mandate to consider the issue of Sharing; however, over the course of the project our mandate was expanded to consider enablers and barriers to Sharing between provinces.

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[5] The Canadian Patient Safety Dictionary (2003).

Our report is divided into four sections. Part One summarizes the findings of our legislative review. Part Two summarizes the findings of our policy review. Part Three summarizes the findings of our surveys and interviews. Collectively, the key findings from these three analyses are used to suggest an integrated series of recommendations for overcoming barriers and promoting Reporting in Part Four.

PART ONE: FINDINGS OF LEGISLATION REVIEW

A. Introduction

Our team reviewed and analyzed relevant federal, provincial and territorial statutes and regulations that relate to Reporting and Sharing and identified seven categories of statutes and regulations[6]. In the discussion and Section B, we summarize the key aspects of each category of legislation. A Legislation Reference Table, found at Appendix 1, identifies the specific statute in each category for each province and territory. In Section C we described legislative enablers and barriers of Reporting and set out in Section D a legislative framework. Collectively, the critical components and levers from lessons learned from jurisdictions have pointed toward the legislative framework, outlined in Section D.

The following qualifications should be noted with respect to the scope of the legislative review. While the legislative review involved a comprehensive examination of the enumerated legislation, we did not review the following: (a) any case law, findings or orders interpreting the legislation that may be available (for example, as may be issued by privacy or information commissioners); (b) other forms of interpretative assistance issued by applicable regulatory authorities, such as guidelines, fact sheets, bulletins, etc; or (c) any documentation relating to the original drafting of legislation (for example, the applicable Hansard records). Similarly, we did not approach any regulatory authorities for their informal views on the intent behind, or their interpretation of, the relevant provisions. Such reviews were beyond the scope of our mandate. However, we would be pleased to conduct this analysis should it be required, perhaps in connection with the work conducted by the panel of experts that we recommend be established.

[6] We also reviewed all current bills in every provincial and territorial legislature and confirmed that no jurisdictions were currently considering bills on Reporting. This was also confirmed in an email from representatives of the governments of Saskatchewan, Manitoba and Nova Scotia.

B. Laws, Inquests and Inquiries, Drug and Medical Device Adverse Event Reporting and Professional Regulation

1. Evidence Laws and Privilege

In nearly all provinces and territories[7], quality assurance records and the proceedings of quality assurance committees are inadmissible as evidence in legal proceedings, and witnesses cannot be questioned in respect of same. The purpose of this "privilege" is to encourage Reporting by healthcare professionals so that Incidents can be investigated and improvements can be made. Generally, this privilege is found in evidence or health services statutes.

It should be noted, however, that this privilege hinges on the definition of "legal proceedings" which varies between jurisdictions. For example, proceedings founded on defamation, civil conspiracy and inducing breach of contract are excluded from this privilege in Saskatchewan and the Yukon, while other jurisdictions exclude discipline proceedings from same[8]. A summary of the relevant provisions across Canada is found at Appendix 2.

It is also important to note that the privilege over quality assurance records does not always protect the information used to create those records. Accordingly, medical charts and information in medical records regarding the provision of health services are admissible as evidence. Similarly, in some jurisdictions, the facts of an Incident, or information or records required by law to be created or maintained by the applicable healthcare entity, whether or not they form part of a medical record, are admissible as evidence.[9]

Beyond the admissibility of evidence, most jurisdictions expressly protect individuals who make disclosures or submissions to a quality assurance committee from any liability that could result from the making of same; however, certain jurisdictions require that such individuals act in good faith in order to be protected from liability.[10] Therefore, by protecting persons who offer information in quality assurance proceedings, the privilege enables Reporting.

2. Privacy Laws

(a) General Privacy Laws

Any Pan-Canadian approach to Reporting and Sharing must address laws that deal with the disclosure of personal information. All provinces and territories have enacted either general privacy statutes or freedom of information type privacy statutes that apply to a public

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[7] The exception appears to be Prince Edward Island as the *Evidence Act* of Prince Edward Island is silent in this regard. See *Evidence Act,* R.S.P.E.I. 1988, c. E-11.

[8] Northwest Territories, Nunavut, British Columbia and Saskatchewan.

[9] In Saskatchewan, Manitoba and Ontario the facts with respect to a quality assurance incident are not privileged.

[10] Determining what constitutes an absence of good faith may be difficult since it speaks to the intent of the submission and the state of mind of the individual. Also, different jurisdictions take slightly different approaches to this qualification (e.g. in the *Evidence Act* (Nova Scotia), the privilege applies if the disclosures or submissions to a hospital committee were not made "with malice"). A review of secondary sources may assist in resolving this ambiguity.

institution's[11] collection, use and disclosure[12] of personal information or information which is about an identifiable individual. These privacy statutes prohibit the disclosure of personal information without the prior consent of the subject individual, unless otherwise required by law.[13] A summary of the relevant disclosure provisions in these provinces is found at Appendix 3. However, it would be a difficult task to obtain consent from each patient or other relevant individual for the purposes of Reporting and Sharing. A more practical approach, to facilitate Reporting and Sharing of information about an Incident, would be pursuant to a permitted exception which avoids the need to obtain consent.

Alternatively, the disclosure of Incident data on a de-identified basis would also enable Reporting and Sharing without contravening general privacy laws, given that, as we have noted above, such laws only apply to personal information or information which is about an identifiable individual. This raises the concern (discussed below) as to what constitutes effective de-identification, such that the Incident data is effectively anonymized but is still useful in respect of Sharing.

(b) Health Information Privacy Laws

In addition to the privacy laws noted above, four provinces have taken the additional step of enacting privacy legislation that is specific to PHI, namely Alberta, Saskatchewan, Manitoba and Ontario. A summary of the relevant disclosure provisions in those provinces is found at Appendix 4. PHI is a subset of personal information, namely information that relates to the health status and the provision of healthcare to an identifiable individual. The PHI statutes govern the collection, use and disclosure of PHI to the exclusion of the more general privacy laws.

Provinces with only general privacy legislation tend to have a unified approach to the disclosure of personal information, whereas provinces with PHI legislation do not. The provisions of PHI legislation (and the various healthcare statutes that relate to quality assurance activities) have a varied approach to disclosure of PHI. In the four provinces noted above, PHI legislation appears to act as both an enabler and a barrier to Reporting and Sharing depending on which entity has custody of the PHI: (a) PHI custodians or trustees; (b) quality assurance committees[14]; (c) third party institutions, including the Government or another regulatory body in the province.

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[11] Hospitals are considered to be public institutions under freedom of information statutes.

[12] As alluded to earlier in this report, it is important to note that in the privacy context, the term "disclosure" refers to the communication of information by a custodian or trustee to another person (i.e. where such person is not considered to be part of the custodian). This should not be confused with the term disclosure in the patient safety context where it is used to denote the communication of information about an Incident to the patient.

[13] In order to properly invoke the "required by law" exception in the context of quality assurance activities, a review of healthcare and related statutes in each jurisdiction would be necessary to determine whether a separate statutory basis requiring such disclosure exists. Such an analysis is beyond the scope of our mandate and has not been addressed in this report.

[14] This refers to committees that have as their primary purpose the carrying out of quality assurance activities. The name of such committees varies between jurisdictions, but for the purpose of this report we refer to them as quality assurance committees.

(i) Custodians or Trustees

PHI legislation enables Reporting to certain persons by allowing custodians or trustees[15] to disclose PHI, without having to obtain the individual's consent, to quality assurance committees for the purpose of reviewing an Incident.

Also in some provinces, such as Alberta and Saskatchewan, the disclosure provisions also act as an enabler to Sharing in that they allow custodians or trustees to disclose PHI to third party organizations with prescribed purposes, without the consent of the individual.[16] These organizations are tasked with coordinating and facilitating quality assurance activities on a province-wide basis. For example, Alberta has made a regulation under the *Regional Health Authorities Act*[17] to form the Health Quality Council of Alberta ("**Alberta Council**"), a province-wide patient safety body.[18] The Alberta Council's mandate is to, in cooperation with health authorities and in accordance with an approved health plan, (a) measure, monitor and assess patient safety and health service quality; (b) identify effective practices and make recommendations for the improvement of patient safety and health service quality; (c) assist in the implementation and evaluation of strategies designed to improve patient safety and health service quality; and (d) survey Albertans on their experience and satisfaction with patient safety and health service quality. The Alberta Council coordinates with the health professions, health authorities, organizations providing health services, academic health centres and others for the purposes of sharing information on patient safety and health service quality issues, identifying and assessing those issues, and developing and recommending effective practices in patient safety and health service quality.

Custodians in Ontario are permitted to disclose PHI to the Ontario Agency for Health Promotion and Protection for the purposes of that agency[19], or at the request of the Minister and subject to certain additional obligations, to a health data institute[20]. We understand however that currently the Agency's mandate does not encompass Reporting but the prospect remains that the Agency's mandate could be amended in order to do so. Moreover, Sharing in Ontario is hampered by the *Quality of Care Information Protection Act*[21], which supersedes Ontario PHI legislation with separate provisions for "quality of

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[15] The definitions of "custodian" and "trustee" vary between jurisdictions, but generally include healthcare institutions and healthcare professionals and related entities that may hold PHI.

[16] Although it does not have PHI-specific legislation, Newfoundland and Labrador has a similar third party organization, the Centre for Health Information. The *Centre for Health Information Act*, S.N.L. 2004, c. C-5.1, section 17.1 (3) ("**CHIA**") amended the *Hospitals Act* to allow hospitals to disclose personal information to the Centre for Health Information in accordance with the CHIA and its regulations. The Centre can make further disclosures of personal information it receives without the consent of applicable individuals (see section 10 of the *Centre for Health Information Regulations*, N.L.R. 57/07).

[17] R.S.A. 2000, c. R-10.

[18] *Health Quality Council of Alberta Regulation*, Alta. Reg. 130/2006.

[19] *Ontario Agency for Health Protection and Promotion Act, 2007*, S.O. 2007, c. 10, Sch. K.

[20] Section 47 of the *Personal Health Information Protection Act, 2004*, S.O. 2004, c. 3, Sch. A. A "health data institute" is an organization that has as its object the performance of data analysis of personal health information, linking the information with other information and de-identifying the information for the Minister.

[21] 2004, S.O. 2004, c. 3, Sch. B.

care information". "Quality of care information" includes any information put before a quality of care committee, whether personal information or other non-personal information. Generally, that Act prohibits the Sharing of "quality of care information" beyond the institution or entity at which the Incident occurred.

In Saskatchewan, the *Health Information Protection Act*[22] and its regulations permit disclosure of PHI to the Health Quality Council (the "**Saskatchewan Council**") without the consent of the subject individual. The Saskatchewan Council may then use the PHI in accordance with the *Health Quality Council Act*,[23] which includes supporting new initiatives and facilitating sharing of best practices among the health regions of Saskatchewan and the Saskatchewan Cancer Agency.[24]

(ii) Quality Assurance Committees

Quality assurance committees receive PHI from custodians or trustees and from other persons as part of an investigation into a particular Incident. Often the ability to disclose PHI to any person other than the institution to which the committee is associated is constrained, whether through PHI legislation or the interaction of other statutes. Therefore PHI legislation acts as a barrier to Sharing Incident data containing PHI with other quality assurance committees within and beyond their respective provinces. Even disclosure of Incident data containing de-identified PHI by a quality assurance committee to another quality assurance committee or other third party in the same jurisdiction and in other jurisdictions is prohibited in most provinces.[25]

(iii) Third Party Organizations

Third party organizations, or the Minister in the case of Manitoba, are tasked with aggregating Incident data in their respective provinces. It is interesting to note that the Alberta Council's authorizing regulations give it the right to have reasonable access, as necessary, to information held by health authorities to carry out its objects noted above. It is unclear, however, whether the Alberta Council would be permitted to share any PHI outside of Alberta; however, such a program would require the approval of the applicable Minister. The Saskatchewan Council is not permitted to disclose PHI as part of its activities. Any Sharing, whether inside or outside of Saskatchewan, would only be permitted on a de-identified basis.

(iv) Variations in Treatment of PHI

While at the outset, there seems to be unity among provinces that have PHI-specific legislation, the potential for disclosure of Incident data that contains PHI to support Pan-Canadian Reporting varies in the jurisdictions:

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[22] *Health Information Protection Act*, S.S. 1999, c. H-0.021.

[23] S.S. 2002, c. H-0.04.

[24] Section 5 of the *Health Information Protection Regulations*, R.R.S. c. H-0.021 Reg. 1.

[25] Alberta seems to be the exception. See footnote 36.

(A) Alberta permits disclosures of PHI to other custodians (i.e. healthcare institutions and practitioners) in Alberta for *internal* "monitoring", "quality improvement" or "evaluation" purposes.[26] What is unclear, however, is the how the word "internal" would operate in this section. For example, in order to effect internal "quality improvement", a hospital may need to share information with other hospitals (effectively for the purposes of benchmarking quality standards). In contrast, internal "monitoring" of a program may not require disclosures to other institutions.

(B) Also, in Alberta, the Alberta Council can receive and have access to PHI held by custodians to carry out its objects related to furthering patient safety as noted above. It is unclear whether the Alberta Council can then disclose information other than on a de-identified basis.

(C) Saskatchewan has similar provisions as Alberta, but appears to permit disclosures to any person in any jurisdiction for the purpose of "evaluating" health services practices in a health services facility (which, like "quality improvement" as set out in (a) above, may or may not require inter-custodian disclosures).[27]

(D) Also, Saskatchewan has a council similar to the Alberta Council, but it is only permitted to disclose de-identified information.[28]

(E) Manitoba permits disclosures of PHI to any person in any jurisdiction if "required" for the purpose of a quality assurance committee or for "risk management assessment".[29]

(F) Ontario only allows disclosures of PHI for the purpose of aggregate analysis to the Ontario Agency for Health Protection and Promotion (the mandate of which we understand does not currently encompass Reporting) or to a health data institute, although "quality of care information" (which could include any information put before a quality assurance committee, whether PHI or non-personal information, other than the facts of the Incident) may not be disclosed beyond the facility or entity at which the Incident occurred pursuant to separate legislation dealing with quality assurance information.[30]

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[26] Section 35(1)(a) with reference to section 27(1)(g) of the *Health Information Act*, R.S.A. 2000, c. H-5.

[27] Section 27(4)(k) of the *Health Information Protection Act*, S.S. 1999, c. H-0.021.

[28] Section 5 of the *Health Information Protection Regulations*, R.R.S. c. H-0.021 Reg. 1.

[29] Section 22(2)(e)(iv) of the *Personal Health Information Act*, C.C.S.M. c. P33.5.

[30] Section 4 of the *Quality of Care Information Protection Act*, 2004, S.O. 2004, c. 3, Sch. B.

In light of the diverse legislative framework across Canada, Pan-Canadian Reporting is severely limited. At best, certain provinces allow Sharing of PHI between individual healthcare institutions (not quality assurance committees of healthcare institutions) and a named third party provincial organization (or the Minister) as noted above. Disclosures beyond such bodies, particularly where the disclosure is to occur to another province or territory is for the most part limited to de-identified information only.

(c) De-identified Information

Generally, de-identified information can be disclosed for any purpose and to any person without the subject individual's consent.[31] "De-identified" commonly means that any information that may be reasonably expected to identify an individual has been removed from the record.[32]

However, even where disclosure of de-identified information is permitted, it is often subject to restrictions. For example, in Alberta, disclosure by the quality assurance committee is barred except for disclosures of *non-identifying* health information to another quality assurance committee, whether in Alberta or in another province or territory.[33] Also, in Ontario, de-identified *factual* information may be disclosed to any person, but quality assurance information, which may include RCA, opinions and the recommendations of a quality assurance committee, can only be Shared with the management of the applicable institution and cannot otherwise be disclosed. As another example, in Saskatchewan, any PHI disclosed to a quality assurance committee by a healthcare institution or a healthcare practitioner cannot thereafter be disclosed by that committee, regardless of whether it has been de-identified.[34]

(d) Findings of Other Reports

In its 2002 report, *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care*, the National Steering Committee of Patient Safety recommended that legislation on the privacy and confidentiality of personal information across Canada be standardized in order to facilitate access to Incident data, while respecting the privacy of patients and providers.[35] The Steering Committee envisioned a system whereby patient safety information could be Shared across all jurisdictions.

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[31] In some provinces, quality assurance committees cannot disclose even de-identified information, and Sharing must be by way of the applicable healthcare institution or healthcare provider.

[32] This standard varies between provinces. For example, British Columbia does not include the qualifier "reasonably" and therefore appears to reflect a stricter standard.

[33] Unlike most provinces which tie disclosures to entities existing under the laws of the applicable province, the Alberta PHI Act uses language that does not require the recipient entity to be formed under Alberta law: disclosures may be made to "a committee that has as its primary purpose the carrying out of quality assurance activities within the meaning of section 9 of the *Alberta Evidence Act.* See *Alberta Evidence Act*, R.S.A. 2000, c. A-18, s.9.

[34] Subsection 27(4)(g) of the *Health Information Protection Act,* S.S. 1999, c. H-0.021.

[35] National Steering Committee on Patient Safety, "*Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care*" (September 2002) at 15.

In a subsequent report, Karen Weisbaum et al.[36] (the "**Weisbaum Report**") concluded that privacy legislation is not - nor will it ever be - standardized.[37] Instead, the authors focused on developing a national harmonized policy for handling Incident data in a privacy protective manner. It is important to note that the Weisbaum Report limited its analysis to medication Incidents and no other type of Incidents. That is the distinguishing feature between the Weisbaum Report and this report.

The Weisbaum Report concluded as follows:

> "… limits on sharing information that stem from privacy rules and other confidentiality provisions are not necessarily applicable to incident data. What counts for determining if sharing is permitted are the characteristics of the data themselves. At least in the case of medication incident data, sharing will be greatly facilitated through harmonization of these characteristics according to an accepted standard or format, and the fact that privacy standards are not harmonized -- or are perceived as not harmonized – will not present a barrier to sharing."[38]

In other words, the authors determined that Incident data need not be identifying data. In their view, nationally accepted categories of de-identified data elements to be included in Reporting (such as those used by the Institute of Safe Medication Practices Canada) would meet privacy requirements and support Sharing about Incidents involving a medication error.

Although we agree that a national consensus on data elements in Reporting and Sharing would be helpful, we are not convinced that nationally accepted categories of data elements for the Reporting and Sharing of all other Incidents (i.e. Incidents not involving medication error) would be sufficient to meet the requirements of privacy laws and support Reporting and Sharing.

First, PHI that is de-identified does not always result in useful information. For example, an individual who has a unique set of characteristics that may make him or her vulnerable to a certain type of Incident would find that the rare combination of characteristics is itself identifiable with that person. If any characteristics were removed in the name of de-identification, this may result in the removal of clinical information that is necessary for effective Reporting.

Second, as noted above, the statute under which personal information is collected can serve to restrict further disclosures, regardless of whether it is de-identified. Some jurisdictions impose a general confidentiality obligation over all information that is collected in the quality assurance process and used by a quality assurance committee. Other jurisdictions expressly restrict

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[36] Karen Weisbaum, Sylvia Hyland and Eleanor Morton, "*Striking a Balance: Facilitating Access to Patient Safety Data While Protecting Privacy Through Creation of a National Harmonized Standard*" (April 2007 Draft) at 2.

[37] It is the view of the authors of this report that standardizing privacy legislation would be difficult. In our view it would not be difficult to standardize privacy legislation from a language point of view; however, it would be difficult to achieve from a political/process point of view.

[38] Karen Weisbaum, Sylvia Hyland and Eleanor Morton, "*Striking a Balance: Facilitating Access to Patient Safety Data While Protecting Privacy Through Creation of a National Harmonized Standard*" (April 2007 Draft) at 3.

disclosures, and the fact that *any* information was collected or otherwise used by a quality assurance committee would serve to limit any subsequent use or disclosure of such information.[39] As a result, de-identification would not facilitate Sharing.

Some jurisdictions have exceptions to the bar against further disclosure of Incident data and information used by quality assurance committees, but they do not seem to be applicable. British Columbia, Northwest Territories and Nunavut permit the disclosure of de-identified information by a quality assurance committee or third party within the province and outside the province only for the purpose of advancing medical research or medical education. Given that quality assurance committees are not engaged in advancing medical research or medical education, *per se*, no disclosure of any information provided to a quality assurance committee in the course of its activities or any resulting findings or conclusions of the committee is permitted. Similarly, most provinces permit disclosure of personal information to prevent harm or injury; however, we have read that exception narrowly, such that a disclosure would be permitted to resolve an immediate harm to a specific individual or group of individuals, and not for broader Reporting in the name of preventing generalized and unspecified harms. While Weisbaum and colleagues argue for a broader interpretation of these harm reduction clauses, it is unclear if such a broad interpretation can be supported. Further consultations with provincial and territorial representatives may be required.

3. Adverse Event/Critical Incident Reporting Laws

Three provinces, Saskatchewan, Manitoba and Quebec, have created statutory adverse event reporting mechanisms. The key provisions of these statutes are summarized in Appendix 5.

Each province defines the Incidents that are to be Reported in a slightly different way, although they all encompass serious Incidents that lead to the actual or potential loss of life, limb or function. Saskatchewan's definition is the most detailed, setting out seven categories of Incidents (surgical, product or device, patient protection, care management, environmental, and criminal).

In each province, the institution is required to notify the responsible Minister of the occurrence of an Incident. Institutions must investigate the event and provide a report to the Minister following the investigation. Few details are provided in the legislation and regulations about what information is to be Reported and what the process is for Reporting. However Saskatchewan has developed detailed guidelines which outline the process.[40] Manitoba and

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[39] Alberta appears to be an outlier on this point, in that quality assurance committees can disclose de-identified health information to other quality care committees within and outside of Alberta. Disclosure by the quality assurance committee is barred except for disclosures of non-identifying health information to another committee that has as its primary purpose the carrying out of quality assurance activities within the meaning of section 9 of the *Alberta Evidence Act*. Had the reference been limited to disclosures to "quality assurance committees" (i.e. a defined term tied to Alberta law), any disclosure would be limited to entities existing under Alberta law (i.e. no disclosures outside of Alberta).

[40] *Saskatchewan Critical Incident Report Guideline, 2004.*

Quebec require that institutions themselves establish written procedures respecting the recording and providing of information about adverse events.[41]

Interestingly, while the Manitoba and Saskatchewan legislation is quite similar in its requirements, Reporting has increased in Saskatchewan but not in Manitoba. The limited impact of the legislative requirements in Manitoba may stem from limitations in resources needed to analyze Incidents and from the limited preparation in terms of education for healthcare organizations about the scope and nature of these requirements. Also, the increase in Reporting in Saskatchewan may also be as a result of the detailed guidelines developed to set out the process.

At present, none of the provinces mandate that the information that is collected by the Minister be made available to the public. Quebec has a provision that would require the Minister to create a register of Incidents for the purpose of monitoring and preventing such occurrence and ensuring control measures are implemented.[42] However, this provision is not yet in force.

All three regimes enable the Reporting and review of Incidents with some restrictions and limitations. The statutes make Reporting mandatory in order to promote patient safety, but place restrictions on Reporting, such as Reporting only de-identified information to Government, in order to protect personal privacy and to encourage health professionals to comply with Reporting requirements.[43]

Finally, by way of comparison, we have included in Appendix 6 Reporting provisions from the laws of California and New York. California's law is substantially similar to the law in Saskatchewan; both are based on the United States National Quality Forum's *Serious Reportable Events in Healthcare: A Consensus Report*. Both states go further than the Canadian jurisdictions in terms of making information available to the public. New York's information is already available to the public through the New York Patient Occurrence Reporting and Tracking System (NYPORTS). Only aggregate information is available to the public; other laws protect the confidentiality of the original source information that is Reported. California's law contemplates going further: it will require information on Reported Incidents to be made available in writing by 2009 and online by 2014, although individually-identifying information will still be protected by other laws.

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[41] Subsection 53.2(1) of *Regional Health Authorities Act*, C.C.S.M. c. R34 and section 235.1 of *An Act respecting Health Services and Social Services,* R.S.Q. c. S-4.2.

[42] Section 431(6.2) of *An Act respecting Health Services and Social Services,* R.S.Q. c. S-4.2.

[43] In Saskatchewan, all notices and reports relating to the critical incident review process must be on a no-names basis (section 10 of the *Critical Incident Regulations*, R.R.S. c. R-8.2 Reg. 3). Manitoba requires that a critical incident review committee must limit the contents of any notices, reports or information disclosed or shared to the minimum amount of personal information that is necessary (section 53.7 of the *Regional Health Authorities Act*, C.C.S.M, c. R.34). Quebec requires that information be Reported in a "non-nominative" form (section 233.1 of *An Act Respecting Health Services and Social Services*, R.S.Q., c. S-4.2).

4. Coroner's Inquests and Public Inquiries

Every province has legislation that governs the investigation of certain fatalities.[44] Under this system, a coroner or medical examiner must investigate deaths that occur in certain circumstances, including:

(a) as a result of suspected misadventure, negligence or accident on the part of others;

(b) where the cause of death is undetermined;

(c) where a stillbirth or neonatal death has occurred where maternal injury has occurred or is suspected either before admission or during delivery;

(d) where the death occurred within 10 days of an operative procedure or under initial induction, anaesthesia or the recovery from anaesthesia from that operative procedure; and

(e) where the death occurred within 24 hours of admission to a hospital.

The coroner or medical examiner shall investigate each death and determine whether or not an inquest must be held. Generally, inquests are open to the public, although a coroner may exclude the public or order that some of the evidence may not be published if certain stringent requirements are met. The findings and any recommendations of the inquest jury are also public. Under the relevant evidence statutes, quality assurance records would be protected by privilege from being accessed by the coroner or revealed in an inquest.

A similar mechanism that could review an Incident that does not result in a death is a public inquiry. The privilege over quality assurance records would also apply in a public inquiry.

The coroner and public inquiry systems enable the review of Incidents, albeit in a limited manner. Only deaths that meet the requirements are reported to the coroner, and the coroner only conducts an inquiry in certain circumstances. Furthermore, there is wide discretion in determining when a public inquiry will be held. Finally, a jury's recommendations are not binding, although the public attention generated by the inquiry may force policy and legislative changes.

It is noteworthy that in two separate coroner's inquests into Incidents in healthcare, the coroner's jury has made recommendations regarding Reporting. In 2004, two coroner's juries in Ontario recommended that hospitals adopt some kind of Reporting scheme. The jury at the inquest into the death of Lana Dale Lewis, who suffered a stroke which was caused by chiropractic neck adjustment, recommended that the Ministry of Health establish an internal database to record cervical manipulations and that a section of the database be used to record the occurrence of Incidents, including stroke, transient ischemic attacks, injury, paralysis and other symptoms.[45]

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[44] We have not prepared an appendix summarizing the relevant provisions of this legislation across Canada given the substantial similarity of the provisions and their limited application to Reporting and review of Incidents.

[45] Ontario, Office of the Chief Coroner, Verdict of Coroner's Jury on Inquest into the Death of Lana Dale Lewis and Recommendations, (Toronto: January 16, 2004) (Presiding Coroner: Dr. B. McLellan).

At the inquest into the death of Marie Tanner, who died as the result of an accidental injection of potassium chloride, the jury recommended that all hospitals adopt a standardized medication safety report program such as the Institute for Safe Medication Practices Canada's "Analyze-err".[46]

5. Drug and Medical Device Adverse Event Reporting

Federal legislation governs Reporting related to drugs and medical devices. These Incidents are fundamentally different from the other Incidents discussed to this point in that device failures or drug effects and interactions, not organizational or administrative failures, cause these Incidents.

Manufacturers are required by law to report certain defined Incidents involving their drugs or devices to the designated branch of Government. These reports must contain a detailed explanation of the Incident and a summary of the actions taken as a result of the manufacturer's investigation. A summary of these provisions is attached at Appendix 7.

Although these schemes make Reporting in certain circumstances mandatory, participation by healthcare professionals is voluntary. This is the major limitation of the schemes: manufacturers and importers can only report the Incidents of which they are aware. Therefore, although the schemes enable Reporting, the efficacy of the schemes is seriously limited.

In her March 2004 report on the regulation of medical devices, Auditor General Shelia Fraser found that "Health Canada has done little work to increase the number and quality of reports received from [healthcare professionals]. As a result, Health Canada is not able to adequately identify adverse events."[47] Furthermore, Ms. Fraser found that Health Canada does not know the extent to which the regulations are being respected. At the time, Health Canada did not engage in any inspection activity at the post-market phase. Health Canada did not know whether manufacturers and importers were "taking appropriate action in response to Incidents or complaints that come to their attention" or "reporting… all serious adverse events that come to their attention."[48] Ms. Fraser noted that Health Canada has completed several studies to assess weaknesses in post-market surveillance and options. However, at the time "Health Canada [acknowledged] that its lower levels of reporting [in comparison to the United States and United Kingdom] are due, in part, to its limited activities in the area of post-market surveillance."[49] Insofar as we are aware, the federal Government has not yet made any changes to the medical device legislation. The Reporting system for drugs suffers from the same limitations as the system for medical devices. Health Canada believes that it receives notice of less than 10% of adverse reactions.[50] In addition, the problems with post-market surveillance that exist with

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[46] Ontario, Office of the Chief Coroner, Verdict of Coroner's Jury on the Inquest into the Death of Marie Tanner, (Peterborough: February 12, 2004) (Presiding Coroner: Dr. J. Cairns).

[47] Office of the Auditor General of Canada, *Report of the Auditor General to the House of Commons, Chapter 2 Health Canada - Regulation of Medical Devices* (March 2004) at 2.87 (http://www.oag-bvg.gc.ca/domino/reports.nsf/html/20040302ce.html).

[48] *Ibid*. at 2.79.

[49] *Ibid*. at 2.89.

[50] Jocelyn Downie et al., *Patient Safety Law: From Silos to Systems, Appendix 2: Country Reports CANADA* (March 31, 2006) at 34.

medical devices also appear to apply to drugs.[51] Nonetheless, we understand that work is currently underway by the federal Government to improve post-market surveillance.

6. Professional Regulation

An Incident that involves the potential misconduct or incompetence of a healthcare professional raises the issues of professional regulation and discipline. The law surrounding professional regulation is large and varied, defined by both jurisdiction and profession. Professional discipline hearings are of very limited use in Reporting. The focus of professional regulation is, of course, the professional, and not more general systemic or department practices that may have contributed to an Incident. Furthermore, regulatory colleges are generally only required to publish very limited information on the facts of an Incident and the result of a hearing. The focus of this report is the review of system performance; therefore, a detailed survey of professional regulation is outside the scope of this report.

One development of note, however, is Ontario's proposed changes to the *Regulated Health Professions Act*. Two of the goals of Bill 171, the *Health Systems Improvement Act, 2007,*[52] are to increase the transparency of health regulatory colleges and facilitate public access to information about the colleges and their members. Proposed changes will mean greater disclosure of regulatory matters on the public register. At present, only the results of discipline and incapacity hearings are available. Bill 171 proposes to make note on the register of referrals from the Inquiries, Complaints and Reports Committee to the Discipline Committee.[53] Furthermore, the register will include a synopsis of the decision in every proceeding and will include notations of reprimands issued to members and, where applicable, a member's resignation and agreement not to practice again in Ontario. Ontario's professional colleges have supported the proposed changes and the increased transparency.

C. Legislative Barriers and Enablers to Reporting and Sharing

Our review of the relevant legislation has identified the following enablers of Reporting and Sharing:

1. The disclosure provisions of the PHI legislation serve as an enabler to Reporting in certain circumstances in that they allow custodians or trustees of PHI to disclose PHI, without the individual's consent, to quality assurance committees for the purpose of reviewing an Incident.

2. Also in some provinces, such as Alberta and Saskatchewan, the disclosure provisions of the PHI legislation also act an enabler to Sharing in that they allow custodians or trustees to disclose PHI to third party organizations to be used for prescribed purposes. Also,

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[51] *Ibid*. at 36-37.

[52] Bill 171, *Health Systems Improvement Act, 2007*, 2nd Sess., 38th Leg., Ontario, 2007. Received Royal Assent on June 4, 2007.

[53] There are a number of gaps in Bill 171. Complaints that are not referred to the Discipline Committee would not be recorded in the register. Furthermore, complaints that are resolved by mediation would also not be recorded. In these circumstances, a member of the public would not know that the regulated healthcare professional had been the subject of the complaint.

although it does not have PHI-specific legislation, Newfoundland and Labrador enacted legislation that created a third party organization to aggregate data from all components of the health and community services system.

3. Provisions in general privacy statutes that allow for the making of regulations respecting the disclosure of personal information to persons or bodies located within or outside the province and the approval of such regulations is an enabler to Sharing.

4. The critical incident reporting legislation in Saskatchewan, Manitoba and Quebec enables Reporting by setting out how certain Incidents are to be investigated and by making the Reporting of such Incidents mandatory.[54]

5. Detailed guidelines to Reporting, like those in Saskatchewan, seem to be an enabler to Reporting.

6. The federal systems for Reporting involving drugs and medical devices provide a mechanism for manufacturers to report problems with respect to same.

7. The privilege over quality assurance information in certain legal proceedings encourages Reporting.

8. Barring of personal liability for any information or disclosure that arises out of a quality assurance committee's activities in all of the larger provinces is an enabler to Reporting given that individuals making submissions or disclosures to a quality assurance committee could not be sued for doing so. The exception to this is where such submissions or disclosures are not made in good faith.[55] Good faith in this context generally means that an individual making a Report does so with an honest belief in what is being Reported and has made such Report without malice or design to gain personally from doing so.

Our review has identified the following barriers to Reporting and Sharing:

9. Incident reports that are outside of the quality assurance process may not be protected by privilege. Since some provinces allow them to be used against a healthcare professional in a discipline hearing[56] or review of hospital privileges[57], healthcare professionals may be inclined to record only limited information in these reports.

10. Provincial privacy and other legislation appears to be a barrier to Sharing given that:

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[54] The federal legislation on drugs and medical devices and the provincial legislation on critical incidents and privacy are all mandatory schemes. From our perspective, these schemes enable reporting; however, we recognize that the mandatory nature of the schemes may influence the behaviour of individual actors and have a counter-productive effect.

[55] Good faith requirement found in British Columbia, Manitoba, Ontario, Nova Scotia, Yukon, Northwest Territories and Nunavut.

[56] Saskatchewan, British Columbia, Northwest Territories and Nunavut.

[57] British Columbia, Northwest Territories and Nunavut.

(a) generally, quality assurance committees are prohibited from disclosing Incident data that contains PHI within and outside of that jurisdiction. Moreover, even disclosure of Incident data containing de-identified PHI by a quality assurance committee to another quality assurance committee or other third party in the same jurisdiction is widely prohibited;

(b) in most jurisdictions that have legislation which addresses quality assurance activities,[58] there are broad confidentiality obligations imposed on quality assurance committees that prohibit the disclosure of quality assurance information, to other persons both within or outside of that jurisdiction; and

(c) in some jurisdictions, third party patient safety organizations are not permitted to disclose Incident data containing PHI inside or outside of those provinces. Therefore, Sharing with a national body to facilitate Pan-Canadian Reporting is prohibited. It could only be done on a de-identified basis.

11. Many of the recording and Reporting responsibilities relating to post-sale of drugs and medical devices fall on the manufacturers and importers, rather than the retailers and hospitals. This information is likely received from retailers and health practitioners who are not mandated to report this information except where they have applied for special approval for a drug or are conducting clinical studies or experimental treatments.

D. Elements of a Legislative Framework for the Jurisdictions

Provincial Legislation

From this analysis, the following considerations are put forward for those provinces and territories that do not have Reporting legislation and are considering developing and tabling such legislation.[59] Accordingly, the following elements should be included in any such legislation:

1. **What is Reported?** The definition of a reportable Incident must be clearly defined so that healthcare professionals and laypersons can easily determine what Incidents must be Reported. For example, Saskatchewan's legislation, particularly the *Saskatchewan Critical Incident Reporting Guideline, 2004*, sets out an expansive definition of "critical incident" and lists over 30 specific Incidents that must be Reported as well as numerous basket clauses to capture other Incidents that lead to death or serious disability.[60]

2. **Who makes a Report?** The group of persons Reporting should be defined. This group may include healthcare professionals, employees of healthcare institutions, students and others. Furthermore, the scheme should provide a mechanism for persons other than

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[58] The exceptions appear to be Alberta and Saskatchewan.

[59] We are not able to say with certainty whether mandatory Reporting increases Reporting. However, it does appear from our understanding of Saskatchewan that legislation coupled with detailed regulations and guidelines has increased Reporting in that province.

[60] These Guidelines are adapted from the U.S. National Quality Forum's *Serious Reportable Events in Healthcare: A Consensus Report* (http://www.qualityforum.org/publications/reports/sre.asp).

those in the defined group (i.e. an individual or the individual's family) to Report a suspected Incident and require an institution to investigate whether an Incident occurred.

3. **How an Incident is Reported?** The legislation must define procedures and timelines for notice and investigation of an Incident and Reporting. The legislation may permit institutions to set these procedures through policy, albeit within certain parameters.

4. **To whom is an Incident Reported?** The legislation should require Reporting by healthcare institutions/healthcare professionals to a quality assurance committee including PHI. The legislation should also require Reporting of Incident data on an unidentified basis to the responsible Ministry or a prescribed third party organization within the province for tracking and analysis purposes.

5. **Confidentiality.** Any published information, including notices and reports, must not include the name of the patient, the name of any healthcare provider, or the name of any other individual who has knowledge of the event. In certain cases of unusual and high profile Incidents where de-identification is insufficient to assure confidentiality, there may be need for further protections in respect of Sharing.

6. **Privilege.** The legislation must explicitly extend this effective "privilege" to all documentation resulting from the quality assurance process including RCA, recommendations, reports and notices.

7. **Non-retaliation.** The legislation must provide that persons who are required to provide information under this process are protected from personal liability, suspension, demotion, harassment and other retaliatory behaviour unless, of course, the person was acting in bad faith.

8. **Expert analysis.** Reports must be classified and critical issues reviewed by experts who have appropriate clinical skills and knowledge of system issues. Such analysis is a critical element in deriving learning from Reporting.

9. **Incidents register.** The Minister or third party organization must maintain a register of Incidents on a de-identified basis for the purpose of aggregating data and Sharing within the province and with a national body that can disseminate warnings across the country. The legislation should encourage the parties involved to develop and use electronic Reporting systems.

10. **Annual review.** Institutions must provide an annual report to the Minister or third party organization that summarizes Reporting and quality improvement recommendations of the previous year. This summary must also include a report on the implementation of quality improvement recommendations of the previous year and an evaluation of the success of those improvements.

Federal Legislation

In our view, federal legislation is not required to enable Reporting. Even so, federal legislation could be developed for the purposes of setting out the objectives of the Pan-Canadian model and

to provide additional funding to support Reporting efforts. Such legislation would not override provincial legislation but could serve to foster cooperation among the provinces and jurisdictions and emphasize the significance of the role of the national body.

PART TWO: FINDINGS OF POLICY REVIEW

A. Introduction

Another key component of this review included conducting a detailed examination of existing provincial, territorial and federal Government policies relating to the Reporting and review of Incidents. This review drew from a representative sampling of policies in place across Canada. 16 separate policies were collected (out of 38 requested). Specifically, the team reviewed these policies to determine their intent and function, whether such policies were compulsory and the manner in which the collected information was used, if at all. Additionally, a number of interviews were conducted to determine the "in the field" perspective and gain an understanding of the practical aspects of the policies in place. From this, enablers and barriers to effective policy were identified and noted. This section outlines the recurring/common themes, general approaches, specific methodologies and weaknesses from the review.

A summary of Reporting policies analyzed is provided in Appendix 8. An outline of the strengths and weaknesses of the policies is provided in Appendix 9. The results of the interviews are set out in Appendix 10.

B. Policy Barriers and Enablers to Adverse Event Reporting

As summarized in Appendix 8, there is a patchwork of policy across Canada in the area of Reporting. In some jurisdictions, policy for Reporting and policy for Disclosure are separate; in other jurisdictions they are combined. In smaller jurisdictions, policy is often created at the provincial level. However for most provinces that are organized regionally, policy is created at the regional level. In Ontario, policy is developed by individual healthcare organizations (e.g., hospitals).

C. Policy Barriers and Enablers to Adverse Event Reporting

Based on our review of the policies obtained and the follow up interviews conducted across jurisdictions, we have identified the following barriers to Reporting:

1. Most policies for Reporting require only voluntary participation. Recently, there has been increased support for mandatory Reporting and the Saskatchewan, Manitoba and Quebec legislation incorporates provisions for mandatory reporting of a defined list of Incidents. Well designed mandatory reporting programmes can promote greater Reporting, but experience in this regard is variable. We understand that although Reporting has increased in Saskatchewan, this is not the case in Manitoba. However, the Manitoba initiative is still in the first year of operation. Also, our interviews with key informants in Manitoba and Saskatchewan suggest that Saskatchewan spent more time informing and preparing its healthcare organizations to respond to the new requirements.

2. All policy reviewed was silent on who (job titles) should participate in Reporting. In some respects this enables all healthcare workers to Report. However, it is a common experience that members of some disciplines are more likely to Report than others. In many settings there is a greater participation of nurses, while members of other health disciplines do not recognize their responsibility to participate in Reporting.

3. Generally, jurisdictional/organizational policy includes clear instruction with regard to whom Reports are submitted and the department or position responsible for collecting those Reports. However, there is a great deal of variance in the methods used to Report ranging from electronic system Reporting to paper generated Reports. The reliance on paper based systems limits participation in Reporting and may slow the analysis and follow up on Reports. Inefficient Reporting systems are likely to reduce the participation of front line staff.

4. The policies reviewed did not include clearly defined accountability or evaluative mechanisms. Although a minority of policies make reference to a quality review process, these are not well formulated in the policy. For most policies, once Reports have been submitted and collected there is little understanding of how they contribute to the improvement process. Policies in general tend to be more robust on the issue of data collection and relatively silent on the issue of quality improvement and evaluation.

5. The absence of common definitions or scope among jurisdictions or healthcare organizations means that information collected across Canada is not comparable. There is no common language or nomenclature used to label Incidents; terminology in use includes: incidents, critical incidents, accidents, adverse events, serious adverse events, sentinel events, hazardous events, close calls and near misses. Thus, there is no ability to compare data from one jurisdiction to another since what is actually being Reported differs along with how each defines these terms. While most jurisdictions Report all Incidents, some policies only include Reporting of 'serious' adverse events. The ability to even recognize an Incident as adverse is among the biggest barriers to Reporting.

Based on our review of the policies obtained and the follow up interviews conducted across jurisdictions, we have identified the following enablers to Reporting:

6. Standardized definitions and a common Classification System for Incidents are seen to be enablers. This is one important area that would be best addressed to ensure consistency both at the provincial level (and possibly a Pan-Canadian level).

7. Development of provincial, regional and organizational policies that enhance the opportunities for all staff to report Incidents.

8. Effective Reporting systems must make it easy and quick for staff to report. Electronic systems (e-systems) may encourage Reporting because they are less time consuming. E-systems also facilitate data analysis, follow up and review, enhancing the value of Reporting systems and encouraging greater participation.

9. Many of those interviewed highlighted the need to build in feedback and follow up mechanisms to those involved in Reporting. Follow up information should be made

available to people who file Reports to avoid the perception that Reporting is not valuable or not used. Presently, most policies remain silent on evaluation of Reporting programs. Such evaluation would highlight ways to improve Reporting and learning and communicate the value of such activities to staff.

10. The presence of legislation that directs Reporting may build support for improved Reporting. In jurisdictions that already have legislation interviewees saw this as an important enabler while those in jurisdictions without legislation saw this as a barrier. Thus Sharing between provinces and more detailed assessment of the experiences of Reporting programs in Canada and elsewhere may clarify the benefits and disadvantages to mandated Reporting.

11. The purpose of Reporting must emphasize improving quality and avoiding future Incidents – not ascribing blame. To support this, Reporting must be confidential and non-punitive. Cultural barriers to Reporting include fear of blame and personal liability. In some areas, Reporting is used for performance management so staff may be reluctant to Report. The extent to which culture can be changed by policy is unclear and since some Incidents are caused by negligence or incompetence there needs to be provisions that allow healthcare organizations to deal with such actions in a distinct manner. However, policy should clearly define different tracks for assessing cases where negligence or incompetence is suspected versus those where individual or system error is suspected. Policies must reinforce that the ultimate goal of Reporting is to improve care and lessen risk and preventable Incidents.

12. Senior management's support of patient safety is important to encouraging Reporting. One way that management can demonstrate its commitment is by providing training programs. Training and education programs on various aspects of Reporting were among the most popular enablers identified. Such programs include information on how to Report, when to Report, how to analyze Reports and what to do with the results.

D. Elements of a Policy Framework

Analysis of the identified barriers and enablers and the existing policies reviewed offers elements of a policy framework for Reporting. As discussed above, current policies contain some of the elements below, but most are incomplete. Consistency in policies across Canada would facilitate use of Shared Incident data. A comprehensive policy framework should include the following elements:

1. Reference to legislation (where applicable). Provincial or regional policies should be based on legislative requirements.

2. Consideration as to whether or not Reporting should be identified as mandatory or voluntary and the range or type of Incidents to be Reported.

3. Scope of policy and responsibilities: does the policy include Disclosure? Who makes a Report? Policy must clearly identify responsibilities for Reporting.

4. Common definitions (which may be linked to legislation) must be included in policy in order to enable comparative Reporting. Common terminology should be used across jurisdictions. In the absence of legislation, policy must set out the terminology as well as characteristics that will be used to define Incidents.

5. Policy must clearly require a proper evaluative framework, Reporting methods and accountability structure which must include a clear Reporting process with an accountability structure; who is responsible for making, collecting and analyzing Reports as well as who is responsible for directing practice changes based on analysis.

6. Policy should specify the goal of establishing accessible electronic Reporting and a reasonable time frame in which systems must be developed to accommodate such Reporting.

7. Policy must encourage a culture of learning and clearly identify the high level goals, principles and commitments that management must make including:

   (a) improving care and lessening risk of preventable Incidents;

   (b) increasing patient safety;

   (c) providing staff training on recognizing Incidents, Reporting, analysis and quality assurance; and

   (d) providing mechanisms and criteria for establishing a separate process for dealing with cases where negligence, incompetence or incapacity is suspected versus those where individual or system error is suspected.

8. Quality assurance and evaluation programs must be mandated in policy and must require member organizations to have such programs for Reporting. Policy must direct that these programs:

   (a) include tracking of Incidents and improvements on outcomes; and

   (b) include feedback to staff based on aggregate data and specific improvements to illustrate status of quality improvement.

PART THREE: FINDINGS OF SURVEYS AND INTERVIEWS

A. Introduction

In addition to reviewing legislation and policy, we designed surveys to identify health region or healthcare organization policy related to the Reporting and review of Incidents. To capture the experiences of these organizations, separate surveys were required: one for health regions and another for individual healthcare organizations in Ontario. The healthcare region survey was also translated into French and mailed to Quebec organizations. The healthcare organization surveys were modified slightly for community and long-term care sectors (see Appendix 11 for the acute care hospital survey exemplar). In addition, interviews with key stakeholders regarding

legislative and policy enablers (see Appendix 12 for interview guide) were conducted. The two data collection methodologies, key findings, including enablers and barriers to Reporting, and recommended changes are described in this section.

B. Survey and Methodology

The surveys were designed to identify organizational policies and practices concerning Reporting and the review of Incidents in Canada.[61] The surveys were mainly comprised of close-ended questions with some open-ended questions. All health regions in provinces and territories were sent the health region survey, while in Ontario a representative sample of hospitals, long-term care facilities and community healthcare agencies were sent their respective survey. The surveys were sent out across Canada in April 2007. Non-responding organizations were contacted by phone or email. However, only one wave of surveys was distributed given the short timelines for this project. Data analysis included descriptive statistics involving frequency mean distribution of the close-ended questions and identification of broad themes from the open-ended questions.

C. Findings of Surveys

This section provides an overview of key findings from the surveys. These key findings are largely consistent with some key points identified from the legislative review (Part One) and policy review, particularly the interviews conducted with "in the field" participants but add some additional issues related to local experience and potential strategies for Pan-Canadian Reporting.

1. **Sample Characteristics**. Overall, 82 surveys from 8 provinces[62] were received from the original 340 that were sent out (response rate of 24%). The final sample included in this analysis was 81 as one survey was incomplete. The sample draws from:

   (a) 37 hospitals;

   (b) 25 health regions;

   (c) 12 from community based organizations; and

   (d) 7 from long-term care organizations.

2. **Implementation of Reporting Systems.** In general the majority of organizations have "fully implemented" systems in place for Adverse Events (N=65) and Sentinel Events (N=66). However, there were lower rates of implemented Near Miss systems in the organizations with 49 systems fully implemented and 16 indicating that their systems are partially implemented.

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[61] Given the move towards broader Reporting systems, the research team also collected information on Sentinel Events.

[62] The hospital, community and long-term care sector samples are from Ontario only, with representation from health regions across Canada with the exception of Quebec and Prince Edward Island.

3. **Type of Reporting Systems.** Of the 77 organizations reporting the use of Adverse Event and Sentinel Event Reporting systems, there are more paper-based systems (N=37, 39 respectively) as compared to electronic systems (N=26 for both). Of the 71 organizations that responded regarding the Near Miss Reporting systems, 32 reported the use of a paper based system and 28 reported using an electronic system. Interestingly, a number of the organizations reported using both systems (N=14 Adverse Events, N=12 Sentinel Events, N=11 Near Miss).

4. **Use of Analytical Approaches to Investigate Events.** The results highlight that organizations in general are either fully implementing analytical approaches or that they are implemented in certain organizations or units in the hospitals. All of the hospitals and health regions did outline that they are at some level implementing these analytical approaches for both Adverse Events and Sentinel Events. Similar to the finding of Reporting systems, fewer hospitals and health regions reported a fully implemented approach to examine Near Miss occurrences (6 hospitals and 4 health regions reported not engaging in examining Near Misses). The long-term care organizations reported lower levels of implementation of analytical approaches for analyzing Adverse Events, Sentinel Events and Near Misses. These responses cannot be used to assess the robustness of the analyses; however, only 43% of responding organizations reported doing more than two RCAs per year, although 60% report doing more than two audits and 74% report doing more than two chart reviews to follow up on safety occurrences. This suggests that most organizations have only limited experience and resources for such work.

5. **Use of Retrospective Tools to Investigate Safety Occurrences.** This section asked participants if they had engaged in various retrospective analytic tools to investigate safety occurrences and, if so, how many were being conducted each year. RCAs are used in the majority of organizations (N=65), with the majority conducting one or two per year (30). Audits are occurring in 59 of the 81 organizations. Chart reviews are the most popular technique being used in all types of organizations (N=67) and at the highest frequency of five or more in most of these organizations (N=48).

6. **Organizational Policies and Practices on Reporting Incidents.** All but two organizations (N=1 hospital; N=1 health region) reported having a Reporting policy in place. Most organizations (N=64) reported that the policy they have in place covers all three patient safety occurrences that were supported by responses to the open-ended question (4b).

7. **Different terminologies**. Different terminologies both (a) within hospital sector (e.g. major vs. minor, good catch, non-employee, unusual occurrence and unusual or unexpected response to standard treatment, not accepted routine operation) and scales (rating from 0-Near Miss to Sentinel Event-4); and (b) across sectors (e.g. unusual occurrence, unexplained injuries in long-term care; client complaints and compliments in community; critical occurrences in health regions).

8. **Policies are under revision and/or development.** A majority of the organizations (N=68) reported that they have a policy in place that requires Disclosure, a finding that

was supported by responses to the open-ended question (4c). Other key themes that emerged included:

(a) Reporting is contingent upon the severity of the occurrence and the perception of the healthcare professional;

(b) in many organizations Reporting policies are under revision and/or development; and

(c) considerable variation exists on what, who and how Reporting occurs, whether it is mandatory, explicitly stated as a policy, and enacted in practice.

9. **Reporting to Board of Directors.** 54 (out of 80) organizations reported having a policy that requires them to Report to the Board of Directors that was supported by responses to the open-ended question (4d). Other key themes that emerged included:

(a) Reporting to the Board of Directors[63] is often not an explicitly stated policy, but is a common practice, ranging from monthly, quarterly, semi-annually, and ad-hoc in frequency (Sentinel Events that involve potential media attention and political implications) and nature of Reporting (trended, aggregate data on Incident, action/plans for improvement, and Sentinel Events); and

(b) variation of what level of the Board of Directors received Reporting ranging from Board of Directors sub-committees (e.g. Quality and Safety Council, Quality Committee, etc.) and by whom (Board of Directors sub-committees to the Board of Directors, CEO to Board of Directors, etc.).

10. **Key themes that emerged from current issues around Reporting.** Key themes (question 4e) included:

(a) revision of policies to align with recent legislative changes (e.g. RHA Act and Evidence Act); accreditation standards (Canadian Council on Health Services Accreditation Required Organizational Practices); and National Disclosure Guidelines (CPSI);

(b) calls for just culture;

(c) broader focus to open Disclosure and Reporting;

(d) need for timely follow up; and

(e) specific sector issues including geographical size and diversity in health regions and amalgamation of CCACs that have different Reporting systems.

[63] Details on what is Reported to the Board of Directors are not available from the survey.

11. **Frequency of Activities Associated with Reporting and Investigating Patient Safety Occurrences**. Key activities and associated frequencies included:

    (a) Reports to the Board of Directors in the organizations occurred at a majority of the organizations (N=77) with these happening to the greatest extent on a quarterly basis (N=52); and

    (b) the majority of organizations reported that they never include patient safety information when reporting Incidents to the community (N=62).

12. **Staff Education.** The majority of organizations engage in some level of staff education (N=74) occurring on a monthly basis for half of these organizations (N=35) with another 34 organizations reporting either quarterly or annually.

13. **Executive Walk Rounds.** 35 organizations reported not engaging in executive walk rounds in their organizations. For community centres this was not seen as relevant. Of those who did engage in the executive walk rounds the majority were reported in the hospital setting (N=17) and all the long-term care facilities reported engaging in these walk rounds. The timing of these walk rounds varied for all types of organizations.

14. **Review Meetings.** A number of organizations reported engaging in meetings to review Incidents (N=58). Of those that did, the majority did so on a monthly basis (N=28). Collectively, there were 21 participants that reported that they did not hold meetings to review Incidents.

15. **FMEA Analysis.** 51 organizations engaged in Failure Modes Effects Analysis ("**FMEA**") with the majority performing these on an annual basis. 29 of the organizations reported never conducting this type of analysis.

16. **Follow up and Resolution.** More than half of the organizations (N=46) reported that they did not engage in any reports on the follow up and resolution of all alerts and equipment recalls to a third party.

17. **Perception of the Extent to Which the Current Reporting System Captures Incidents**. When asked to respond to how well their current Reporting system captures the numbers of types of Incidents that are occurring in their organizations, most respondents reported frequently (N=40) with 34 reporting within the range of limited extent (N=11) to somewhat (N=23).

18. **Perception of the Extent that the Reporting System and Structures Create Capacity to Analyze and Act.** When asked to report on how well the current system allows for analysis and action based on Reporting, the majority of the respondents perceived this to be somewhat (N=29) or frequently (N=28) occurring.

19. **Reporting to External Agencies.** Participants were asked to outline the various external agencies to which they Report Adverse Events, Sentinel Events and Near Misses. Key findings include:

(a) in relation to Reporting to the Ministry of Health, most health regions (N=20) and all long-term care facilities (N=7) outlined that they made such Reports, whereas the community and hospitals were mixed in their responses. For example, in the hospital sector only 11 (out of 37) engaged in such Reporting;

(b) in relation to Reporting to a regulatory body, the health regions mostly reported that this did not occur (N=20) and the other organizations were mixed between yes and no;

(c) most of the organizations indicated that they did not Report to an external third party body (N= 66/79); and

(d) a majority of the organizations responded that they Report to their insurers (N=55). However, only two of the long-term care organizations reported yes and the others (N=5) indicated that they did not have to Report to their insurers.

20. **Internal and External Enablers.** Respondents were asked to identify both internal (question 8) and external (question 10) enablers that facilitate enactment of policies associated with the Reporting and review of Incidents.

(a) Key internal enablers, organized under structures, processes and culture, included:

(i) structures: education; electronic databases for Reporting and analysis; committees (e.g. Risk Management, Quality Assurance); analytical tools (e.g. FMEA); designated resources (e.g. director level position); and communication strategies;

(ii) processes: organizational policies that include definitions and procedures for Reporting, follow up and review; timely feedback; walk rounds; clear human resources policies around hiring practices and performance management; and

(iii) culture: executive leadership/senior management support; champions at executive and director/management level; just-culture; Board of Director support; front-line staff desire and engagement to provide safe care.

(b) Key external enablers included:

(i) legislation (e.g. *Quality Care Information Protection Act* (Ontario), mandatory reporting in Manitoba and Saskatchewan) and accountability agreements;

(ii) Canadian Council on Health Services Accreditation Required Organizational Practices;

(iii) organizations/networks and associated educational/knowledge management resources (e.g. CPSI, Ontario Hospital Association with

toolkit, hospital report card, Safer Health Care Now, Quality Health Network, Institute of Safe Medication Practices);

(iv) professional/regulatory bodies (e.g. College of Physicians and Surgeons, Canadian Medical Protective Association, College of Nurses of Ontario) and professional expectations;

(v) increased public attention and media; and

(vi) support from insurers (Health Insurance Reciprocal of Canada).

21. **Internal and External Barriers.** Respondents were asked to identify both internal (question 9) and external (question 11) barriers that present challenges to the enactment of policies associated with Reporting and review of Incidents.

(a) Key internal barriers include:

(i) culture of fear, litigation and disciplinary action;

(ii) lack of physician engagement;

(iii) competing priorities within organizations and sectors;

(iv) variation in resources and human resources support;

(v) workload can be a barrier to Reporting, documenting and the audit process;

(vi) lack of awareness/education around the need to Report;

(vii) staffing shortages;

(viii) electronic systems that are not user-friendly;

(ix) funding and financial constraints;

(x) lack of leadership/role modeling; and

(xi) specific sector responses include geographical size and diversity in health regions; mobile, virtual workforce in community; and the Canadian Council on Health Services Accreditation process for the long-term care sector.

(b) Key external barriers include:

(i) culture of fear, litigation and disciplinary action;

(ii) lack of available resources (financial/human). Accountability to external agencies comes at a cost and many organizations do not have the capacity to implement Reporting systems;

(iii) legislation (*Quality Care Information Protection Act* as a double edge sword);

(iv) regulatory bodies (e.g. College of Nurses of Ontario);

(v) public education around safety and Reporting and how organizations will use data to compare;

(vi) lack of standard approach/variation in review approaches and patient safety information; and

(vii) sector specific: reluctance to Share due to managed competition in the community sector and focus on compliance but do not have funding to address issues in long- term care).

22. **Recommended Changes.** As a final question, participants were asked what changes at a practical, policy or legislative level would encourage or facilitate the Reporting and review of Incidents. Key recommended changes included:

(a) province wide mandatory, standardized (with common Taxonomies) Reporting[64] and follow-through aligned with infrastructure (funding and technology);

(b) mandatory, standardized/consistent educational programs for health professional students, practitioners and consumers;

(c) clearer legislation around protection for quality assurance discussions;

(d) agreement support with regulatory bodies (e.g. College of Physicians and Surgeons, Canadian Medical Protective Association);

(e) shift to culture of learning/just culture (from blame);

(f) focus on achieving the Canadian Council on Health Services Accreditation Required Organizational Practices;

(g) resources to implement process changes/quality assurance efforts;

(h) physician engagement through legislation;

(i) research required identifying common high-risk categories and testing of strategies aimed at improving safety; and

[64] Some respondents also identified anonymous reporting.

(j) funding tied to enactment of legislation.

D. Key Informant Interview Methodology

Building on the results from the analysis of legislation and policy and the findings of the survey of health regions and healthcare organizations, interviews were held with key informants across Canada and internationally. These individuals were selected because of their knowledge and experience with Reporting systems or with the Reporting and use of healthcare information more generally. A semi-structured questionnaire was developed to guide the interviews, but the focus of each interview was tailored to the experience and knowledge of each interviewee. Teams of two with one person asking questions and the second taking notes carried out the interviews.

E. Key Findings of Interviews

This section provides highlights of key themes that emerged from the 14 interviews[65] that spanned a broad range of experience and locations represented (five provinces: Ontario, Alberta, Saskatchewan, Nova Scotia and three countries: United States, United Kingdom and Australia).

Several years ago, the United States expert Lucian Leape outlined the goals of Reporting in the following way:

> *"The primary purpose of reporting is to learn from experience. Many other methods are also used to identify threats to safety, but a good internal reporting system ensures that all responsible parties are aware of major hazards. Reporting is also important for monitoring progress in the prevention of errors. Thus, the reporting of close calls, as well as adverse events, is valuable. External reporting allows lessons to be shared so that others can avoid the same mishaps. State-run mandatory reporting systems have an additional purpose: to hold hospitals accountable for safe practices."*[66]

The international experiences with Reporting systems and, in particular, state or national (in addition to organizational) systems, is developing quickly. Even five years ago when Leape outlined the purposes and barriers to Reporting there were few such systems. Leape noted four in the United States, of which only one (the Joint Commission Sentinel Event Reporting System) covered more than medication Incidents. Some United States healthcare systems, notably the Veteran's Health Administration, had created Reporting systems for healthcare organizations in their systems. But lessons learned in these systems were not broadly Shared outside of the systems. The Australian Incident Monitoring System began as an anaesthesiology critical event Reporting system (patterned after similar work in the United States) that then broadened into a system that included a wide range of Incidents. The Australian system and the English system created by the National Patient Safety Agency (NPSA) are now the largest systems reported in the literature. Although a legislative framework for United States systems was created by federal legislation passed in 2005, the regulations supporting such systems have not been enacted. Still,

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[65] Given the short time frames to arrange and carry out interviews it was not possible to interview some individuals identified as key informants.

[66] Lucien Leape, *New England Journal of Medicine*, 2002

many states in the United States have developed Reporting systems and have considerable experience with Reporting issues. The growing experience with Reporting systems has provided information that is relevant to Canadian efforts.

F. Critical issues

Questions for the key informant interviews were based on the issues identified in the initial parts of this report, as well as an examination of key articles and documents. The interviews with key informants thus permitted examination of a number of critical issues and potential approaches to Sharing in Canada. Our review of the interview findings is organized in terms of these critical issues and approaches.

1. **Is there a need to Share Incident information beyond individual organizations?** Most existing Reporting systems exist within individual organizations, health systems or health regions. However, many Incidents are rare events - hence the need to Share such information with other jurisdictions or to a national body that is capable of disseminating such information. However, at the same time, there is a growing recognition that the complexities of a national reporting system have limited their impact. For example, the English National Reporting and Learning System which receives nearly one million reports per year, has been criticized for failing to turn these reports into useful alerts and bulletins and disseminating these in a timely fashion to provider organizations. Many large data collection efforts have allowed considerable leeway in the types of Reports and the types of Reporting systems that have fed information into centralized repositories. As a result, the usefulness of data is often compromised.

2. **What are the Potential Barriers to Sharing Incident Information?** Privacy, evidence and health sector legislation appears to limit the disclosure of personal information, particularly in the context of quality assurance committee proceedings. In addition, the legislation of many provinces prevents data collected in their jurisdiction to be transmitted outside the province, particularly in the manner in which health sector entities are defined.[67] As a result it seems unlikely that it would be possible in the near future to Share information about specific Incidents with quality assurance committees in different provinces. There are concerns in some provinces about the ability to Share information between quality assurance committees, even *within* the province.[68]

3. **Should reporting be mandatory or voluntary?** The issue of mandatory versus voluntary Reporting has been a traditional source of disagreement. On the one hand, some have felt that mandatory Reporting is necessary, particularly in an environment where there is liability for Incidents and organizations and individuals are thus likely to avoid creating risks of legal action. On the other hand, some have claimed that most Reporting is voluntary (even when mandated) since many Incidents are difficult to discover and fear of litigation may be more powerful than concerns about Reporting. At

[67] For example, a statute may permit the sharing of PHI among "health information custodians"; however, by defining "custodian" as an entity formed pursuant to a specific provincial enactment (e.g. "hospitals formed pursuant to the *Hospitals Act*"), the statute precludes the disclosure of PHI to a hospital in another jurisdiction, formed under the laws of that jurisdiction.

[68] For example, British Columbia, Saskatchewan, Manitoba, Quebec, Northwest Territories and Nunavut.

a national level, the issue of mandatory or voluntary Reporting is complicated by differences in provincial legislation. Some provinces, such as Saskatchewan and Manitoba now have mandatory Reporting for a defined range of Incidents. Others have no formal requirements for such Reporting and rely on voluntary efforts within healthcare organizations. In Saskatchewan and Manitoba the results of mandatory Reporting have differed. Saskatchewan has had more success than Manitoba. This could be due to a number of variables including: (a) differences in resources available; (b) education of staff regarding the scope and nature of the Reporting requirements; and (c) the existence of detailed guidelines in Saskatchewan. However, Manitoba's mandatory Reporting system is new compared to Saskatchewan's system and time could demonstrate an increase in Reporting in Manitoba as well.[69]

4. **What are the information challenges in creating a centralized system?** Several of the key informants described challenges that would need to be addressed in a centralized system. Specifically, there are challenges associated with integration of the existing local IT and communications systems. This would require standardizing the coding and Classification Systems to be used. Another key challenge of a centralized system is to make use of the information that is obtained from regional, provincial and national systems.

5. **What legislative, legal and political issues face the development of a Pan-Canadian system?** According to key informants, the variation between provinces of relevant legislation including privacy legislation, limits the patient safety and quality agendas in healthcare. As noted in the Weisbaum Report, there is little likelihood of standardization of such privacy provisions. From a broader policy standpoint, the variation in expectations by public and healthcare providers of balance between privilege, protection, and transparency to patients and the public at large and the political barriers in Sharing between regions and jurisdictions, present challenges that also need to be addressed in the early stages of development. As one stakeholder stated:

> "*a pan Canadian vehicle may be suitable, but politically difficult*".

6. **What are possible models to study?** In our interviews we examined the experience of several existing international patient safety Reporting systems. Several of these offer opportunities for further study. These include the Australian Incident Monitoring System which operates in most Australian states and territories, the English National Reporting and Learning System (NRLS), the Pennsylvanian Patient Reporting System (PA-PSRS), the Massachusetts Board of Registration in Medicine's Confidential Reporting System and the National Reporting System for Adverse Events in Denmark.

PART FOUR: RECOMMENDATIONS

Based on our legislative and policy reviews, surveys and interviews, our team has developed the following recommendations with respect to a Pan-Canadian Reporting system:

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[69] As noted above, we are not able to say with certainty whether mandatory Reporting increases Reporting. However, it does appear from our understanding of Saskatchewan that legislation coupled with detailed regulations and guidelines has increased Reporting in that province.

1. Pan-Canadian Reporting Organization. A Pan-Canadian Reporting system should be developed to disseminate Incident data and recommendations on a national basis. We recommend that this be done by a national third party organization whose primary agenda is the promotion of patient safety. Given CPSI's knowledge, expertise and mandate, we are of the view that CPSI should have an integral role in the development and management of this system, and for the purposes of these recommendations, that CPSI act as that national organization.

2. Federal Funding For Patient Safety Programs. In order to achieve a Pan-Canadian Reporting system, Reporting programs and initiatives must be encouraged and stimulated at the jurisdictional and institutional level. Funding programs are needed to, among other things, help local systems that lack technical and human resources to properly run Reporting programs. Given the national scope of the recommended system, such programs should be funded by the federal Government. The federal Government should set aside additional funds for patient safety initiatives. These funds should be delivered through CPSI as the national third party organization referred to above.

3. Funding Allocated by CPSI; Contingent on 'Best Practices'. Funding would be provided by CPSI to jurisdictions implementing Reporting programs that meet certain criteria, which could include, in part, the creation of provincial legislative and policy Reporting frameworks grounded in best practices, as described previously in this report. The jurisdictions would then grant funding to institutions in their respective provinces or territories that implement Reporting programs in accordance with such legislative and policy Reporting frameworks. In our view, assessing eligibility for grant funding at an institutional level would be an arduous task for CPSI. We therefore recommend that it be the task of the province or territory to make such assessments. Reference to province or territory in this regard can either be the Government of each province or territory or a third party organization in each province whose mandate it is to ensure patient safety within such province or territory (e.g. the Alberta Health Quality Council).

4. Collection of Provincial/Territorial Incident Data. To facilitate Pan-Canadian Reporting by a national organization, we recommend that provinces and territories adopt a model similar to Saskatchewan, Alberta or Newfoundland and Labrador, in that a central body in each province or territory collect Incident data from healthcare facilities or entities for the purposes of tracking and analysis. Incident data would be collected and processed at the local or regional level for the purpose of analysis and developing recommendations, and de-identification where necessary. Thereafter, Incident data would be transmitted to a provincial body and aggregated with data from across the province. While the Government in each province could perform this aggregation function, it is likely more efficient and effective to create or designate an arms-length Government funded agency (a "**Provincial Patient Safety Organization**") for this function. The designation or creation of a Provincial Patient Safety Organization in each province and territory could be done in stages, beginning with those jurisdictions that are most amenable. This staged roll-out would also be enhanced by linking the formation of Provincial Patient Safety Organizations with grant funding, pursuant to Recommendation 3 above.

5. Upward Reporting of Provincial/Territorial Incident Data. Each Provincial Patient Safety Organization should be permitted to disclose Incident data on a de-identified basis to a national patient safety organization, such as CPSI, to disseminate information and warnings and provide statistics and other guidance on a national basis. The creation or designation of a Provincial Patient Safety Organization should be done in the context of each jurisdiction's approach to information transfers and privacy. This may require special regulatory provisions or minor statutory amendments in light of each jurisdictions legal framework. Given the necessity for local knowledge and clinical expertise in the formulation of recommendations, we assume that any de-identification would be done at the institutional or regional level.

6. Limit CPSI's Use of Personal Information. In the case of CPSI, any personal information received would need to be collected, used and disclosed in compliance with the privacy laws of its jurisdiction of operation (i.e. Alberta).[70] We recommend that CPSI not receive personal information unless it is necessary for CPSI's purposes. Personal information is subject to statutory restrictions noted above, and its use by CPSI would expose CPSI to the risk that the privacy of individuals may be breached. Even if CPSI determines that it needs personal information in order to effectively analyze Incident data, CPSI would still face barriers to the disclosure of that information on an identifiable basis. Generally, de-identified information, however, can be collected, used and retained without limit, and CPSI could share de-identified information on a national basis. We recommend, however, that CPSI assess whether the benefits would counterbalance the obligations imposed on CPSI in respect of the collection, use and disclosure of personal information. This assessment could be conducted as part of the consultations and the roundtable outlined in Recommendation 9 below.

7. National Guidelines for Reporting. CPSI should also take a leadership role in the development of national guidelines for Reporting (the "**Guidelines**"), which would include common definitions and Taxonomy. Also, CPSI should collaborate with other stakeholders to develop nationally-accepted and consistent definitions, categories for data elements and de-identification standards for all types of Incident Reporting to guide the Provincial Patient Safety Organizations. Such definitions, data elements and de-identification standards should also be consistent with the Guidelines, but would permit each jurisdiction some flexibility in accommodating applicable legal standards in force in that province or territory. Development of these Guidelines and standards could be conducted as part of the consultations and the roundtable outlined in Recommendation 9 below.

8. Demonstration Reporting System. A demonstration project should be conducted for all provinces or territories wishing to implement a provincial Reporting system. This demonstration project would build on the efforts and experiences of Saskatchewan and Manitoba and provide an opportunity for other provinces to learn about the development of Reporting systems and the benefits of same. Such demonstration project could be organized by CPSI with the assistance of representatives from Saskatchewan and Manitoba.

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[70] *Personal Information Protection Act*, S.A. 2003, c. P-6.5.

9. Roundtable Discussion. Given the complexity of the issues, and in order to accurately assess the Recommendations above, we propose that a round-table discussion be held to bring together each province's and territory's position on Reporting. This round-table discussion would involve legal, medical, academic and public sector experts, who would bring together local assessments of applicable legislation, case law and existing practice and discuss common standards and approaches to Reporting, including common Classifications Systems and standards of de-identification of personal information. The roundtable could also consider whether data relating to various types of Incidents (other than medication Incidents) could be non-identifiable and yet still effective. The greater the use of de-identified Incident data, the easier it is to share such data between provinces without contravening provincial privacy legislation. This would require the establishment of categories of data elements to be used for all types of Incidents, similar to that done by the Institute of Safe Medication Practices for medication errors. It is our view that bringing together these experts would be the most efficient and effective way to facilitate what would otherwise be a long and arduous process.

10. Federal Legislation (Optional). Federal legislation could be developed for the purposes of furthering the objectives of a Pan-Canadian Reporting system and to make provision for additional funding to support Reporting and Sharing. Such legislation and funding would encourage provinces and territories to participate because it would yield substantial benefits to those participating jurisdictions.

PART FIVE: CONCLUSION

Our analysis of the key enablers and barriers in legislation, policy and healthcare organizational (or regional) practices associated with Reporting indicates a considerable patchwork of Reporting across Canada. Of immediate urgency is the need for Guidelines and the establishment of a common Taxonomy consistent with the efforts of the World Health Organization.[71]

Closely aligned with the Guidelines and a common Taxonomy is the need for the development of a legislative and policy framework in most of the provinces and territories. However, in order for institutions to comply with such legislative or policy frameworks, an investment in technology and resources will be required. As was noted in our interview process, a lack of available resources was stated to be a barrier to Reporting. The federal Government should earmark funds for the development of Reporting programs in the provinces and territories as a means to incentivize the provinces and territories to undertake this important initiative. CPSI could oversee the allocation of such funds based on a set of specific criteria.

Moving toward an effective Pan-Canadian Reporting system requires establishing effective Reporting systems at both the provincial or territorial level and the national level. Healthcare institutions in each province and territory should be required to disclose de-identified Incident data, RCA and recommendations, to a Provincial Patient Safety Organization funded by the Government of that province. Such data would subsequently be Shared by the Provincial Patient

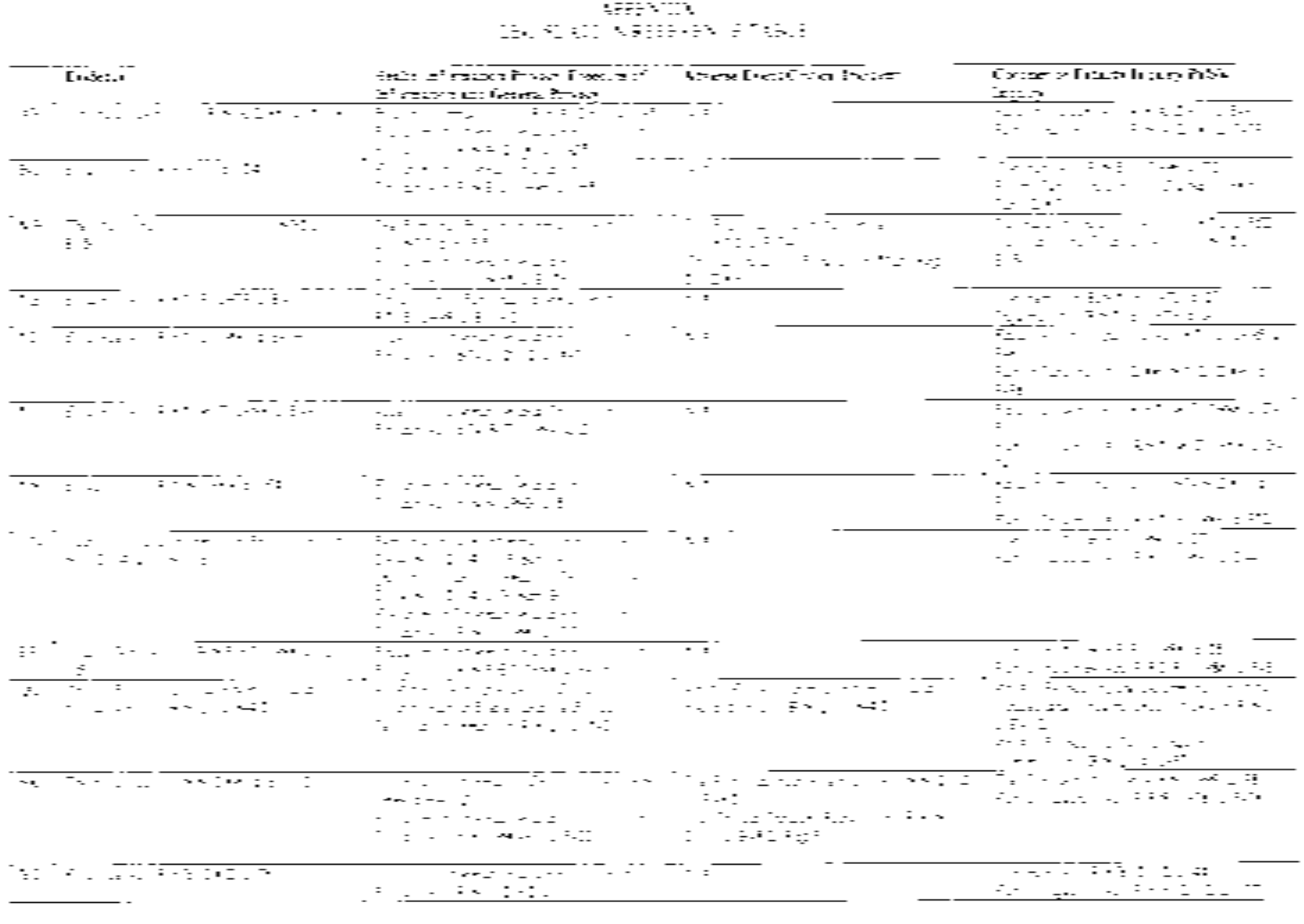
[71] WHO, World Alliance for Patient Safety (2005, October) "*Project to Develop the International Patient Safety Event Taxonomy*": Report of the World Alliance for Patient Safety Drafting Group.

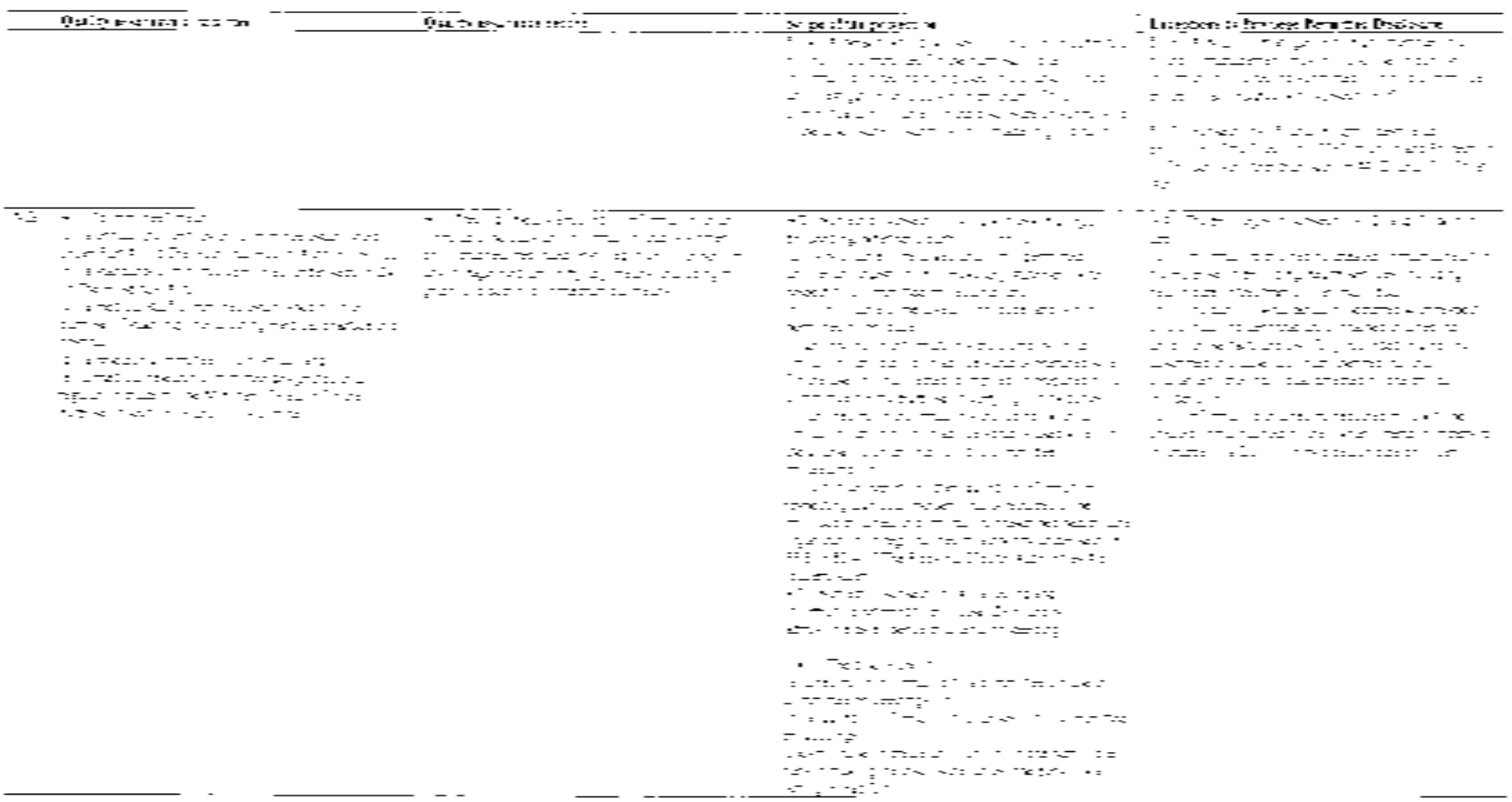
Safety Organization with a national patient safety body, such as CPSI, for dissemination and warning purposes across Canada.

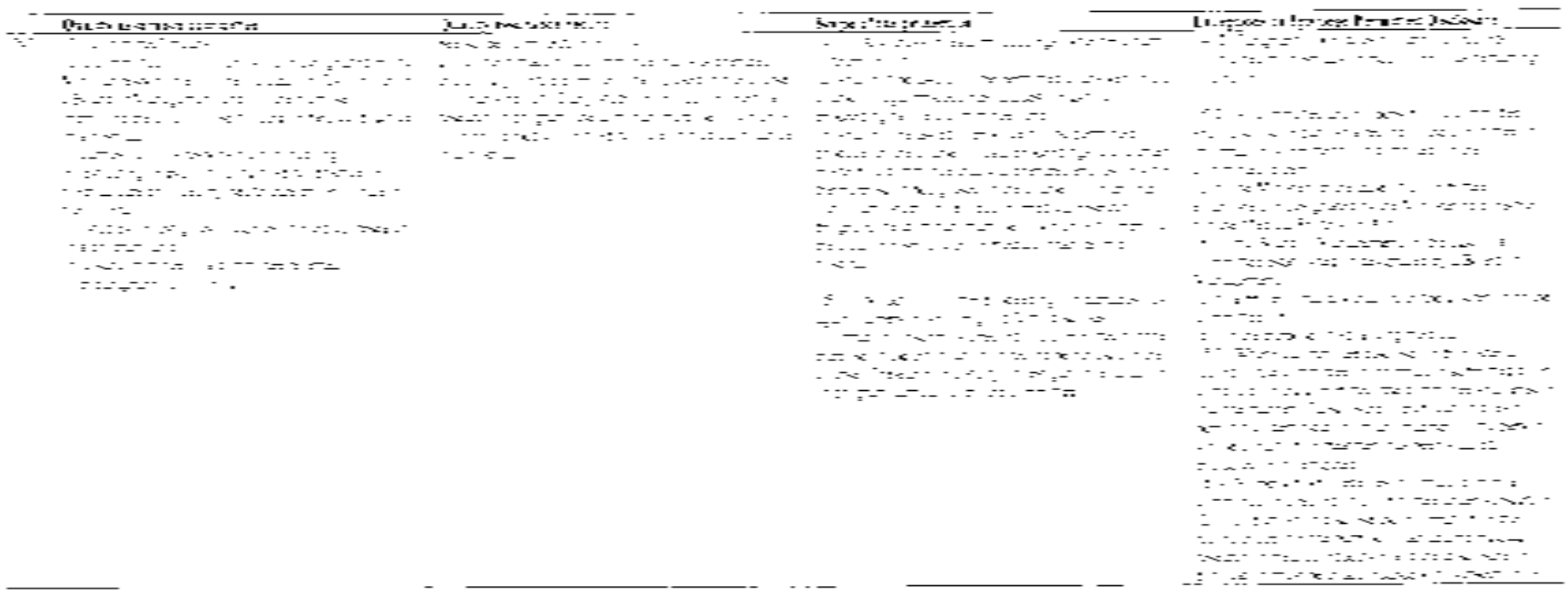
CPSI is well-positioned for this role and it can obtain assistance from other third parties as necessary by leveraging collaborative partnerships with the federal, provincial or territorial Governments, health professional regulatory bodies, patient safety associations and the national accreditation body.

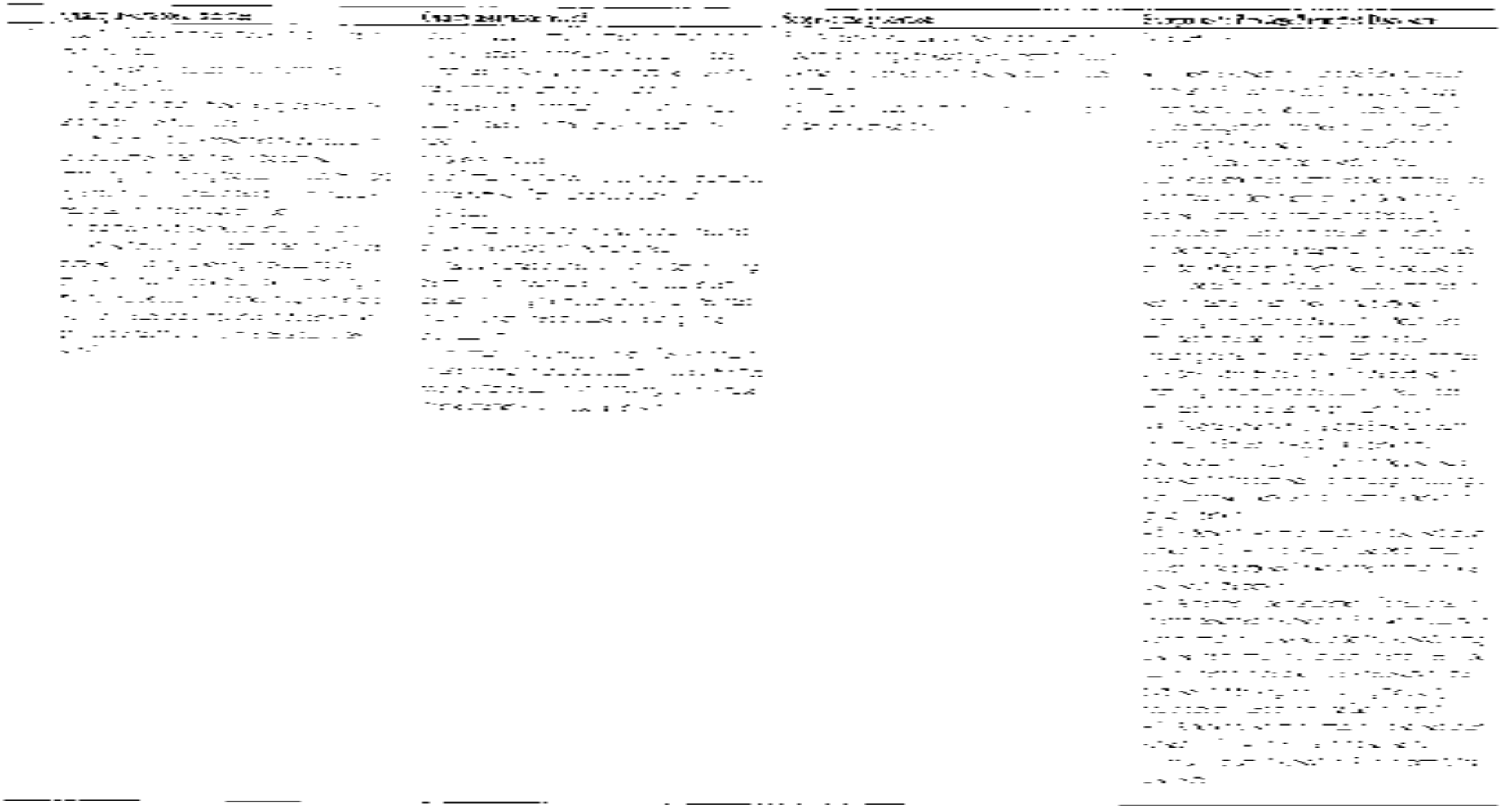
This strategy will, of course, require a significant investment from the federal Government. This model is currently in place at a provincial level in a few provinces (absent reporting to a national body, of course). We suggest that these models be considered for the remaining provinces and territories. We therefore recommend that a panel comprised of legal, medical, academic and public sector experts from each province collectively determine the feasibility and design of our suggested approach to Pan-Canadian Reporting. This may help speed the development of changes in such provincial legislation as is necessary, even in the absence of mandatory reporting legislation.

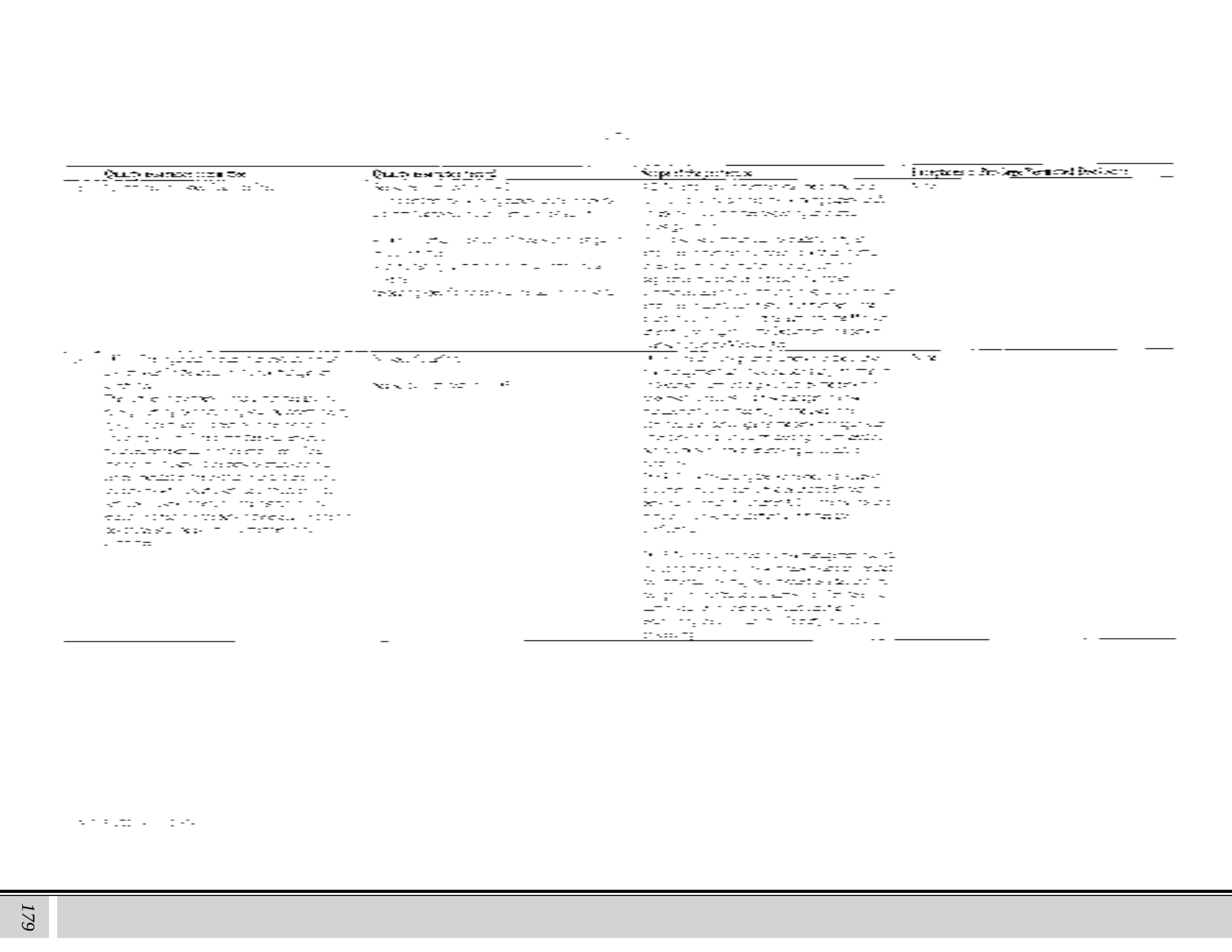
At this point we do not think federal legislation is necessary for the development of a Pan-Canadian model of Reporting given the potential constitutional roadblocks surrounding the provincial and federal division of powers. However, the enactment of federal legislation would demonstrate to Canadians the importance of patient safety to the federal Government and emphasize the significant role of CPSI in this regard. It may also foster cooperation among the provinces and territories toward the development of a Pan-Canadian model of Reporting.

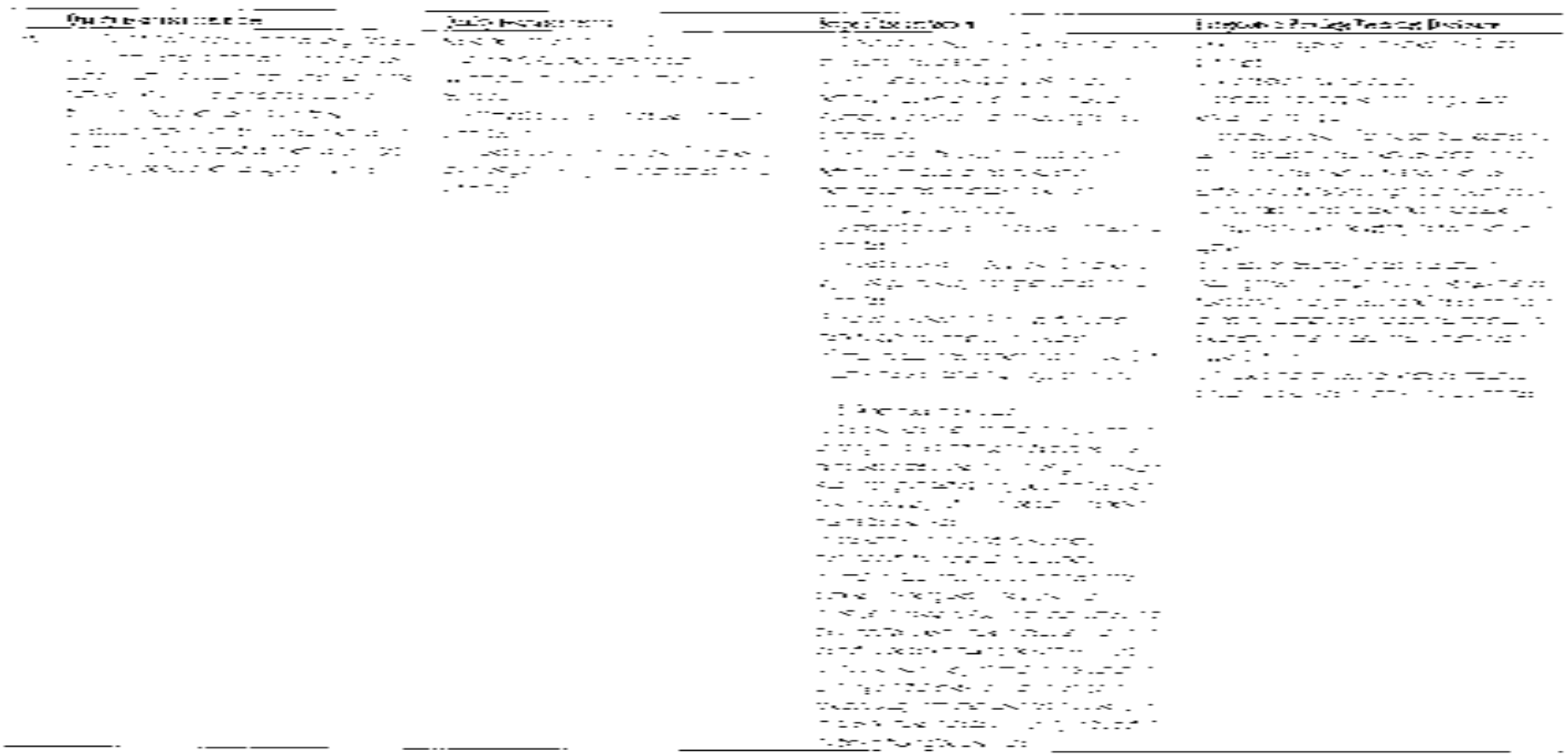


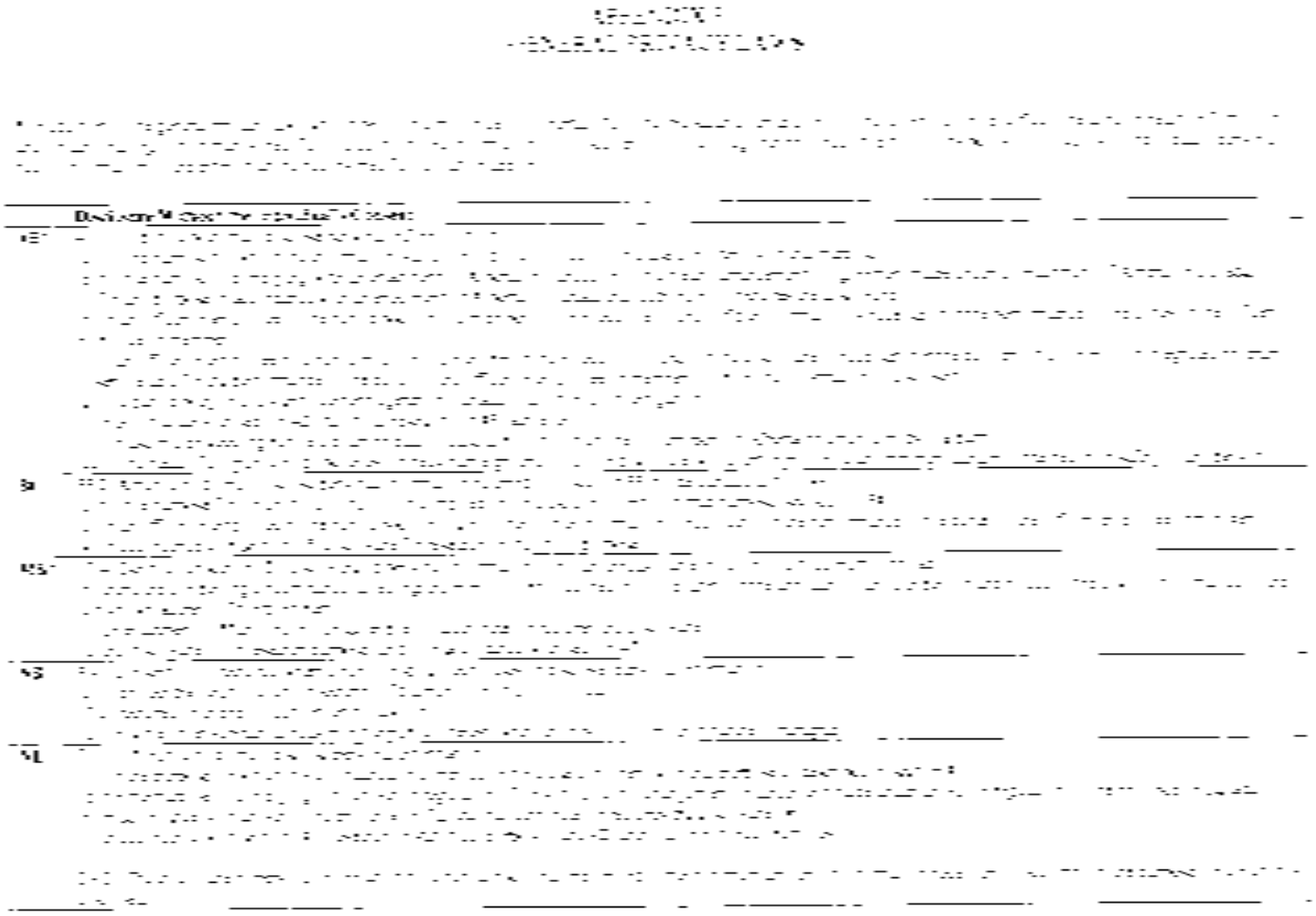


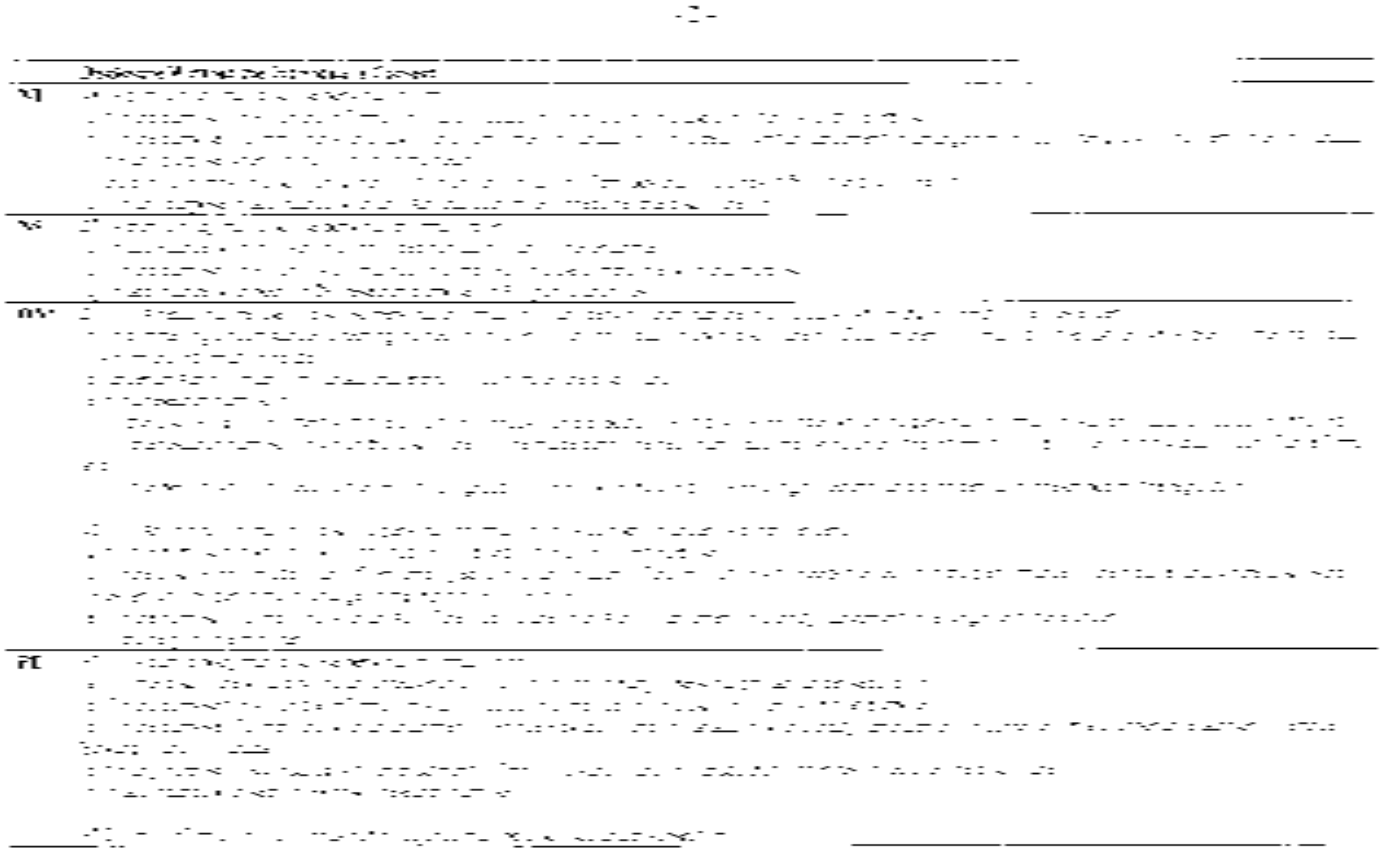


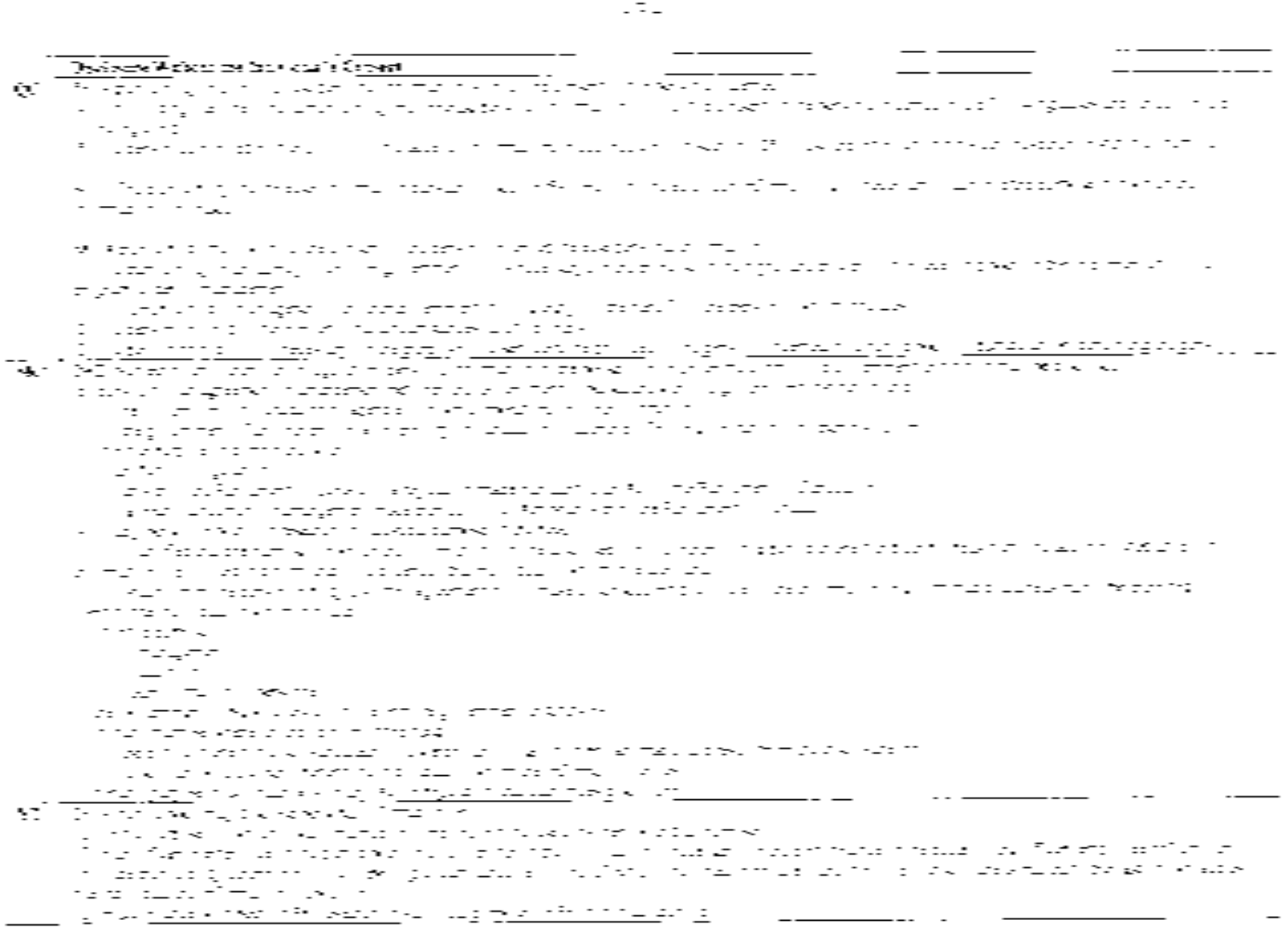


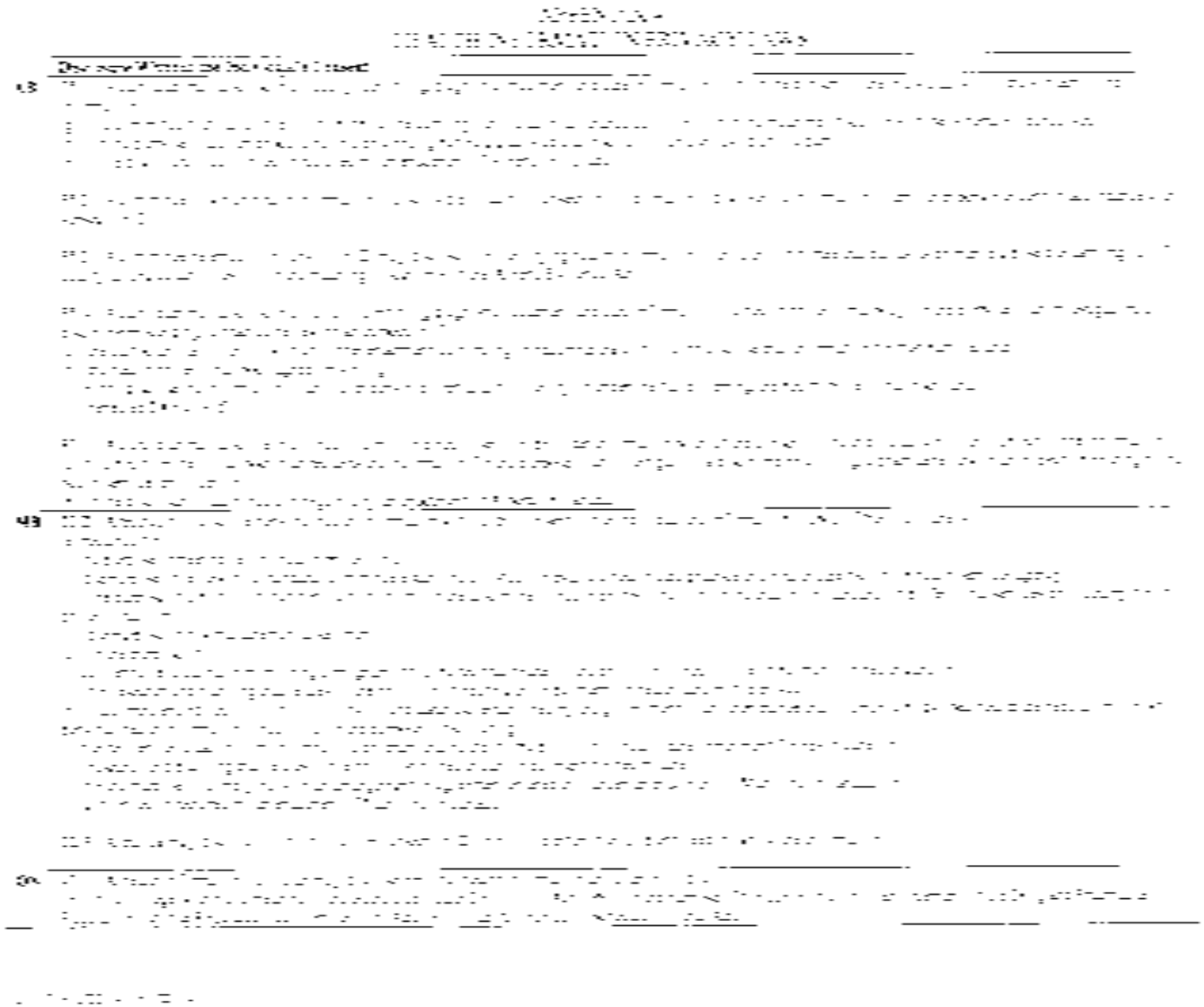


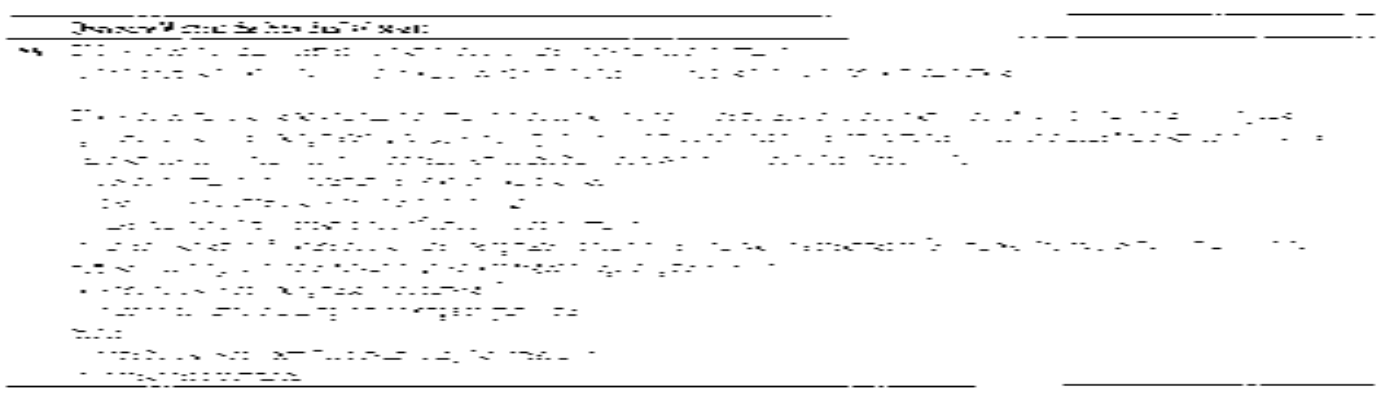


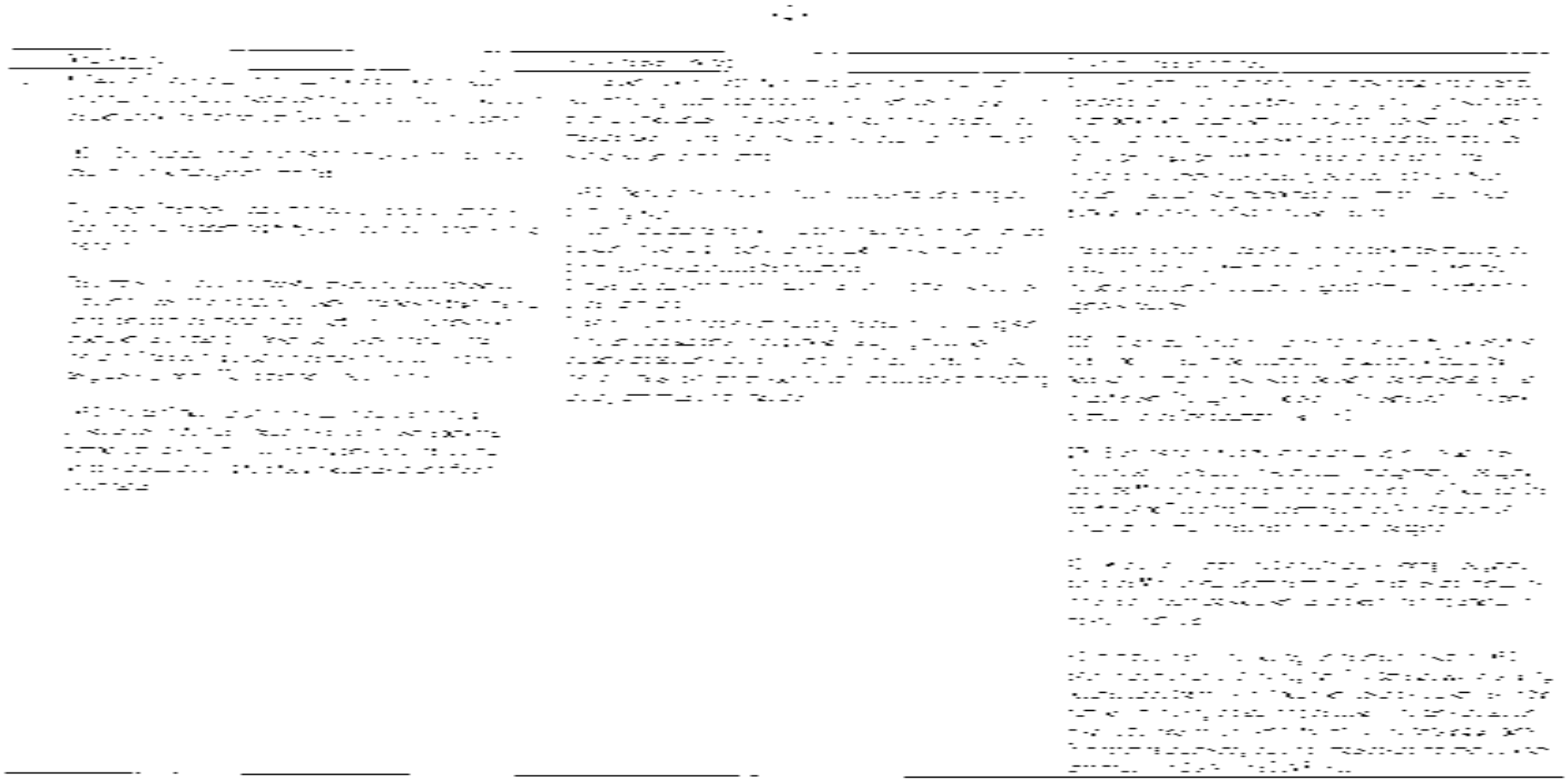


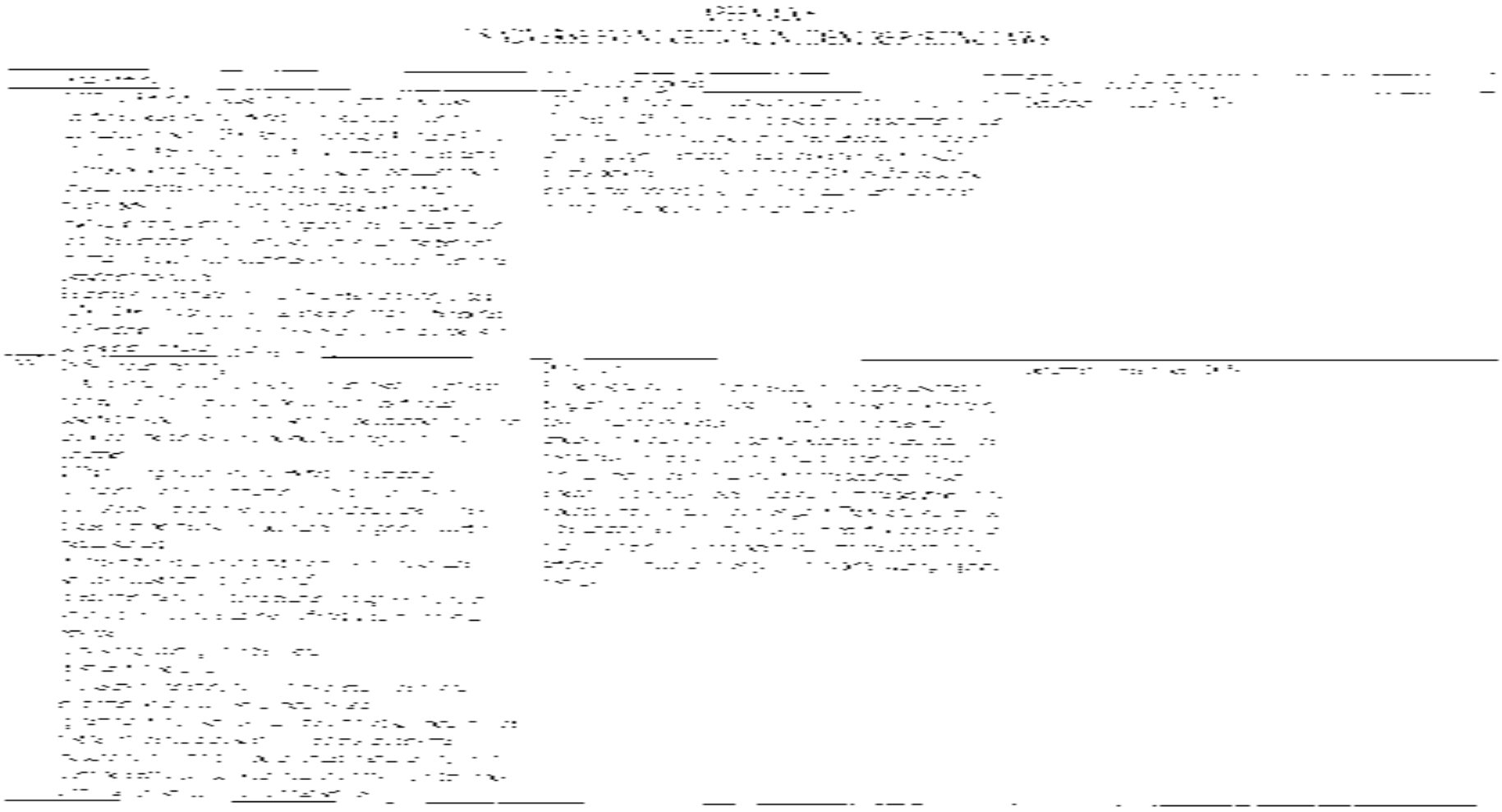


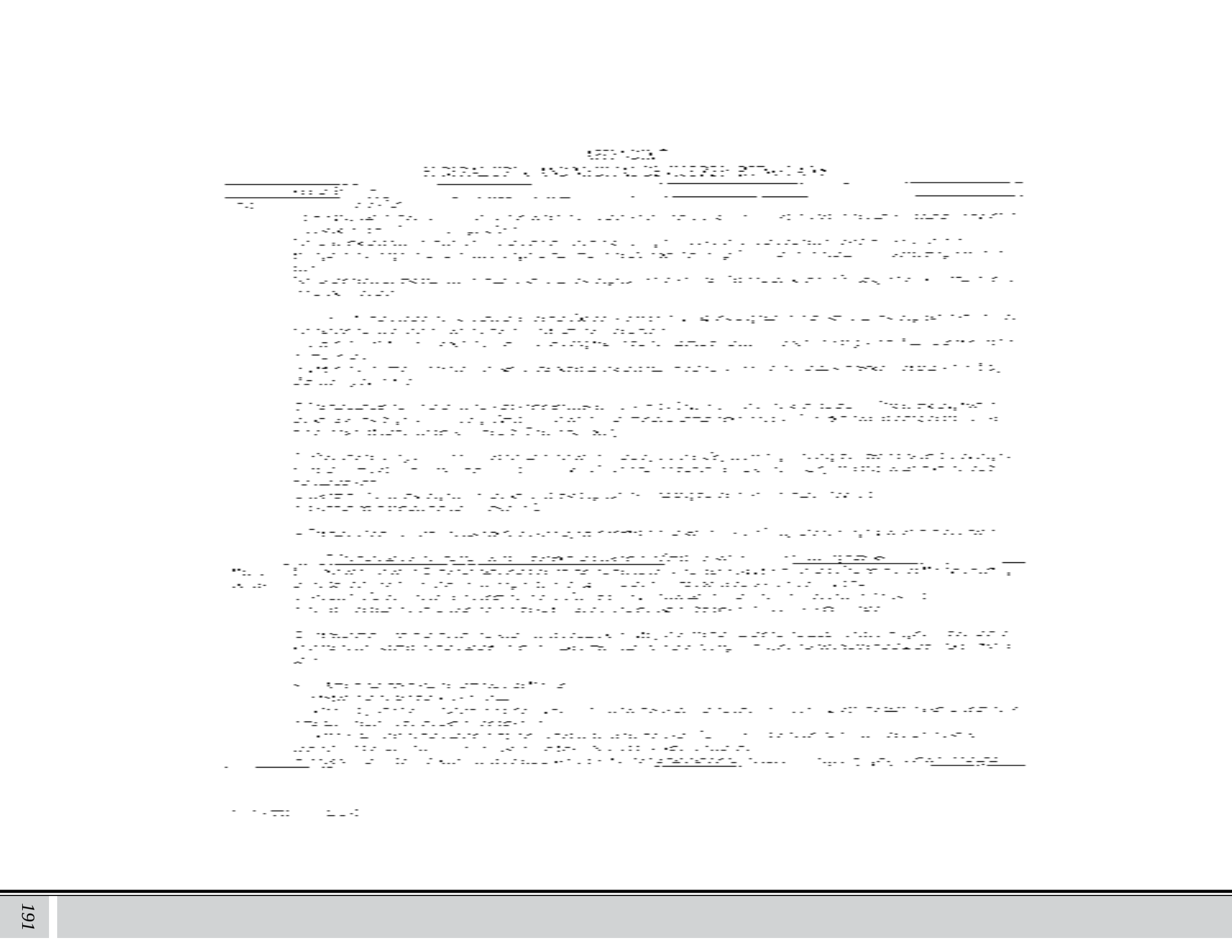


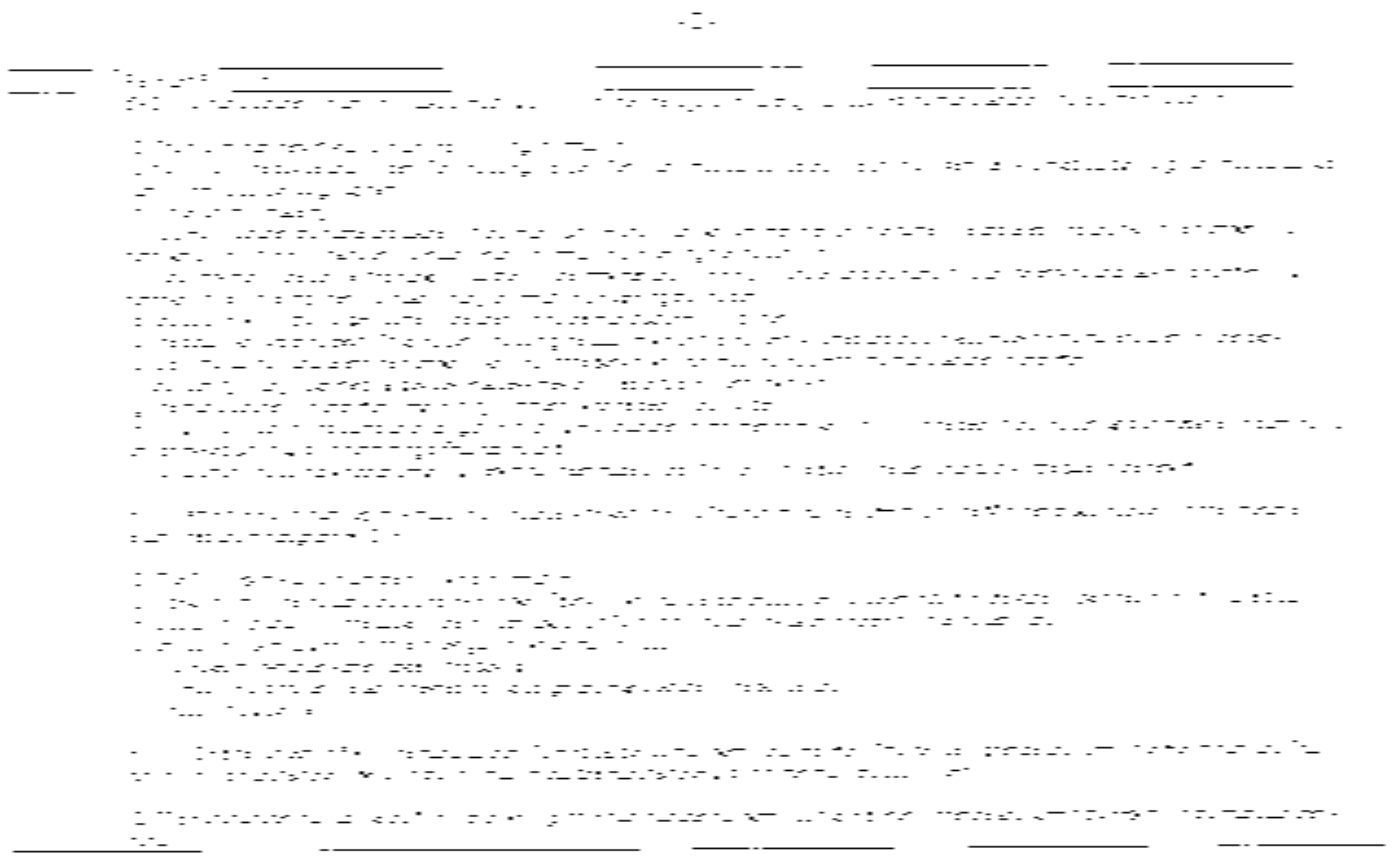








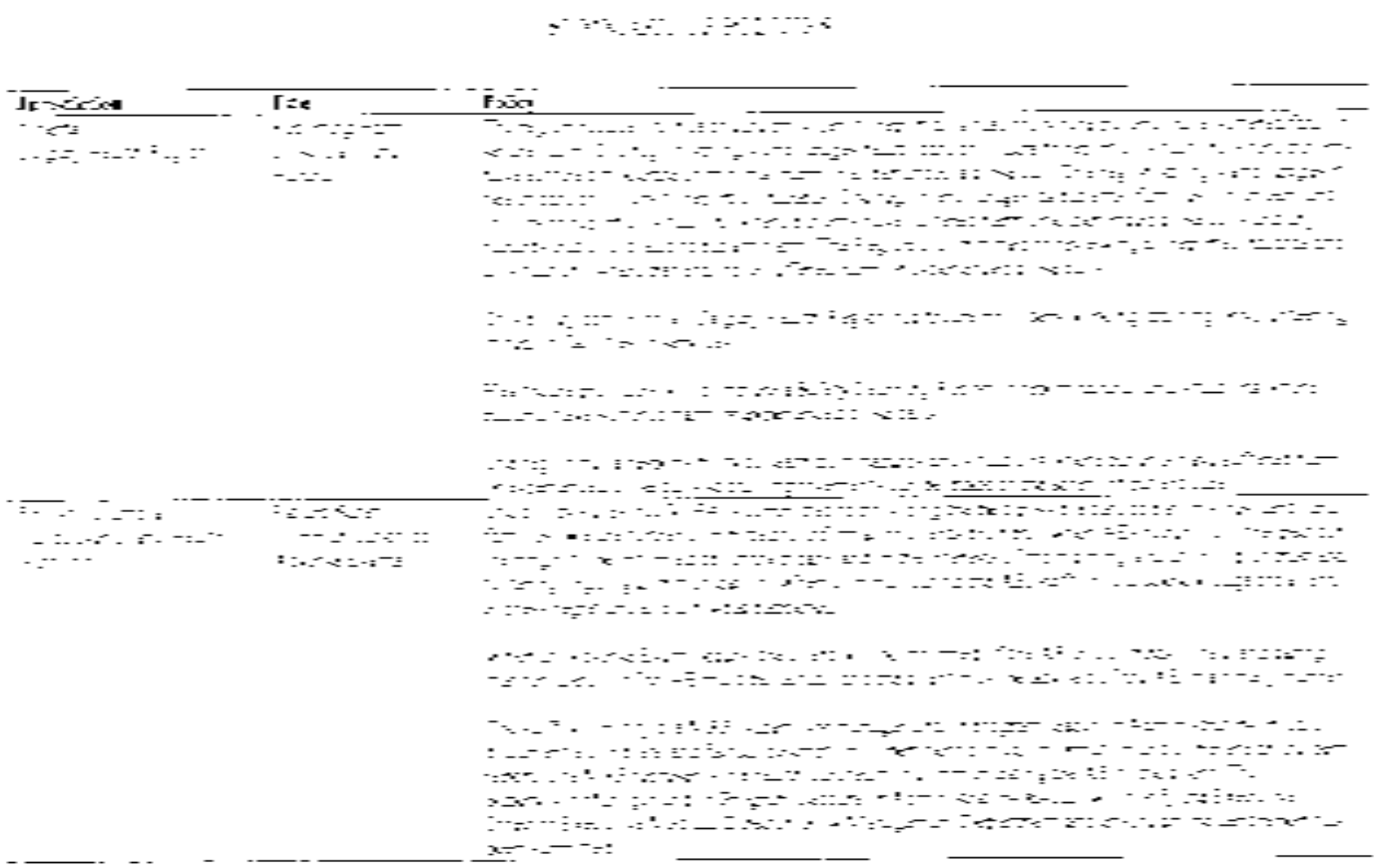




APPENDIX 8

LIST OF POLICIES REVIEWED

INSTITUTE	PROVINCE
Calgary Health Region	Alberta
Vancouver Island Health Authority	British Columbia
Providence Health Centre	British Columbia
Health Canada	
Manitoba Health	Manitoba
Brandon Regional Health Authority Inc.	Manitoba
South Shore Health Authority	Nova Scotia
Hay River Health & Social Service Authority	North West Territory
Ministry of Health and Long-Term Care	Ontario
Sunnybrook Health Sciences Centre	Ontario
Trillium Health Centre	Ontario
University Health Network	Ontario
Department of Health	Prince Edward Island
McGill University Health Centre	Quebec
Shriners Hospital	Quebec
University of Saskatchewan	Saskatchewan



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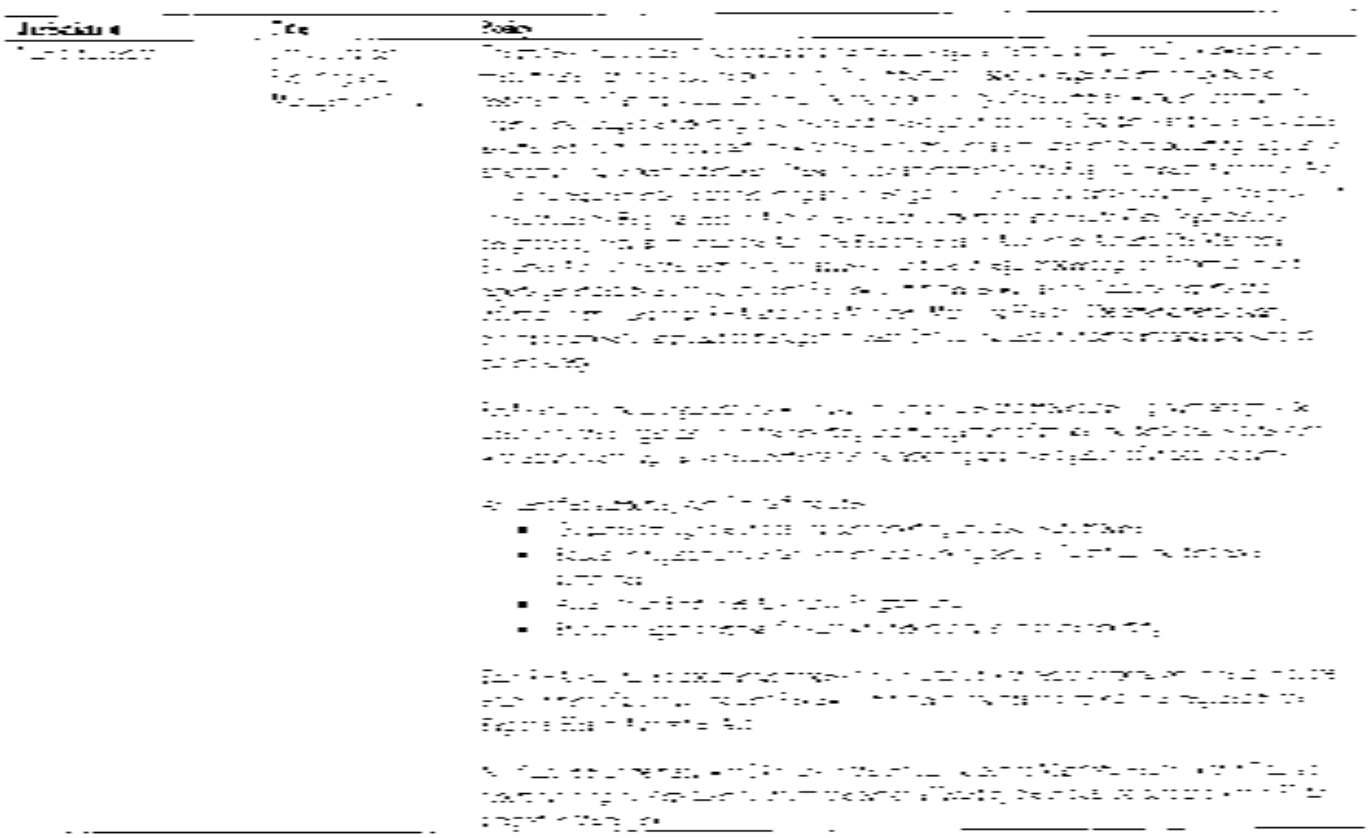

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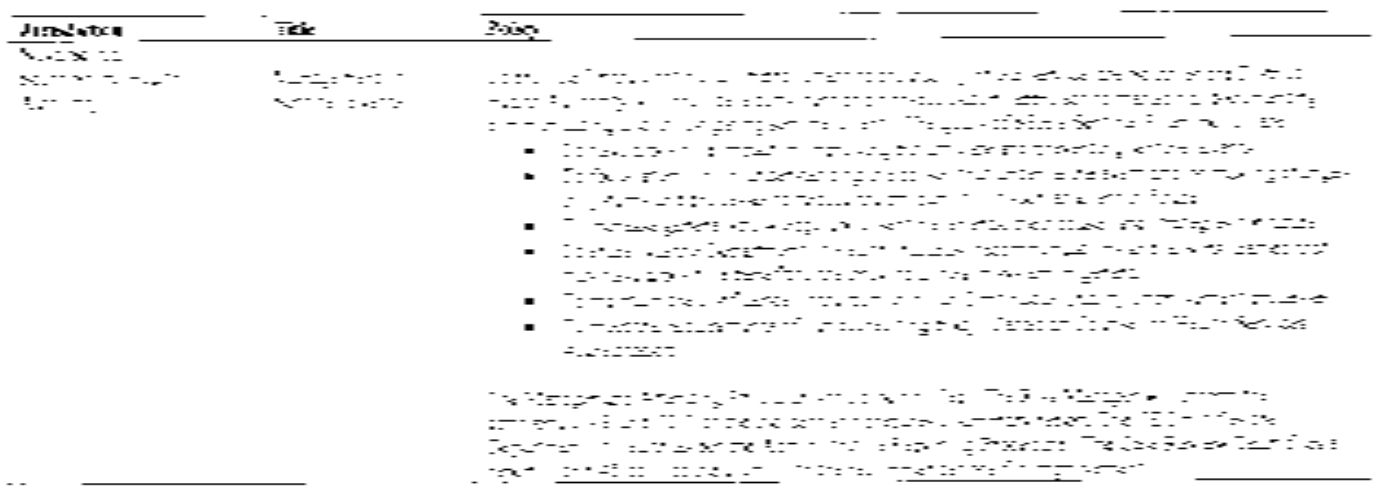

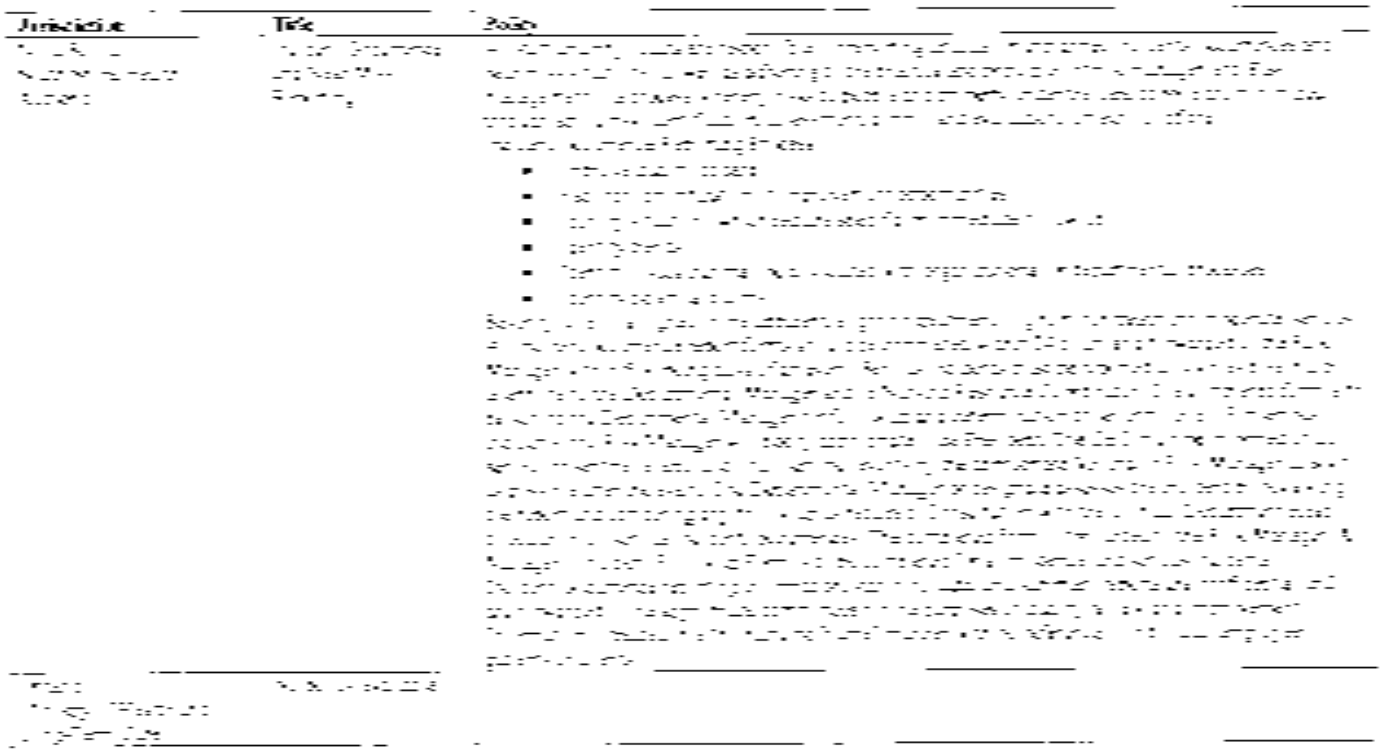

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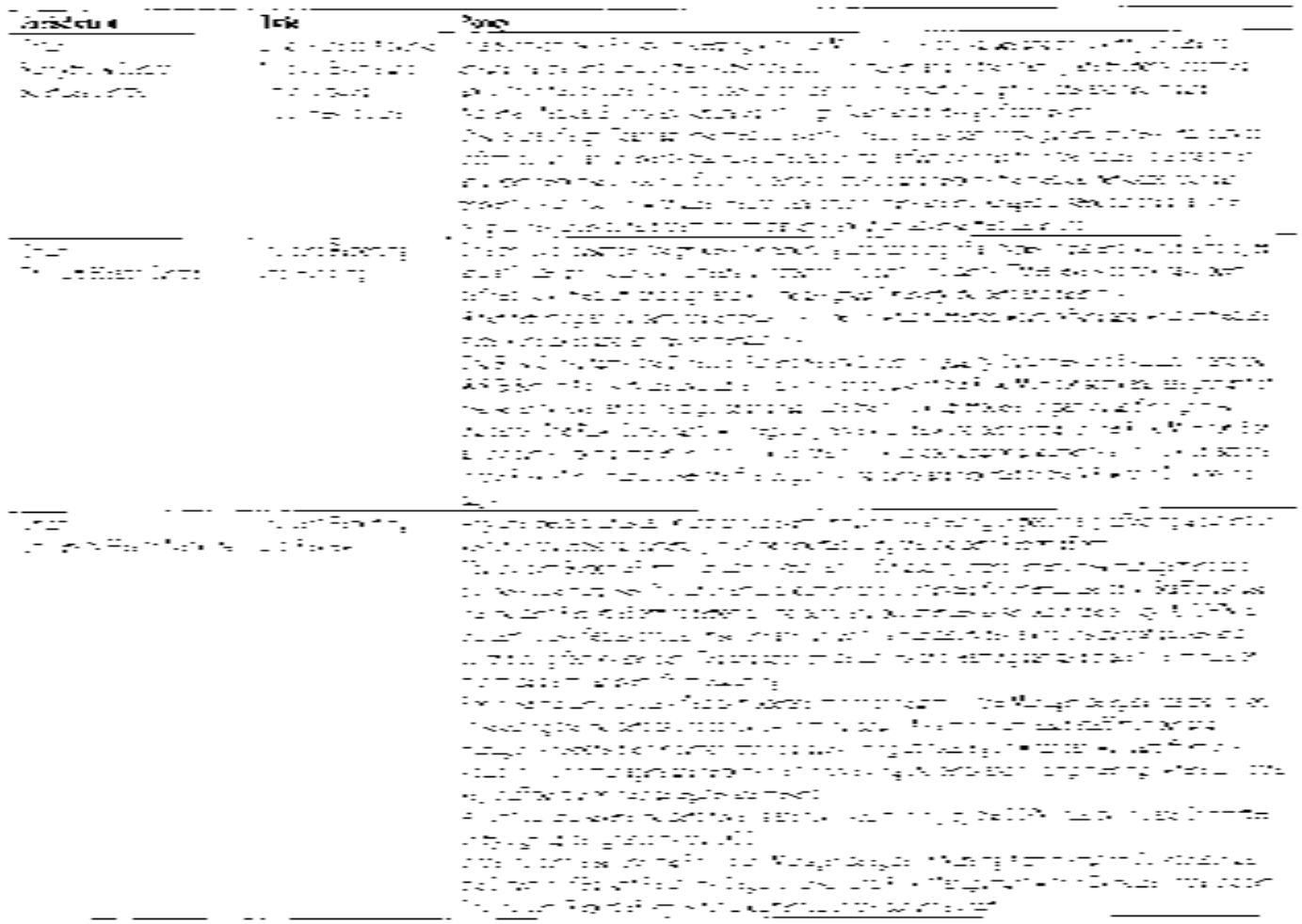

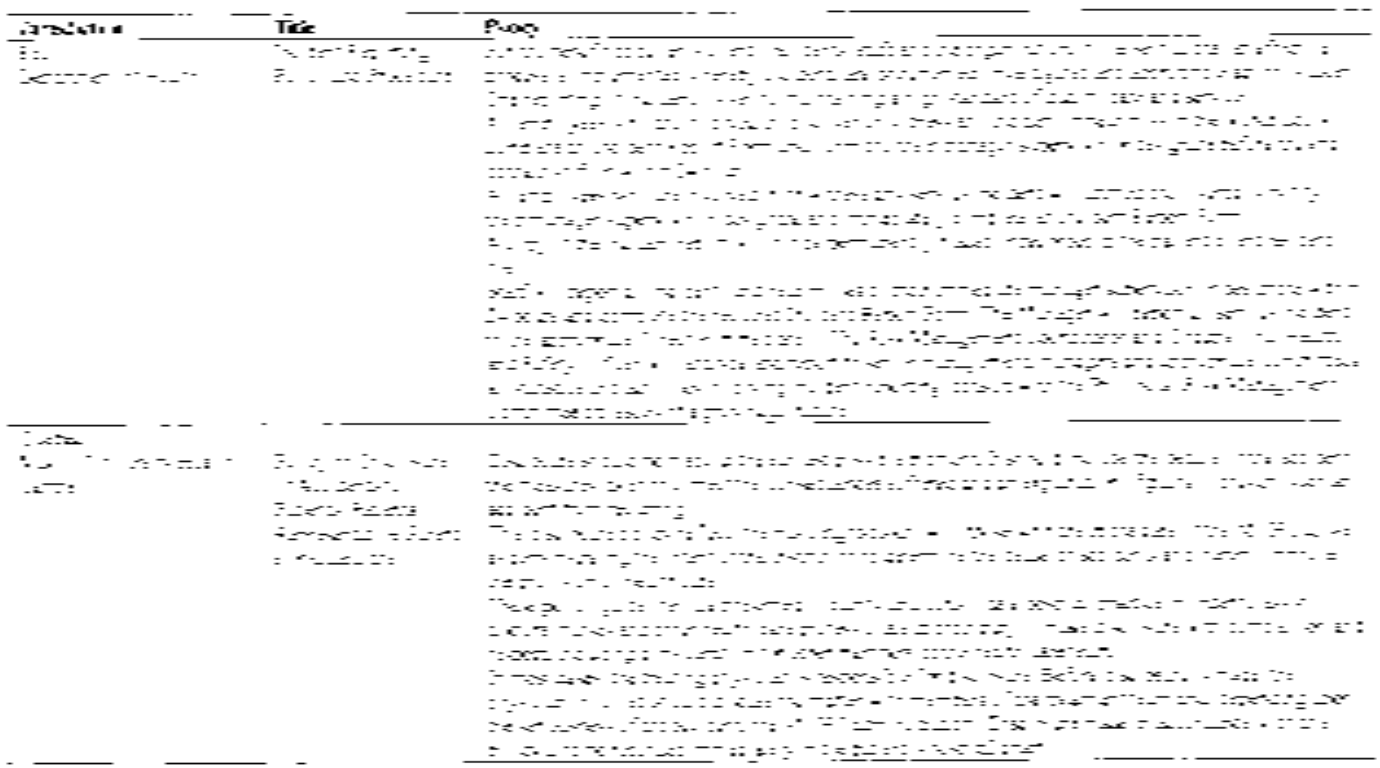

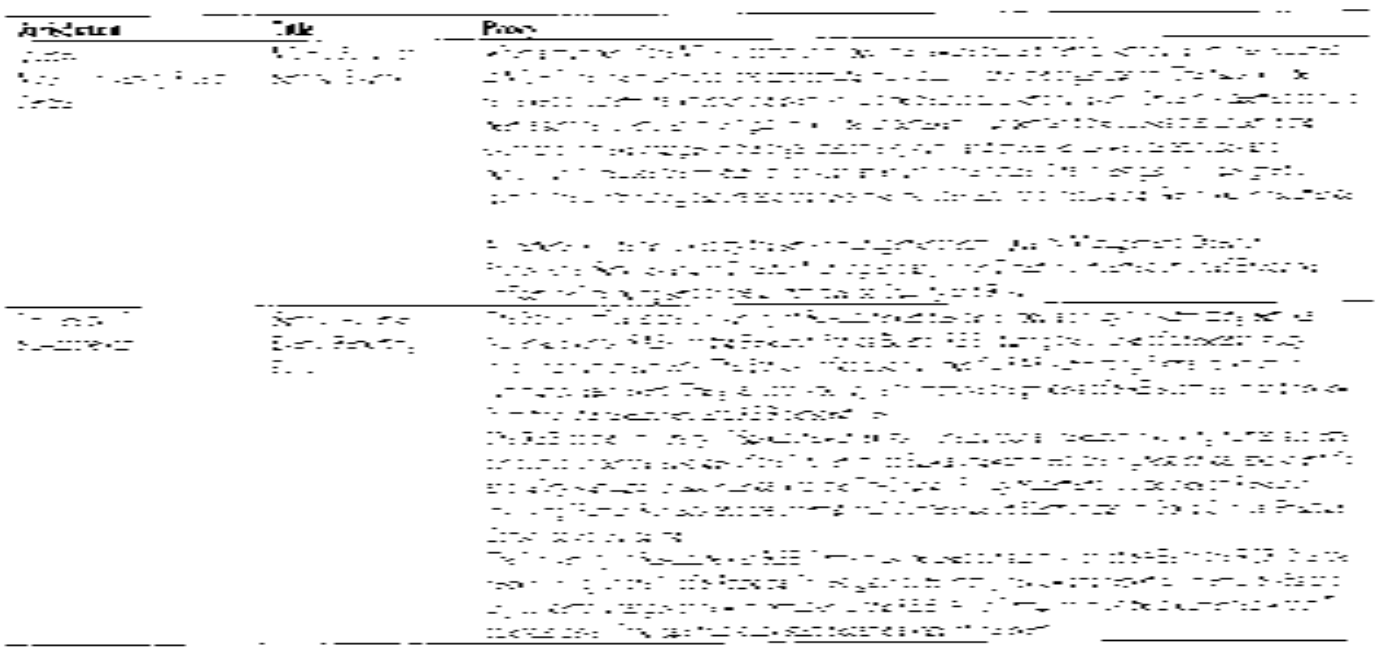

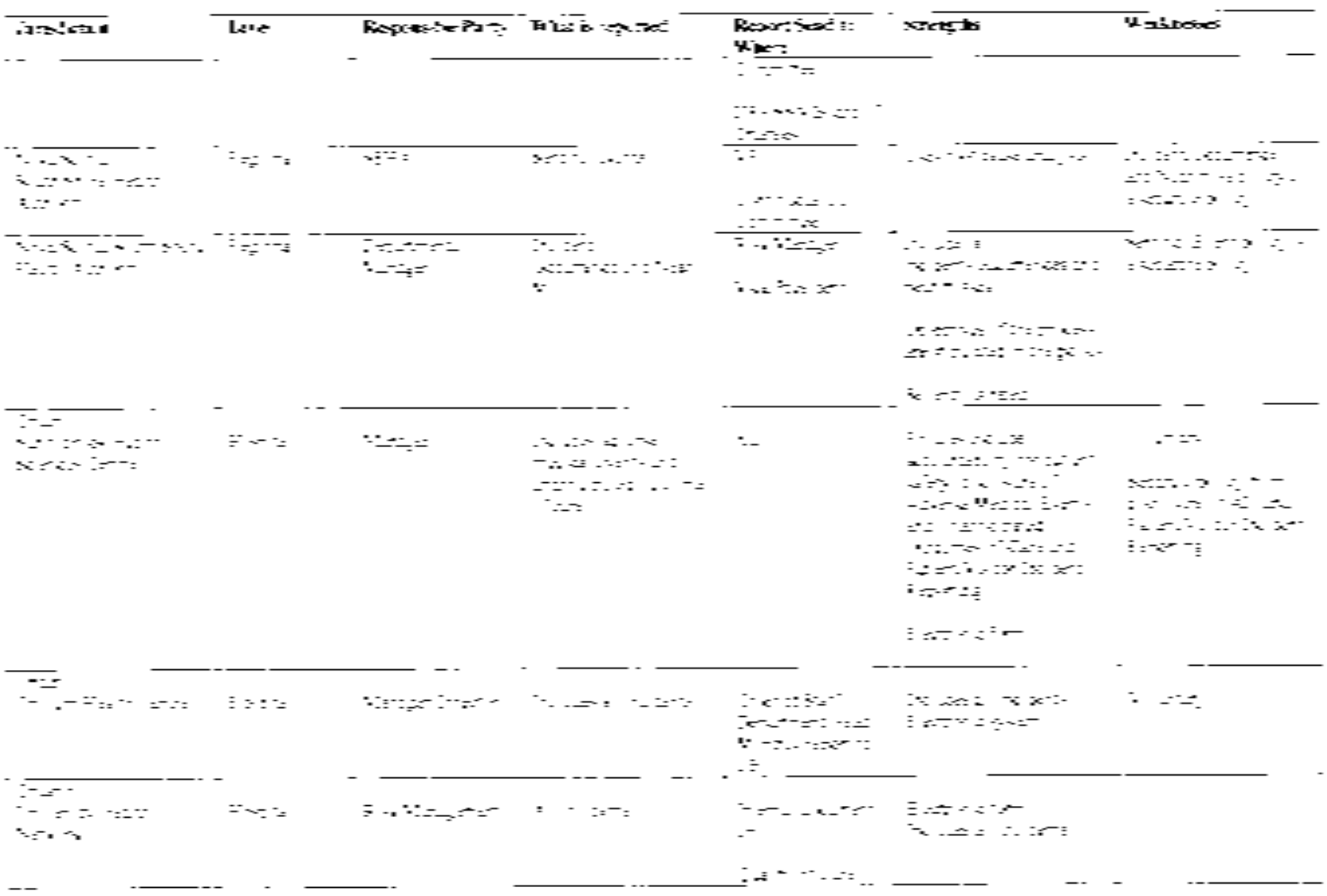

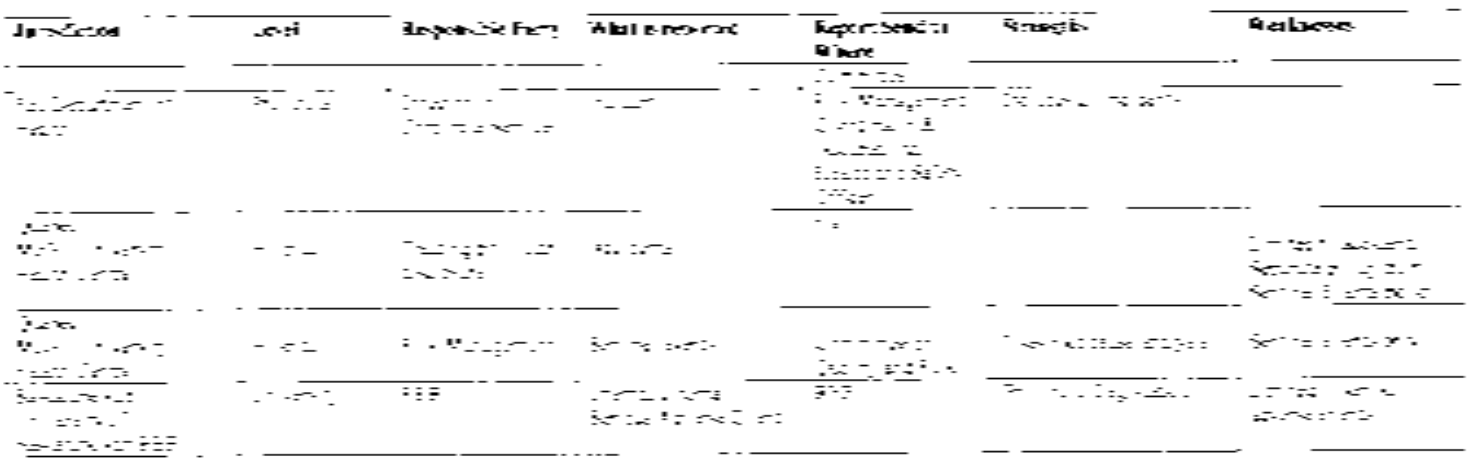

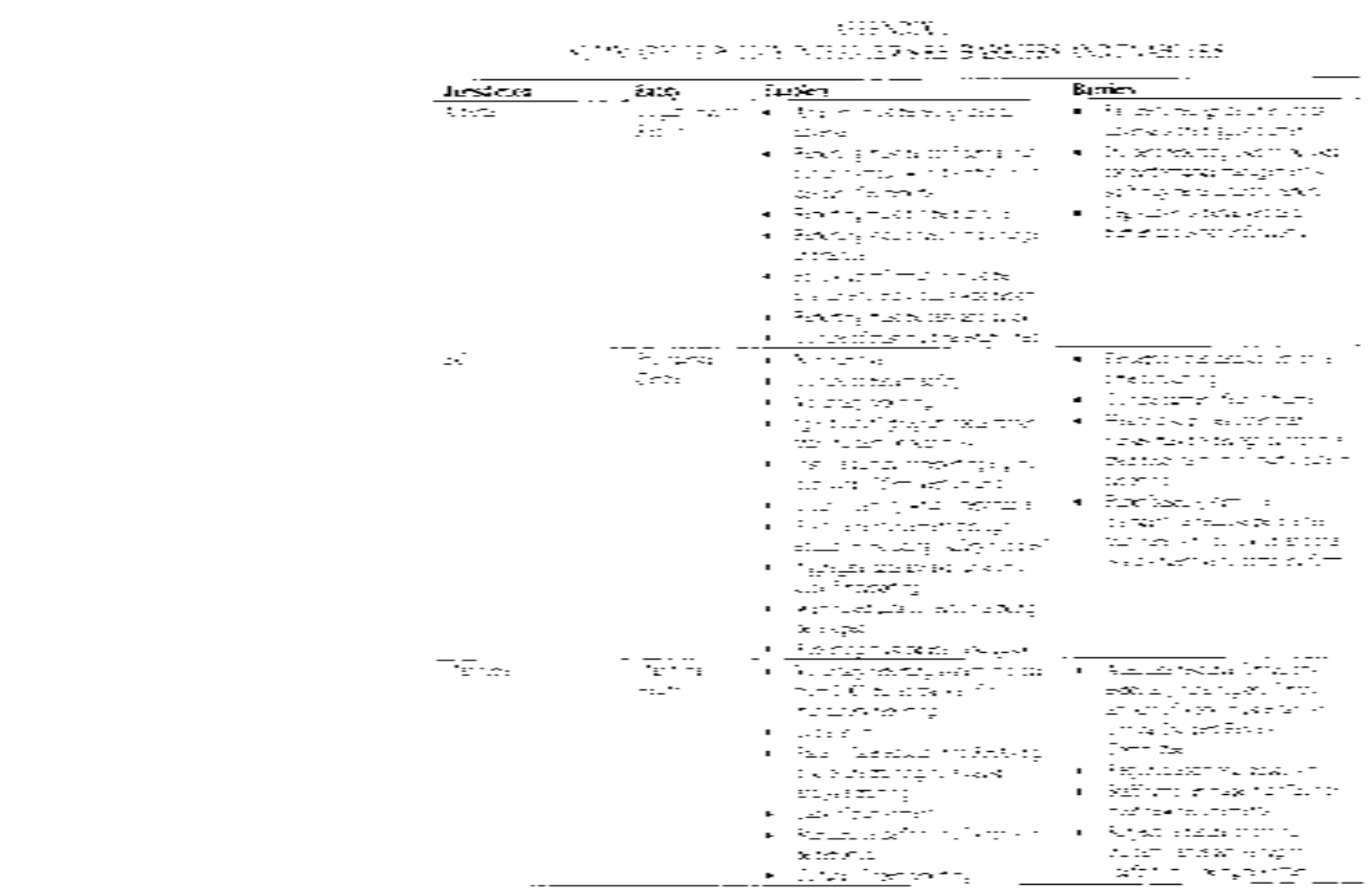

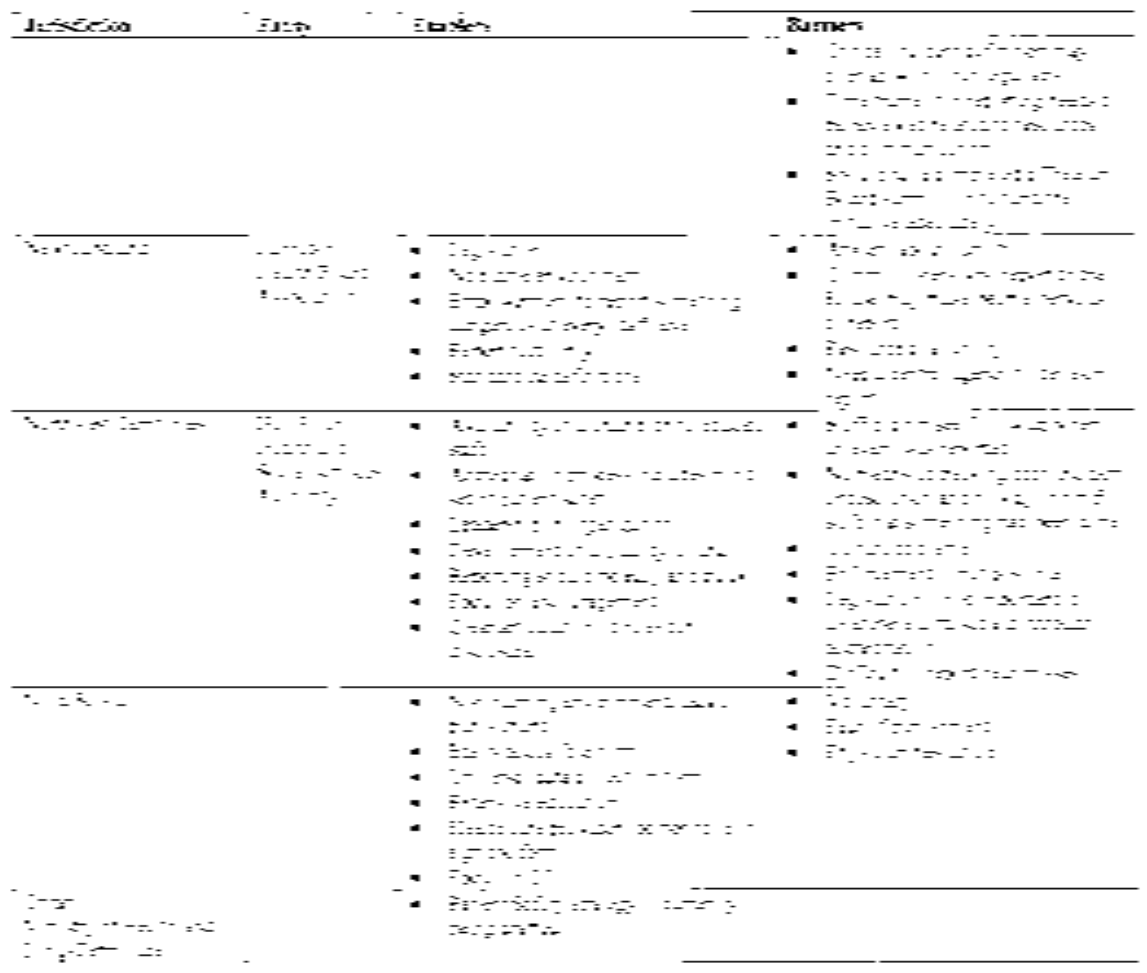

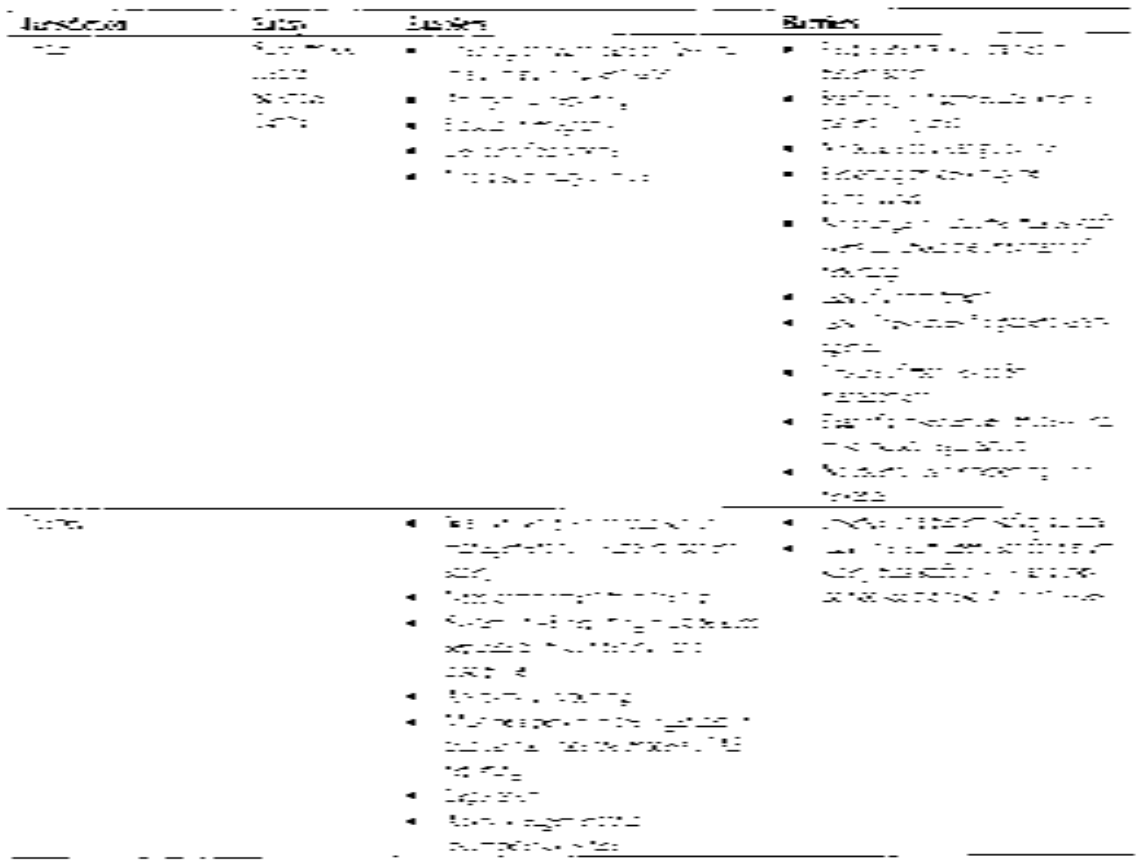

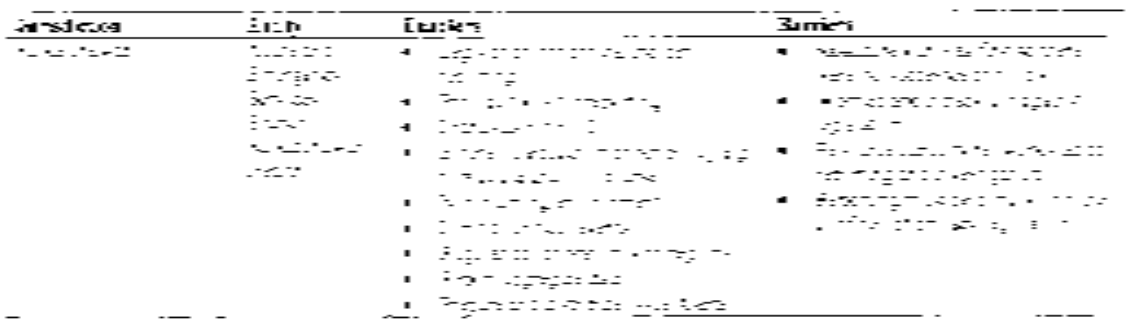

APPENDIX II

Adverse Event, Sentinel Events and Near Miss Reporting Survey
Acute Care Hospitals Version

On behalf of the Canadian Patient Safety Institute, we are reviewing the barriers and enablers to the reporting and review of adverse events, sentinel events and near misses in Canadian hospitals. The following survey has been designed to identify organizational policies and practices concerning the reporting and review of adverse events, sentinel events and near misses reporting in acute care hospitals. This survey asks for information on both internal reporting and review and external reporting to regions or other bodies. This survey is mainly comprised of closed-ended questions with some open ended questions. Please note that all information provided in this survey is confidential and the analysis will report only aggregate (that is, group or trend) results.

When you have completed the survey, please return it in the envelope provided addressed to Dr. Ross Baker at the University of Toronto.

Hospital

Hospital Name: _____

Hospital Size - Number of acute care beds _____

Key Contact Name: _____ Phone Number: _____ Email: _____
(To be used if clarification is needed)

Reporting Systems and Analytical Tools

Definitions

Safety Occurrence Taxonomy:

Adverse Events: are unintended injuries or complications that are caused by health care management, rather than the patient's underlying disease and that lead to death or disability or require additional use of hospital resources, such as prolonged hospital stay, additional testing or interventions.

Sentinel Events: An unexpected incident related to system or process deficiencies, which leads to death or major and enduring loss of function for a recipient of health care services.

Near Misses: An event or circumstance, which has the potential to cause serious physical or psychological injury, unexpected death, or significant property damage, but did not actualize due to chance, corrective action, and/or timely intervention.

Reporting System: Organizational routines used to collect information about one or more types of patient safety events. Reporting systems can be paper-based, electronic or a combination of both.

The following questions concern the types of reporting systems for patient safety events (adverse events, sentinel events and near miss occurrences) that exist in your hospital

1. **To what extent has your organization implemented a reporting system for adverse events, sentinel events and near misses and indicate whether system is paper and/or electronic based?**

Reporting System	Please check ✓ your response				Please check ✓ your response	
	Not at all	Partially Implemented (few units)	Majority of Units Implemented	Fully Implemented	Paper Based	Electronic Based
Adverse Event Reporting System						
Sentinel Events Reporting System						
Near Miss Reporting System						

2. **To what extent does your organization use specific analytical approaches (e.g., root cause analysis or quality improvement tools e. g., Flow Diagrams) to investigate reported adverse events, sentinel events, and near miss occurrences? Please check ✓ your response.**

	Not at all	Partially implemented on selected units	Majority of units Implemented	Fully implemented
Adverse Events				
Sentinel Events				
Near Misses				

3. **In the last year, how often has your organization used retrospective analytical approaches for safety occurrences (adverse events, sentinel events, and near misses)? Please check ✓ your response.**

	0	1-2	3- 4	5 or more
Root Cause Analysis				
Audit				
Chart Review				
Other, please specify				

* for those hospitals that circled other, please describe the retrospective analytical approaches you used in the past year

Organizational Policies and Practices

4. a) Does your hospital have a policy on reporting patient safety events?

Please check ✓ your response :: YES :: NO

If yes, please answer the following questions.

b) Does your policy cover all events (adverse events, sentinel events and near misses) or selected events?

Please describe the specific events that your policy covers.

c) Does your policy require disclosure to patients and family members on reported patient safety events?

Please check ✓ your response :: YES :: NO

Please describe.

d) Does your policy require that a summary of patient safety events be reported to the Board of Directors?

Please check ✓ your response :: YES :: NO

Please describe.

e) Are there any current issues around your reporting policy under review in your organization, please describe.

Please append a copy of your policy to your completed survey.

5. In the last year, how often did your hospital participate in the following activities associated with reporting and investigating safety occurrences (adverse events, sentinel events, and near misses)? Please check ✓ your response.

	Never	Daily	Weekly	Monthly	Quarterly	Annually
Included as measures for corporate reporting to the Board.						
Included as measures for reporting to the community.						
Education sessions for staff on safety cultures that include reporting and learning from events and incidents.						
Executive WalkRounds with a formal feedback on actions taken						
Meetings at the unit, division, and portfolio level for the review of safety indicators, and evaluation of planned initiatives						
Failure Mode Effect Analysis						
Reports on the follow up and resolution of all alerts and recalls of equipment to a third party (e.g. ORNT)						
Other, please describe						

6a. To what extent does your current reporting system capture the number and types of patient safety events that you believe to be occurring in your organization. Please circle your response.

1	2	3	4	5
None	Limited Extent	Somewhat	Frequently	Always

6b. To what extent do your current reporting system and structures create a capacity to analyze and act on these patient safety event reports to improve the design and delivery of care? Please circle your response.

1	2	3	4	5
None	Limited Extent	Somewhat	Frequently	Always

7. To what external agencies does your hospital report adverse events, sentinel events and near misses that have taken place in your hospital? (Check all that apply)

- ☐ Ministry of Health
- ☐ Regulatory bodies for health care professionals (e.g. College of Physicians and Surgeons, College of Nurses, College of Pharmacists, etc.)
- ☐ Report to a regional authority
- ☐ Report to other third parties, please specify (e.g. Ombudsmen)
- ☐ Report to insurers (e.g. HIROC, Canadian Medical Practice Association, Canadian Nurse Protective Society, and others)

Other, please describe

Enablers and Barriers for Reporting

For these series of questions, patient safety events refer to adverse events, sentinel events and near misses.

8. In your view, what are the key enablers within your hospital that facilitate enactment of policies associated with reporting and review of patient safety events? Please describe below.

9. In your view, what are the barriers from within your hospital that are challenges to enactment of policies associated with reporting and review of patient safety events? Please describe below.

External

10. In your view, what are the factors outside your hospital that facilitate enactment of policies associated with reporting and review of patient safety events?* Please describe below.

11. In your view, what are the factors outside your hospital that are challenges to the enactment of policies associated with reporting and review of patient safety events?* Please describe below.

12. In your view, what specific changes in practice, policy or legislation would encourage or facilitate the reporting and review of patient safety events? Please describe below.

*Some examples include privilege over quality assurance information, requirements of professional colleges potential lawsuits and provincial privacy legislation.

APPENDIX 12

Interview Questions For CSPI Project on Adverse Event Reporting

Introduction

We are working on behalf of the Canadian Patient Safety Institute to identify and analyze legal and policy barriers and enablers for the reporting and review of adverse events and/or critical incidents on a national scale. As part of this analysis we are conducting key informant interviews with experts in Canada and abroad. We would like to talk with you for 30 minutes about these issues.

Definitions

Patient safety events refer to adverse events which are unintended injuries or complications that are caused by health care management, rather than the patient's underlying disease and that lead to death or disability or require additional use of hospital resources, such as prolonged hospital stay, additional testing or interventions.

Critical incidents are incidents resulting in serious harm (loss of life, limb, or vital organ) to the patient, or the significant risk thereof.

Questions

1. Is there a need for information on patient safety events or critical incidents to be shared more broadly beyond the institutions in which these events are identified?
    a. If so, what types of information?
    b. To whom should this information be reported?
    c. Should this reporting be mandatory or voluntary?

2. Assuming such information can be collected centrally? How should information that is reported be used? Not used? Who should have access to the information?

3. One of the critical issues in reporting is the privileging of information on patient safety events. Are the current protections in your province/state adequate to support reporting or sharing of information on patient safety events?
    a. If not, in your view is it clear what types of legislative or other protections are needed in your province/state?
    b. What is the likelihood that such protection might be established in the near term (i.e., next two to three years)?

4. Will the development of effective privileging to permit information on patient safety events to be used improve care and moderate opposition to mandatory reporting?

5. Do you think that it would be possible to share information on patient safety events across provinces states?
    a. What are the barriers to such sharing?
    b. Could a set of principles be established to harmonize the reporting and sharing of such information?
    c. Would you thank this is likely?

6 What are other critical barriers to reporting and sharing of information on patient safety events?
    a. To what extent could these be addressed without new legislation?
    b. What resources are needed to remove these barriers?
    c. Do you think efforts to remove these barriers would be successful?

7. Some have suggested that a good first step would be the creation of a policy framework and best practices on sharing of information. Do you think this would be useful? Is it feasible? Who should take the lead?

8. A commonly stated barrier is the culture of blame that limits reporting. What do you think is needed to address this barrier?

Submitted by

Canadian Public Relations Society
Newfoundland and Labrador

Submitted to
Commission of Inquiry on Hormone Receptor Testing
and also to the
Chair of the Task Force on Adverse Health Events

Submission to the Commission of Inquiry on Hormone Receptor Testing

By

Canadian Public Relation Society – Newfoundland and Labrador (CPRS-NL)

May 15, 2008

Acknowledgements

I would like to thank the Honourable Justice Margaret A. Cameron and Co-counsels Bernard Coffey, Q.C. and Sandra Chaytor, Q.C. for providing CPRS-NL the opportunity to submit a formal brief to the Commission of Inquiry on Hormone Receptor Testing.

On behalf of our members, I would like to extend our support and best wishes to breast cancer patients and their families.

The difference between relations with the public and professional public relations (PR) is not well understood outside the profession itself as evidenced by comments in the media, comments of witnesses at the Commission hearings to date, and particularly questions asked of panelists at the April 23 Symposium. CPRS-NL appreciates this opportunity to inform the Commission and the public generally about our profession.

I would like to thank the Executive and members of CPRS-NL for their assistance in preparing this submission. I also want to thank Karen Dalton APR, Executive Director of CPRS for her helping us find the expertise in other CPRS Societies to assist with the content of this paper. In particular, I want to extend a special word of thanks to Sarah K. Jones APR, Partner, Kennedy Jones & Sweeney Inc, Toronto, and a past-President of CPRS, for her contribution to this submission and for taking the time from her busy life to help colleagues in a fellow public relations society.

Sean Kelly B.A., B.Ed. APR
President
CPRS-NL

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APPENDICES i

I. Introduction

In July 2007, the Government of Newfoundland and Labrador appointed the Honourable Margaret A. Cameron to head a Commission of Inquiry on Hormone Receptor Testing.

The Commission's terms of reference include:

- an inquiry into problems with estrogen and progesterone hormone receptor tests conducted between 1997 and 2005 in the Newfoundland and Labrador health care system;
- what happened to cause or contribute to the problems, when the problems came to light and whether they could have been detected earlier.
- whether protocols were in place during the relevant time frame and what steps, if any, were taken by responsible authorities upon becoming aware of the problems.
- a review of both policy and legal issues and the duties, if any, of the responsible authorities to patients, other parties within the health care system, and the public respecting differences in test results on re-testing.
- examination of whether the estrogen and progesterone hormone receptor testing systems and processes and quality assurance systems currently in place are reflective of "best practices".
- examination into the response of authorities when the problems were discovered, including the communications with affected patients and others. Further, the Commission is to study present practices related to estrogen and progesterone receptor testing.

Over the past several months, several witnesses have spoken at the Commission of Inquiry on the issue of public disclosure of adverse health events. As well, the Commission has heard from experts who presented papers on the topic of public disclosure. However, the Commission has not yet heard from public relations staff employed at the Eastern Health Corporation or within the Provincial Government, not has it heard from experts in public relations (PR). CPRS-NL believes that PR experts with expertise in issues management, risk communications and PR best practices could add to the Commission's understanding of this profession. For this reason, the Canadian Public Relations Society of Newfoundland and Labrador (CPRS-NL) has decided to submit this brief to the Commission of Inquiry on Hormone Receptor Testing.

CPRS-NL hopes that this paper will inform the Commission about the profession of public relations and promote a better understanding of how best practices in PR can help authorities to respond more effectively in the future when faced with issues around disclosure of adverse health events.

In fairness to our colleagues at the Eastern Health Corporation and within the Provincial Government, CPRS-NL wishes to state that it does not intend to pass judgment on the actions or inactions of public relations practitioners involved in the hormone receptor testing controversy. Our purpose is to inform, not judge. CPRS-NL encourages people to wait until all the evidence has been presented to the Inquiry and the Commissioner's Report is made public before drawing conclusions.

In this submission, we will provide for the Commission a definition of public relations and description of what PR practitioners do at various levels within the organizational structure. We will discuss best PR practices and the importance of including PR in decision-making at the most senior levels of the organization. This submission will highlight key elements of effective risk and crisis communications. Further, we will briefly discuss how strategic public relations can assist management in its efforts to communicate effectively with different audiences.

Also included in this submission is information about the Canadian Public Relations Society (CPRS), which is the national professional organization for public relations practitioners, its ethical guidelines and accreditation process. Finally, we will discuss gaps and challenges in the development of public relations best practices in Newfoundland and Labrador and some of what CPRS-NL plans as next steps to address the gaps and challenges.

II. Professional Public Relations and Best PR Practices

Definition of Public Relations

The evolution of public relations has seen numerous attempts to define the concept and practice of public relations. The Canadian Public Relations Society defines public relations as

> ***"the management function which evaluates public attitudes, identifies the policies and procedures of an individual or organization with the public interest, and plans and executes a program of action to earn public understanding and acceptance."***

Some common elements in many definitions suggest that public relations:

(a) conducts a planned and sustained program as part of an organization's management
(b) deals with the relationships between an organization and its publics
(c) monitors awareness, opinions, attitudes and behaviour inside and outside an organization
(d) analyzes the impact of policies, procedures, and actions on publics
(e) adjusts those policies, procedures and actions found to be in conflict with the public interest and organizational survival
(f) counsels management on the establishment of new policies, procedures and actions that are mutually beneficial to the organization and its publics
(g) establishes and maintains two-way communication between the organization and its publics
(h) produces specific changes in awareness, opinions, attitudes and behaviours inside and outside the organization
(i) results in new and/or maintained relationships between an organization and its publics.

It is important to understand that the practice of PR in an organization can range from a tactical role where practitioners are engaged primarily in activities like media monitoring, media relations and events planning to a more strategic counseling role. Some of the points listed above clearly illustrate a role for senior

public relations people in the policy making process. Progressing from a tactician to strategist takes years of experience, training and sound judgment. Not every practitioner makes it to this level and such a progression is even more difficult in the absence of certain necessary conditions, like training and mentoring.

Public relations is no stranger to criticism and practitioners strongly object to the use of pejorative descriptions, such as 'spin doctoring' to describe the valuable work that we do for our organizations and clients. This description, and similar characterizations, has appeared in several articles written recently by local journalists and in comments made about the ER/PR matter. CPRS-NL wishes to state that public relations activity that attempts to deceive the public or manipulate the truth for the benefit of the client is not condoned in any way by CPRS or CPRS-NL.

Strategic Communications Planning

Some of the criticism has come from what may be an unclear understanding of strategic public relations. Strategic public relations planning, also referred to as strategic communications planning, refers to a process of using research to identify problems and opportunities, establishing goals and objectives, defining key messages for specific audiences, determining actions for achieving the goals and objectives and establishing methods of evaluating effect and impact. In principle, they are not unlike other strategic planning processes used to identify and achieve desired goals and objectives. For example, financial advisors help people develop strategic financial plans to meet economic goals. Strategic communications plans are common industry practice for achieving measurable communications objectives, such as increasing awareness or informing target audiences.

There are many templates available for strategic communications plans, but the value of these plans for management is in the content, not the organization of the document. Therefore, it is important that the development of strategic communications plans be overseen by qualified, experienced public relations practitioners with the skills and training necessary to prepare strategic plans. A key purpose of strategic communications should be to make communications more effective, not to make the organization look good in the media. CPRS-NL wishes to inform the Commission that strategic communications is an important management tool that helps remove some of the guess work in communications. The intent in developing a strategic communications plan should be to achieve desired public relations and communications goals. Plans should be evaluated on the basis of how well they worked in achieving the goals.

At the most senior level, public relations is uniquely positioned to act as a 'corporate conscience' -- advising management when policy decisions are at odds with both the public's and the organization's interest and how to adjust the policy to address the situation. To coin a phrase, "*Good PR cannot make a bad policy good, but bad PR can make a good policy bad*." PR has a responsibility at the management table to identify when policy decisions can affect the reputation, integrity and credibility of the organization. Bad decisions can have negative financial, legal and operational impacts, but if the organization's integrity and credibility are at risk, the result can be catastrophic.

III. Risk Communications for Health Care

The Nature of Risk Communications

First, it is important to say that there is no template for risk communications. There are principles and best practices that practitioners turn to in risk communications that increase the probability of handling an emergency successfully and effectively, but generally speaking, emergencies are unique and require unique responses. Decisions are made immediately under duress and often without complete information, so there is always a chance that the wrong decisions will get made. The important thing is to correct any problem as quickly as possible.

Below are nine key elements of successful risk communications for consideration in the development of a policy on public disclosure of adverse health events.

Key Elements of Successful Risk and Crisis Communications

(i) The primary goal of the risk communicator should be protection and promotion of public health.

The public should be given sufficient information and knowledge to place the risk in proper perspective. The risk communicator should try to foster autonomous decision-making by the public as a means to the primary goal of health protection. In the age of the Internet, it is reasonably safe to say that people can access information about adverse health events and effects with the touch of a button. However, information obtained through the Internet is not always from a reliable source. Public relations can guide patients towards sanctioned websites that contain information relevant to the patient's need.

(ii) A single authoritative source of information is essential.

One thing that is absolutely critical in an emergency is the need for a single authoritative source for information during the crisis. Having more than one source of information increases the risk of the wrong information going to the public and this could make matters worse. Emergencies are by their very nature dynamic situations and things change constantly, so it is vital to control communications in a crisis. Accurate, honest and timely information is essential in risk communications.

Often in an emergency, communicators cannot afford to spend time correcting misinformation reported in the media because it takes them away from the important job of acquiring facts and getting them out to the public. For this reason, it is important to take the time to explain things once in as much detail as possible using the right spokespersons. However, misinformation should be corrected when it is revealed.

(iii) The longer it takes to establish control and demonstrate effective management in an emergency, the more likely it is that the situation will become a crisis.

In risk communications, trust and credibility are your most precious assets. An emergency becomes a crisis when it is not managed effectively and the public loses confidence in the organization's ability to manage the situation. A crisis does not necessarily involve a risk to life, but it can be anything that poses a serious threat to an individual or organization's reputation, credibility and integrity.

(iv) Disclose information as early as possible.

Some experts in the field of risk communications have suggested that responsible authorities have only 24 to 48 hours to respond publicly when a serious problem first becomes known. In some cases it is even more immediate. When spokespersons tell reporters 'no comment', the immediate reaction is that they must be trying to hide something. If this happens, it can create very serious problems because they have created bad will with the reporters and lost the trust of the public. Standby statements are common practice in the field because it identifies for the media the authoritative source of information, even when the answers to any questions could be months away.

When the authoritative source of information chooses to avoid the media, or is perceived to be avoiding the media, the media seek information from other sources that have legitimate perspectives on the issue. This is a reality of the news business. The perspectives of stakeholders should, in fact, be part of the reporting, but so must the information and perspectives of those in the authoritative agency or agencies.

(v) Communicate even when there is nothing to communicate.

Problems become known much more quickly than answers. If you wait until you have all or some answers before you say anything publicly, the situation could turn much worse. Reporters may decide the progress report is not newsworthy, but they appreciate being kept informed because they know they will be contacted when there is something significant to report.

(vi) A significant challenge in risk communications is selecting a spokesperson, deciding what information to release and how?

There are three criteria that must be met to be a spokesperson. First, the person must have the information necessary to answer reporters' questions. Second, he or she must have the authority to speak to the media. Third, he or she must be accessible to the media.

Selecting and presenting to the media an appropriate spokesperson is difficult at times in a hospital setting. In some matters, doctors are the appropriate spokespersons, but they are not always easily accessible to the media. Doctors may also feel reluctant to discuss sensitive matters in the media when they believe it is best addressed directly with patients. Additionally, without significant media training, many individuals are reluctant to answer a barrage of media questions which will certainly be about sensitive matters.

(vii) Accept and involve the public as a partner

People have a right to participate in decisions that affect their lives, their health, their property and the things they value. Involving the community early will produce an informed public that can be part of creating a solution to whatever crisis exists. Listening to their specific concerns and responding accordingly is important. Communications is a two-way street.

(viii) Make the media your partner. You have to meet the needs of the media.

What is also important to know in a crisis situation is that the media can be your best friend or your worst enemy. To ensure it is not the latter, it is best to make the media your partner in risk communications. Despite some of what has been written in local papers about PR practitioners and their relations with the media, the reality is that both public relations practitioners and the media have common objectives in an emergency situation. The public are always better served when the media and public relations work together to inform.

(ix) Coordinate and collaborate with other credible sources

Building trust can be easier when other credible and authoritative sources of information lend their support to your efforts. Building bridges with other authoritative organizations will assist you in your communications.

IV. The Canadian Public Relations Society (CPRS)

Who We Are

The Canadian Public Relations Society (CPRS) is an organization of men and women who practice public relations in Canada and abroad. Members work to maintain the highest standards and to share a uniquely Canadian experience in public relations, while working with our North American and international partners to promote recognition of the practice as a profession world-wide.

Membership in CPRS is restricted to public relations practitioners, whereas the International Association of Business Communicators extends its memberships to a broader group of communications professionals.

CPRS was founded 60 years ago in 1948 from two original groups - the first in Montreal and the second in Toronto. In 1953, these became associated as the Canadian Public Relations Society, and, in 1957, the organization was incorporated as a national society.

Today, CPRS is a federation of 16 Member Societies based in major cities or organized province-wide., CPRS works to advance the professional stature of public relations and regulates its practice for the benefit and protection of the public interest. Ethical standards are established through the CPRS Declaration of Principles, the Code of Professional Standards, the organization's by-laws and regulations, as well as through its statements regarding Confidentiality, Privacy and Conflict-of-Interest. Members are required annually to affirm their commitment to the standards of practice established in the Code of Professional

Standards. Both the Code and the Declaration of Principles are attached as appendices to this submission.

Global Alliance

The Global Alliance is a framework for collaboration with a mission to enhance the public relations profession and its practitioners throughout the world. The Alliance was formally established in Chicago, Illinois, USA, on 25 October, 2000, after a Public Relations World Congress sponsored by the Public Relations Society of America and the International Public Relations Association. More than 20 national and international associations were actively involved in the founding of this historic framework. CPRS is a proud partner in the Global Alliance.

The mandate of the alliance is to:

- Unify the profession
- Assist in building and growing public relations associations
- Develop and propose universal standards for the profession
- Be an advocate on behalf of the profession
- Serve the needs of the individual members of GA member organizations
- Offer reciprocal benefits to our collective membership

Global Alliance projects include the establishment of a global code of ethics and benchmarking of accreditation and curriculum standards.

What We Do

The Canadian Public Relations Society, as a distinct Canadian association, seeks:

- to group all public relations practitioners in Canada and to foster their professional interests
- in cooperation with its regional Member Societies and with like-minded organizations in other countries, to advance the professional stature of public relations
- to regulate its practice for the benefit and protection of the public interest
- to serve the public interest by upholding a standard of proficiency and code of ethics, and by providing ongoing professional development to its members and public relations practitioners across Canada.

Like other professional associations, CPRS places emphasis on providing professional development opportunities for its members at the local and national levels.

Accreditation in Public Relations

CPRS offers a globally recognized accreditation program in public relations (APR). This professional designation is a cornerstone of the society's recognition of professionalism and competence and all members are encouraged to seek the designation when they are eligible.

CPRS Accreditation (APR) is a respected measure of professional experience in the field of public relations. This program recognizes the dedication, energy, perseverance and competence of successful public relations professionals. To pursue the accreditation process, a member must satisfy the following eligibility requirements:

- Member in good standing of the Canadian Public Relations Society.
- Employed full-time in a public relations position for at least five years; and
- Spends at least half of your professional time involved in specific public relations activities.

The examinations, offered in French and English, consist of three parts: a review of a work sample, a written examination and an oral examination. The exams are designed to test the breadth and depth of a candidate's public relations experience and ability.

The goals of CPRS National Council on Accreditation are to assure professional competence; establish standards for professional practice; increase recognition for the profession within business organizations and the community, and influence the future direction of the profession.

Below are suggested reasons for practitioners to pursue accreditation in public relations:

- Accreditation establishes professional credentials and enhances the professional image
- Accreditation improves skills and knowledge and prepares you for greater on-the-job-responsibilities
- Accreditation reflects achievement and builds self-esteem
- Accreditation improves earnings potential and improves career opportunities and advancement
- Accreditation offers greater professional recognition from peers

This is not to say, of course, that only public relations practitioners with an APR after their name are competent professionals. On the contrary, there are many fully qualified and competent PR practitioners across Canada and here in this province who do not yet have an APR designation.

V. Next Steps in Development of PR Best Practices

Membership in a Professional Association and Accreditation

As noted above, membership in a professional public relations society can greatly benefit practitioners and the organizations they represent. CPRS has a

national committee formed to examine ways of encouraging more practitioners across the country to apply for accreditation.

CPRS-NL hopes that the work of the Cameron Commission will be useful in highlighting the value of belonging to a professional organization and that it will encourage many senior public relations practitioners in the province to join and become involved in CPRS and the local member society.

Professional Development through Public Relations Societies

Each year, CPRS holds its national conference and annual general meeting in a location sponsored by a local member society. This is an opportunity for practitioners from across the country to learn about current best practices and explore recent trends and issues affecting the PR practice today. The CPRS national conference is open to members and non-members and employers are encouraged to support the attendance at this event of their public relations staff.

The national CPRS Board of Directors supports numerous professional development sessions throughout the year. Some of these opportunities are web-based, while other initiatives include workshops and courses at locations across Canada. CPRS-NL has been actively seeking more web-based seminars given the cost associated with travel outside the province to attend professional development events.

CPRS has also been supportive of local societies' efforts to organize professional development. A few years ago, CPRS and CPRS-NL held a one day mini conference where experts from across the country came to speak on a broad range of current topics in public relations.

CPRS-NL has formed a committee to assess PR training needs in the province and to formulate an action plan for improving access to professional development for local PR practitioners.

Post-Secondary Education in PR

There is no degree granting PR program available in this province at present. The nearest available Bachelor of Public Relations (BPR) program is at Mount St. Vincent in Halifax. The absence of such a program is a major obstacle to developing and improving best PR practices among local practitioners. Many PR practitioners entering the field come from journalism or marketing backgrounds and many possess degrees in various social sciences. However, there are a growing number of BPR graduates in the province, which is encouraging.

CompuCollege, a private school, is the only institution in this province offering a Diploma in Public Relations.

In Newfoundland and Labrador, a small number of private companies offer training in some aspects of PR, such as the three courses available through the College of the North Atlantic (CNA) – the Fundamentals of Public Relations, Message Driven Media Relations and Strategic Communications Planning. Efforts are underway to expand the number of courses available through CNA in areas where there are gaps.

What this means is that local practitioners interested in developing their skills and broadening their knowledge must frequently look outside the province for training opportunities. Because this is often cost prohibitive for many practitioners, CPRS-NL has been moving more towards web-based and distance education programs.

VI. Conclusion

Although public relations practitioners have received some criticism in relation to the handling of the ER/PR issue, the answer is not to exclude PR from decision-making, but rather to include PR at the most senior levels. Contrary to what some might expect, the answer is not less PR, but more.

All organizations are facing much more complex public relations and communications issues these days and they require expert assistance in dealing with these challenges in an effective manner. This means that organizations with intensive public responsibilities are well served when they have senior accredited public relations practitioners heading departments, which are also staffed with personnel who are capable in media relations, risk communications, community relations, internal communications, and other specialty areas.

APPENDICES

APPENDIX A

CPRS DECLARATION OF PRINCIPLES

The National Society, in setting forth its Declaration of Principles and Ethics of Professional Conduct, strives to:

- affirm that the obligations of a public trust are inherent in the practice of public relations;
- promote and maintain high standards of professional practice and conduct among the membership, so as to ensure that public relations shall be esteemed as an honourable profession;
- safeguard good taste and truthfulness in all material prepared for public dissemination and in all aspects of the public relations practitioner's operations;
- ensure that membership represents surety of ethical conduct, skill, knowledge and competence in the practice of public relations;
- foster increased attention to public relations as a course of study in universities, colleges, institutes and other similar educational organizations in order to further the proficiency, knowledge and training of anyone engaged in or interested in entering public relations;
- adhere to the Global Protocol on Ethics in Public Relations of the Global Alliance for Public Relations and Communications; and
- subscribe to the principles of Canada's Charter of Rights and Freedoms

APPENDIX B

Code of Professional Standards

Members of the Canadian Public Relations Society are pledged to maintain the spirit and ideals of the following stated principles of conduct, and to consider these essential to the practice of public relations.

1. **A member shall practice public relations according to the highest professional standards.**
   Members shall conduct their professional lives in a manner that does not conflict with the public interest and the dignity of the individual, with respect for the rights of the public as contained in the Constitution of Canada and the Charter of Rights and Freedoms.

2. **A member shall deal fairly and honestly with the communications media and the public.**
   Members shall neither propose nor act to improperly influence the communications media, government bodies or the legislative process. Improper influence may include conferring gifts, privileges or benefits to influence decisions

3. **A member shall practice the highest standards of honesty, accuracy, integrity and truth, and shall not knowingly disseminate false or misleading information.**
   Members shall not make extravagant claims or unfair comparisons, nor assume credit for ideas and words not their own.

   Members shall not engage in professional or personal conduct that will bring discredit to themselves, the Society or the practice of public relations.

4. **A member shall deal fairly with past or present employers / clients, fellow practitioners and members of other professions.**
   Members shall not intentionally damage another practitioner's practice or professional reputation. Members shall understand, respect and abide by the ethical codes of other professions with whose members they may work from time to time.

5. **Members shall be prepared to disclose the names of their employers or clients for whom public communications are made and refrain from associating themselves with anyone who would not respect such policy.**
   Members shall be prepared to disclose publicly the names of their employers or clients on whose behalf public communications is made. Members shall not associate themselves with anyone claiming to represent one interest, or professing to be independent or unbiased, but who actually serves another or an undisclosed interest.

6. **A member shall protect the confidences of present, former and prospective employers / clients.**
   Members shall not use or disclose confidential information obtained from past or present employers / clients without the expressed permission of the employers / clients or an order of a court of law.

7. **A member shall not represent conflicting or competing interests without the expressed consent of those concerned, given after a full disclosure of the facts.**
Members shall not permit personal or other professional interests to conflict with those of an employer / client without fully disclosing such interests to everyone involved.

8. **A member shall not guarantee specified results beyond the member's capacity to achieve.**

9. **Members shall personally accept no fees, commissions, gifts or any other considerations for professional services from anyone except employers or clients for whom the services were specifically performed.**

Submitted by

Health Professional Education
— Memorial University

Interprofessional Education and Patient Safety Competencies

Submission to:

The Task Force on Adverse Health Events
June, 2008

Prepared by:

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Director of Academic Research and Development

Executive Summary

The Canadian Patient Safety Institute (CPSI) has undertaken work to develop a Canadian interprofessional competency-based framework for patient safety through collaborative efforts. CPSI has partnered with the Royal College of Physicians and Surgeons of Canada in coordinating and facilitating the development of *The Safety Competencies Framework.* The Safety Competencies define seven core domains of abilities for all health professionals to incorporate into their work and identifies the key knowledge, skills and attitudes related to patient safety for institutions and individuals responsible for education and professional development of practitioners in medicine, nursing, pharmacy and the therapy groups (PT, OT, RT). These domains include: Creating a Culture of Patient Safety; Working as a Team; Communicating Effectively; Using Safe Strategies to Enhance Practice; Managing Human Factors and Cognitive Processes; Managing High-Risk Situations; and Responding to an Adverse Event. The *Working as a Team* domain specifically describes the ability of health professionals to effectively collaborate with others to maximize patient safety and the quality of care.

When health care professionals are expected to work and function collaboratively as part of interprofessional teams, they should be prepared to engage in these activities through their education, clinical training and professional development. Traditionally, health professional students have experienced minimal contact with each other in the process of their education and even less collaborative learning experiences designed to promote interprofessional health care team relationships. This has largely been exacerbated by the fact that health professional education occurs largely in an environment of separately housed professional schools and separate clinical arenas. As a result, health professionals are socialized in isolation, hierarchy is fostered, and individual responsibility and decision making are relied upon almost exclusively. A lack of appreciation of the potential contributions of each of the health professions is reinforced by such settings, and more important, students learn little about ways to coordinate and collaborate in providing quality care.

There is a growing body of literature that demonstrates that when healthcare professionals understand each others' roles and are able to communicate and work effectively together, patients are more likely to receive safe, quality care. Interprofessional education (IPE) involves members (or students) of two or more professions associated with health or social care engaged in learning with, from and about each other. There is evidence that IPE can help to break down stereotypical views that professionals hold about one another and can result in an increased understanding of the roles, responsibilities, strengths and limitations of other professions.

Recent commissions, committees and policy documents in Canada have all identified the importance of reshaping educational preparation and the professional training of health care professionals. Federal and provincial funding initiatives have fostered significant growth and development of IPE in post-secondary institutions across Canada. The Canadian Interprofessional Health Collaborative (CIHC) has been established as a network of faculty and other stakeholders with an interest in IPE. The National Health Sciences Students Association (NaHSSA) has been established to foster and promote interest at the student level and to develop future champions.

This submission is intended to discuss the potential for IPE to contribute to improvements in the current approach used by our health and community services system to

manage adverse events. In particular, the submission is intended to highlight the potential for IPE to enhance interprofessional teamwork and other Patient Safety Competencies identified by the Canadian Patient Safety Institute. There is clear evidence that demonstrates that improved interprofessional and intraprofessional communications, information sharing and collaboration can reduce medical error and improve patient safety and patient/health outcomes. IPE has been identified internationally and nationally as a fundamental policy initiative to respond to the increasing demands on health and community services systems and enhance the quality and safety of care through increased coordination, communications, information sharing and collaboration between health and human services providers.

Interprofessional Collaboration

Increased attention through governmental policy and greater societal expectations have increased the need to promote and foster more effective collaborative approaches in the health care system (Commission on the Future of Health Care in Canada, 2002; Health Canada, 2003; Health Council of Canada, 2005; Watson & Wong, 2005). According to Drinka (1996) interprofessional collaboration involves a group of health providers from different professions who engage in planned, interdependent collaboration in the provision of coordinated and integrated care. The Institute of Medicine (2003: p. 54) defines an interprofessional team as "composed of members from different professions and occupations with varied and specialized knowledge, skills, and methods." Interprofessional teamwork involves a process by which "team members integrate their observations, bodies of expertise, and spheres of decision making to coordinate, collaborate, and communicate with one another in order to optimize patient care" (Institute of Medicine, 2003: p. 54).

Interprofessional collaborative approaches are believed to have the potential for: improving professional relationships; increasing efficiency and coordination; increasing patient safety and reducing medical errors; decreasing cost of care; enhancing provider and patient satisfaction; and ultimately enhancing patient and health outcomes (Baldwin, 1996; Cullen, Fraser, & Symonds, 2003; Institute of Medicine, 2003; Reeves & Freeth, 2002; Wee, Hillier, & Coles, 2001).

When health care professionals are expected to work and function collaboratively as part of interprofessional teams, they should be prepared to engage in these activities through their education, clinical training and professional development (Drinka, 2000; Gilbert, 2005). However, health professionals have traditionally been socialized with a strong professional identification to their own respective profession (Horsburgh, Lamdin, & Williamson, 2001; Rogers, 2001). Such socialization is believed to result in very limited knowledge of other professionals on the team. Members of each profession know very little of the practices, expertise, responsibilities, skills, values and theoretical perspectives of other professionals and/or disciplines (Institute of Medicine, 2003; San Martin-Rodriguez, Beaulieu, D'Amour, & Ferrada-Videla, 2005). This is considered to be one of the main obstacles to collaborative practice in health care teams (Fagin, 1992; Mariano, 1999).

Traditionally, health professional students have experienced minimal contact with each other in the process of their education and even less collaborative learning experiences designed to promote interprofessional health care team relationships (Baldwin, 1996). This has largely been exacerbated by the fact that health professional education occurs largely in an environment of separately housed professional schools and separate clinical arenas (Hall & Weaver, 2001). As a result, health professionals are socialized in isolation, hierarchy is fostered, and individual responsibility and decision making are relied upon almost exclusively. A lack of appreciation of the potential contributions of each of the health professions is reinforced by such settings, and more important, students learn little about ways to coordinate and collaborate in providing quality care.

Interprofessional Education

Recent commissions, committees and policy documents in Canada have all identified the importance of reshaping educational preparation and the professional training of health care

professionals (Commission on the Future of Health Care in Canada, 2002; Health Canada, 2003; Health Council of Canada, 2005). The Health Council of Canada (2006) has recommended the need to increase the number of interprofessional education (IPE) and training programs available in Canada, including recommendations that each university health sciences program in Canada offer an IPE program. IPE involves members (or students) of two or more professions associated with health or social care engaged in learning with, from and about each other (Barr et al., 2005). IPE is now widely perceived as a potentially effective method for enhancing collaborative practice between health and social care professionals because it provides opportunities for professionals or those in training to meet and interact, whereas uni-professional education does not. The origin of IPE is widely attributed to a World Health Organization (WHO) report published in 1988 *"Learning Together to Work Together for Health"* (WHO, 1988), which encouraged the development of IPE activities across the world to promote effective teamwork.

IPE initiatives are based on the notion that shared learning can lead to more comprehensive care and treatment for clients (Barr, 1994). There is evidence that IPE can result in more positive perceptions of other professions; increased insights into the work of other professional groups; enhanced interprofessional communication; and greater preparation for interprofessional working (Clark, 1991; Parsell & Bligh, 1999; Parsell, Spalding, & Bligh, 1998; Reeves & Freeth, 2002). The necessary prerequisites for successful IPE have been described as: appropriate faculty development; collaboration with other health care disciplines to develop, implement and evaluate new models of IPE; common goals and clear communication among involved parties; resolution of organizational and structural differences, such as scheduling and timing variations; and commitment of substantial institutional resources (Bulger, 1995; Fagin, 1992; Lindeke et al., 1999; Makaram, 1995; Mariano, 1999; Reeves & Pryce, 1998). Clarke (2004) recommends that sustainability of IPE is largely dependent upon sponsorship by an academic centre whose mission is to develop or sustain IPE (e.g. IPE unit); strong support of the highest university administrators; and key advocates and champions for IPE within the institution.

Interprofessional Education Evidence

According to Cooper et al. (2004) the drive towards IPE has raised questions about its value, about what types of interventions can produce most benefit and about its effects on service users (Wood, 2001). Various reviews and reports have attempted to address these questions (Barr, 1999a; 1999b; 2002; Cooper et al., 2001; Freeth et al., 2002; Zwarenstein et al. 1999; 2000; 2005). The emerging evidence suggests that IPE at the pre-licensure level for both health and social care students can contribute to: raising knowledge of team working and of roles and responsibilities; altering students' attitudes towards each other; and facilitating the acquisition of group working skills. However, the transfer of these effects into professional practice and/or healthcare outcomes is not yet known, primarily because studies have lacked methodological rigour and longitudinal perspectives.

Hammick, Freeth, Koppel, Reeves and Barr (2007) have conducted the most recent, best evidence systematic review of evaluations of IPE. Two approaches were used to locate the studies used in this review. The first included a bibliographic database search (Medline 1966-2003, CINAHL 1982-2001, BEI 1964-2001, ASSIA 1990-2003). The second method included a targeted hand search of journals that were repeatedly publishing high quality IPE evaluations. Studies were considered if they met the following criteria:

- Involved education experiences that included two or more professions learning with, from, and about each other;
- Involved formal IPE experiences (where explicit planning of IPE occurred);
- Involved learners from at least two professional groups in health and social care;
- Discussed outcomes to either service organizations, learners' reactions, changes in learners' skills knowledge or perceptions of and attitudes towards others, and changes in learners' behaviour;
- Were peer reviewed;
- Were published or had an abstract, and were in English or French.

Studies were scored out of five for the quality of the study and the quality of the information provided. Only studies that received at least four out of five on both factors were included in the review. The aim was to enhance the effectiveness of future IPE and maximize the potential for interprofessional learning to contribute to collaborative practice and better care. The initiatives all had the objective of improving care; and enabled learning with, from and about one another. Biggs (1993) 3-P model (presage, process, product) and Kirkpatrick's (1967) four-level model of educational outcomes were adapted as analytical frameworks for the systematic review.

This systematic review brought together evidence from 21 of the strongest contemporary evaluations of IPE. The studies were published between 1981 and 2005, were from North America and Europe, with the majority (15) evaluating IPE delivered to undergraduate health professional students, with each study involving between two and six different professions. IPE has been developed in response to the need to meet new government policies surrounding health care as well as in support of the notion that teamwork training can reduce medical errors.

It was found that students who were more mature and who had more educational experience were more favourably disposed towards IPE, however little evidence has been found on the influence of previous IPE on attitudes towards ensuing IPE activities. Some studies found that reluctance to participate in IPE was often times linked to structural issues such as differences with profession-specific teaching or inequalities in assessment, more so than due to general opposition. A number of studies also identified stereotyping of other professional roles as a factor. One study in particular found that many first year students had entered their professional courses with a stable set of negative stereotypes of other professionals.

Several factors were found to influence the process of interprofessional teaching and learning including facilitation, curriculum design, learner choice, customization and authenticity, reflection, and informal learning. The need for ongoing coaching and mentoring by interprofessional facilitators emerged as a factor to assist learners to develop and maintain their teamwork skills. Curriculum design was also deemed a key factor in the process of IPE. It has been suggested that adults tend to learn best when there is collaboration between the learners and facilitators and when there is mutual respect. With regards to learner choice, a very mixed picture was presented. One study that did measure differences in outcomes between voluntary and mandatory attendance in an IPE course reported no discernable differences between the groups. IPE activities that included simulated patients (SPs) were found to be tremendously useful. Students enjoyed the authenticity of these activities as it provided them with a powerful learning experience. Several studies reported the use of team reflection time as being beneficial

to participants as well. Finally, it was found that social factors (such as time spent together socially) were a key part of the IPE experiences of the learners.

It should be noted that not all changes are for the better, as some studies have found that IPE can in fact worsen attitudes, however for the most part more positive outcomes have been reported. This is particularly true for learners' reactions to IPE and changes in knowledge and skills. The findings showed that IPE is generally well received, enabling knowledge and skills necessary for collaborative working to be learnt. Staff and faculty development is a key influence on the effectiveness of IPE and all learners in IPE bring unique values about themselves and others. IPE that reflects the authenticity of practice is more effective. In quality improvement initiatives IPE is frequently used as an effective way of enhancing practice and improving services. Approximately one third of the studies reviewed in this synthesis described changes in service delivery of patient care.

Competency-based IPE

Competency-based curriculum has become widely accepted in health professional education as a way to define the knowledge, skill and attitudinal outcomes expected of the pre-licensure learner. According to Barr et al. (2005) the need for competency-based outcomes in IPE has been largely based on the *"belief that changing attitudes alone is not enough to prepare practitioners for collaboration in complex situations"* (Barr et al., 2005: p. 84). Experts in the field of competency-based education define "competency" as an integrated set of knowledge, skills, attitudes and judgments that enable one to effectively perform the activities of a given occupation or function to the standards expected in employment (Roegiers, 2000; Scallon, 2004; Tradif, 2006). A competency extends beyond the notion of the learning objective because it is related to a specific context and describes the characteristics a person needs to develop in order to demonstrate effective performance in a given situation or environment. Competencies apply to learners of varying levels of education and experience and should guide growth and development throughout one's working life.

Nearly three decades ago the World Health Organization (WHO) published an important report by McGaghie et al. (1978) entitled "Competency-based Curriculum Development in Medical Education". This document argued that competency-based curriculum was necessary to bring about a better match between education for the health professions and the corresponding needs of our health systems. In recent years there has been a growing emphasis on competency-based education principles in the design and evaluation of health professional education curricula (Davis & Harden, 2003). Competency-based education has been defined as *"an educational system that emphasizes the specification, learning and demonstration of those competencies that are of central importance to a given task, activity or career"* (Alspach, 1996: p. 15). The fundamental characteristics of a competency-based curriculum include: organized around and contributing to the learner's competency development; based on real world performance requirements; derived from and validated by practitioners; structured by competency statements and performance criteria; learner-centred; flexibility in instructional strategies; shared expectations with learners; and opportunities for remedial instruction as necessary. A logical and essential aspect of competency-based education approaches is the assessment of student's achievement of the necessary competencies (Davis & Harden, 2003).

The Canadian Patient Safety Institute (CPSI) has undertaken work to develop a Canadian interprofessional competency-based framework for patient safety through collaborative efforts.

CPSI has partnered with the Royal College of Physicians and Surgeons of Canada in coordinating and facilitating the development of *The Safety Competencies Framework* (Appendix A). The Safety Competencies define seven core domains of abilities for all health professionals to incorporate into their work and identifies the key knowledge, skills and attitudes related to patient safety for institutions and individuals responsible for education and professional development of practitioners in medicine, nursing, pharmacy and the therapy groups (PT, OT, RT). Table 1 summarizes the 7 domains and specifies the content within *"Domain 2: Working as a Team"*.

Table 1 The Safety Competencies Domains (Canadian Patient Safety Institute, 2008)

Domain 1: Creating a Culture of Patient Safety
The ability of health professionals to contribute to healthcare organizations, large or small, in ways that promote patient safety in their structure and function.

Domain 2: Working as a Team
The ability of health professionals to effectively collaborate with others to maximize patient safety and the quality of care. All health professionals need to be able to effectively collaborate interprofessionally and intraprofessionally within their practice context to provide high quality patient-centred care. Content in this domain could include, but is not limited to:

- Awareness of team members, their competencies, roles, expertise, and scope of practice
- Respect and professionalism
- Conflict prevention and management
- Effective handovers, transfers, and care transitions
- Shared authority and decision making, as appropriate
- Team learning, including setting team goals and measuring them
- Continuity of care
- Appropriate and effective consultation
- Team dynamics and authority gradients
- Feedback
- Debriefing / team support
- Readbacks

Domain 3: Communicating Effectively
The ability of health professionals to effectively receive and convey information and facilitate the interpersonal and interorganizational relationships needed to support safe and effective patient care.

Domain 4: Using Safe Strategies to Enhance Practice
The ability of health professionals to incorporate best practices in patient safety into daily activities.

Domain 5: Managing Human Factors and Cognitive Processes
The ability of health professionals to recognize the relationship between human performance and human and cognitive factors that may lead to adverse events.

Domain 6: Managing High-Risk Situations
The ability of health professionals to recognize, mitigate, and avoid common high risk clinical practices.

Domain 7: Responding to an Adverse Event
The ability of health professionals to recognize an adverse event when it occurs and respond effectively to mitigate harm, ensure disclosure and prevent it from happening again.

National (Canadian) Initiatives on IPE

In Canada, the Interprofessional Education for Collaborative Patient-Centred Practice (IECPCP) initiative[1] of Health Canada has funded 20 IPE projects across Canada involving universities and community colleges. The specific objectives of the IECPCP initiative have been to:

- promote and demonstrate the benefits of interprofessional education for collaborative patient-centred practice;
- increase the number of educators prepared to teach from an interprofessional collaborative patient-centred perspective;
- increase the number of health professionals trained for collaborative patient-centred practice before, and after, entry-to-practice;
- stimulate networking and sharing of best educational approaches for collaborative patient-centred practice; and
- facilitate interprofessional collaborative care in both the education and practice settings.

Through this initiative, the Centre for Collaborative Health Professional Education (CCHPE) of Memorial University received $ 1.25 million over three years to undertake an IPE research and development project. This project was developed as part of collaborations involving the Faculties of Medicine and Education, the Schools of Social Work, Nursing and Pharmacy, and Memorial's Counseling Centre. The project activities support the policy direction of the provincial Department of Health and Community Services for greater coordination of health care through team-based, interprofessional collaboration in service provision. This project has expanded and promoted IPE activities in both education and practice settings and enhanced the collaborative patient-centred practice competencies of an increased number of learners and practitioners in Newfoundland and Labrador. The project included the development, implementation and evaluation of IPE programming from the undergraduate to the continuing professional education level. IPE activities at the undergraduate level have been integrated within and across the curriculum of participating academic units. The project has been successful in introducing:

[1] Health Canada. http://www.hc-sc.gc.ca/hcs-sss/hhr-rhs/strateg/interprof/index_e.html

Undergraduate

- *Interprofessional Common Learning Blocks*: Two 4-hour blocks developing collaborative competencies in Health Promotion and Professionalism in Teamwork.
- *Interprofessional Service Learning Project*: One 12 hour interprofessional learning project developing collaborative competencies in providing service to the community.
- *Interprofessional Education Modules*: Six 4 hour modules developing collaborative competencies in patient/client-centred care for a variety of patient populations: Rehabilitative Care; Collaborative Mental Health Practice; Health and Wellbeing of Children; HIV/AIDS; Geriatric Care; Newborn Care.
- *Interprofessional Practice-Based Learning*: Promoting interprofessional learning in practice-based learning settings.

Postgraduate/Continuing Professional Education

- *Interprofessional Collaboration Workshop*: Eight 1 day workshops developing collaborative competencies amongst post-graduate residents and allied health and nursing practitioners across six residency programs and four program areas in Eastern Health.
- *Rural Mental Health Interprofessional Training Program*: 3 day continuing professional education program fostering collaborative mental health practice in primary health care sites.

A complementary project funded through the IECPCP initiative has been the Canadian Interprofessional Health Collaborative (CIHC).[2] CIHC is described as a national hub for IPE, collaboration in healthcare practice and patient-centred care. A main goal of CIHC is to strengthen the knowledge base about IPE and to share this knowledge with those who make policy, planners in the health and education systems, health professionals and educators. As a Canada-wide initiative, the CIHC has also allowed all interprofessional projects across the country funded through Health Canada's IECPCP initiative to have a shared venue for exchanging ideas and promising practices related to IPE, collaborative practice and patient-centred care.

A related group which has emerged within Canada with initial funding support through the IECPCP initiative has been the National Health Sciences Students' Association (NaHSSA).[3] NaHSSA is the first and only national interprofessional student association in the world and seeks to involve Canada's health and human service students in IPE while promoting the attitudes, skills and behaviours necessary to provide collaborative patient-centred care. NaHSSA objectives include:

- promoting interprofessional education for collaborative patient-centred practice;
- facilitating opportunities for interprofessional interaction;
- fostering student champions to lead interprofessional efforts now and in the future.

[2] Canadian Interprofessional Health Collaborative (CIHC). www.cihc.ca
[3] National Health Sciences Students' Association (NaHSSA). http://www.nahssa.ca/index.php?lang_en

The *Accreditation of Interprofessional Health Education (AIPHE)* project, funded by Health Canada, has also brought together a partnership of 8 national organizations that accredit pre-licensure education for 6 Canadian health professions: physiotherapy, occupational therapy, pharmacy, social work, nursing and medicine. The long-term vision of the AIPHE project is that all students in health-related fields will develop the knowledge, attitudes and skills needed for collaborative, patient-centred practice as a result of interprofessional education (IPE) in health professional education programs. The overarching project goals are to develop common principles for the accreditation of IPE in six health professions and to educate a wider audience about the value of IPE.

A number of organizations have subsequently begun to review standards pertaining to accreditation of IPE. The Canadian Association of Schools of Nursing (CASN) has established a Taskforce on Interprofessional Education[4] *"to provide advice and recommendations regarding strategic directions on how CASN can demonstrate leadership in creating a role for nursing education within the context of IPE."* This Taskforce has been mandated by CASN to work collaboratively with other nursing organizations and health professionals to establish a role for nursing in the current initiatives for IPE; develop a position statement on IPE; and identify interprofessional initiatives, either currently in place or planned for implementation, in CASN member schools.

In Ontario, IPE has been identified as a cornerstone of the *HealthForceOntario* strategy[5]; a comprehensive Health Human Resources Strategy to ensure Ontario has the right number and mix of appropriately educated health care providers. In support of IPE, the Province of Ontario established the Interprofessional Health Education Innovation Fund (IHEIF) in 2006-07 to fund IPE in post-secondary institutions. Eight main proposals and seventeen seed proposals received funding. Successful projects provided opportunities to enhance IPE in universities, community colleges and teaching practice sites, to use simulation labs to prepare learners to work in cohesive, collaborative teams and to develop a comprehensive approach to IPE - including modules on interprofessional competencies, clinical placements, assessment tools, faculty courses and preceptorship programs in universities.

In 2007-08, the Ontario government, through the Ministry of Training, Colleges and Universities (MTCU) and the Ministry of Health and Long-term Care (MoHLTC) also established the Interprofessional Care/Education Fund (ICEF).[6] Priority has been given to two types of proposals: new project ideas that support and further interprofessional care and IPE; and proposals that advance the work of projects that received funding from the Interprofessional Leadership, Mentorship, Preceptorship and Coaching Fund or the IHEIF in 2006-07 and will build on, and further support interprofessional care or education.

Barker (2004) also conducted a survey of Canadian initiatives in IPE during the year 2003. One hundred and seventy-seven (177) respondents reported that they knew of an IPE program. Of the 162 respondents who went on to describe the IPE program of which they knew, successful programs were reported in 96.9% of cases. When respondents reported why they described the programs/initiatives as "successful" or not, some respondents highlighted various

[4] CASN. *Taskforce on Interprofessional Education*. http://www.casn.ca/content.php?doc=136
[5] HealthForce Ontario. http://www.healthforceontario.ca/
[6] HealthForceOntario. *Interprofessional Care/Education Fund (ICEF) 2007-08. Program Description/Request of Proposals Document. Ministry of Health and Long-term Care. Ministry of Training, Colleges and Universities.* https://www.healthforceontario.ca/upload/en/whatishfo/icef%202007-08%20program%20description_request%20for%20proposals.pdf

enablers and barriers to the programs, or what features either encouraged or discouraged the success of the programs. These are summarized in Table 2.

Table 2 Enablers and Barriers to Interprofessional Education Programs

Enablers	Barriers
• Sound program logistics & administration • Balanced participation from different professional/discipline groups • Programmatic and financial sponsorship • Organizational support • Critical mass of learners • Participant compensation • Quality improvement paradigm	• Regarded as non-typical experience • Lack of one's own role understanding • Timing (lack of time, scheduling) • Lack of organizational-culture support • Curriculum leaders failed to introduce course material

Respondents to Barker's (2004) survey were also asked to classify where the program took place: 50% specified higher education institution; 10% service setting; and 40% mixed setting (a higher education with service setting links or vice versa). Seventy seven respondents reported the characteristics of learners participating in IPE programs. The professions which were reported as participating the most included: Medicine (74%), Nursing (70.1%), Physiotherapy (50.7%), Occupational Therapy (49.4%) and Pharmacy (45.5%). Respondents were asked to also identify the education levels of the IPE program participants and the majority of programs in post-secondary institutions (80%) included pre-licensure learners. Regarding funding, 71% of respondents stated the educational programs received funding and 73% that ran 3 or more times received funding versus 33% of those programs that ran once or twice. Respondents also indicated that 89.3% of programs were evaluated.

International Initiatives on IPE

United Kingdom (UK)

In the United Kingdom, there is a clearly articulated policy agenda (Department of Health 1998a; 1998b; 1999; 2000a; 2000b) and legislation (e.g. Health Act 1999 and the Health & Social Care Act 2001) that has paved the way for change around IPE (Cooper et al., 2004). The UK's National Health Services Plan (NHS) has called for the development of new common foundation programs for healthcare professionals which would enable students and staff to switch careers and training paths more easily, promote teamwork, partnership and collaboration, skill mix and flexible working, and lead to the development of new types of workers (Cooper et al., 2004). Partly in response to these policy directives there has been a large increase in the UK in the proportion of IPE at the undergraduate level.

The Quality Assurance Agency for Higher Education in the UK has proposed *"subject benchmark statements"* for the health and social care professions.[7] The education and training of certain professions in the UK is governed by subject benchmarks statements which serve to describe the general academic characteristics and standards of programs of study across the UK. These statements also articulate the attributes and capabilities that those possessing such qualifications should be able to demonstrate. Subject benchmark statements are an external source of reference when new programs are being developed and provide general guidance for articulating and evaluating program learning outcomes. The statements result from an extensive consultation process involving appropriate specialists drawn from higher education institutions, subject associations, service commissioners and providers, and the professional and statutory regulatory bodies.

In the UK, cross-professional benchmarks and statements of common purpose have been developed in response to integrated service delivery in the NHS as well as the growth in IPE. The challenge confronting the establishment of such cross-professional statements has been to not subsume one discipline or professional activity into another, but to integrate perspectives in a manner that maximizes the synergies and distinctive contributions of each. Appendix B summarizes the proposed cross-professional subject-specific benchmark statements in health and social care.

United States

In the United States, a number of initiatives related to IPE and academic accreditation have taken place over the years. Historically, recommendations by the Pew Health Professions Commission, the American Association of Colleges of Nursing (AACN), the National League for Nursing (NLN), and the Council on Graduate Medical Education (COGME) have all emphasized the need for IPE to assure that collaboration is enhanced (AACN, 1995; COGME, 1999; O'Neil, 1993; Watson, 1996). Initiatives by the W.K. Kellogg Foundation, the Institute for Healthcare Improvement, and Area Health Education Consortiums have been successful in implementing IPE, primarily in outpatient settings (Headrick et al., 1996; Lough et al., 1996; Zungolo, 1994). Significant initiatives by the National Academies of Practice, Institute of Medicine, American Council on Pharmaceutical Education and the American Association of Colleges of Pharmacy are described.

In 2001 the Institute of Medicine (IOM) published the report *"Crossing the Quality Chasm: A New Health System for the 21st Century"* (Institute of Medicine, 2001). This report concluded that a major overhaul of the health care system in the United States was required and stressed that such a redesigned system should be predicated on interdisciplinary teams. A follow-up IOM report *"Health Professions Education: A Bridge to Quality"* (Institute of Medicine, 2003) identified a new vision for clinical education in the health professions centered on a commitment to, first and foremost, meeting patients' needs:

> *"All health professionals should be educated to deliver patient-centered care as members of an interdisciplinary team emphasizing evidence-based practice,*

[7] The Quality Assurance Agency for Higher Education. *Statement of common purpose for subject benchmark statements for the health and social care professions.* http://www.qaa.ac.uk/academicinfrastructure/benchmark/health/StatementofCommonPurpose06.asp

quality improvement approaches, and informatics." (Institute of Medicine, 2003: p.3, 45, 121)

From this vision, the IOM also identified a set of five core competencies that all clinicians should possess, regardless of their discipline, to meet the needs of the twenty-first century health system. The IOM recommended that these core set of competencies - shared across the professions – should be integrated into health professions oversight processes. Health professions oversight processes, such as accreditation, were viewed as a key leverage point for system wide change. The IOM report recommended that it was imperative to have linkages among accreditation, certification, and licensure as *"it would be pointless if accreditation standards set requirements for educational programs, yet these requirements were not then reinforced through testing on the licensing exam"* (IOM, 2003: p. 7).

According to the IOM (2003) strategies for incorporating the competencies into oversight processes would need to differ across the oversight framework based on history, regulatory approach, and structure. The IOM also recommended the oversight bodies should proceed with extensive consultation on draft language, initial testing of new requirements (e.g. provisional standards), and monitor new requirements to ensure they were useful and not overly burdensome.

A review conducted by the IOM (2003) revealed that accrediting organizations varied in their approach to the recommended core competencies, ranging from assessing such competencies in their standards, to requiring related curricula and education experiences, to encouraging educational institutions to include the competencies. The IOM recommended that any collective movement by the health professions to reform education would need to begin with defining a shared language that would enable the professions to communicate and collaborate with one another.

Licensure was a further oversight process examined by the Institute of Medicine in the 2003 report. In the United States, like in Canada, professional licensure laws are enacted to assure the public that practitioners have met the qualifications and minimum competencies required for practice. Licensing boards evaluate when a health professional's conduct or ability to practice warrants modification, suspension, or revocation of the license. To be licensed, licensees must pass an examination - sometimes national, and in the United States sometimes administered by the state, or both. The committee reviewed national licensure examinations for content related to the five competencies and found only the registered nursing exam had content on interdisciplinary teams.

As a result of the work of the IOM, a number of professional associations in the U.S. have responded. The American Association of Colleges of Pharmacy (AACP) has identified IPE as a key strategic goal. Goal VII of the 2004 AACP Strategic Plan states that AACP will *"provide leadership for the development of inter-professional and multidisciplinary education, research, and patient care opportunities for faculty and students at all colleges and schools of pharmacy."* The AACP Professional Affairs Committee[8] was also tasked with studying and offering recommendations on strategies that could advance the goals to significantly improve IPE and practice. The Committee determined that the ultimate objective for efforts to build IPE

[8] American Association of Colleges of Pharmacy. *Getting to Solutions in Interprofessional Education. Report of the 2006-07 Professional Affairs Committee.* http://www.aacp.org/Docs/AACPFunctions/Governance/8442_GettingtoSolutionsinInterprofessionalEducationfinal.pdf

was to thread meaningful interprofessional coursework and experiences from the earliest opportunity and throughout the course of study with all relevant disciplines. The Committee endorsed the recommendation from the IOM "*Bridge to Quality"* report that urged the accrediting bodies of health professions education programs to coordinate their efforts and revise their standards. The Accreditation Council for Pharmacy Education (ACPE) also responded to the IOM recommendations and included the "Interdisciplinary Team" core competency statement verbatim in the accreditation standards for pharmacy education that will be effective in July 2007 (Accreditation Council for Pharmacy Education, 2006)[9].

Conclusion

The Canadian Patient Safety Institute (CPSI) has undertaken work to develop a Canadian interprofessional competency-based framework for patient safety through collaborative efforts. CPSI has partnered with the Royal College of Physicians and Surgeons of Canada in coordinating and facilitating the development of *The Safety Competencies Framework.* The *Working as a Team* domain specifically describes the ability of health professionals to effectively collaborate with others to maximize patient safety and the quality of care. Traditionally, health professional students have experienced minimal contact with each other in the process of their education and even less collaborative learning experiences designed to promote interprofessional health care team relationships. There is a growing body of literature that demonstrates that when healthcare professionals understand each others' roles and are able to communicate and work effectively together, patients are more likely to receive safe, quality care. Interprofessional education (IPE) involves members (or students) of two or more professions associated with health or social care engaged in learning with, from and about each other. Recent commissions, committees and policy documents in Canada have all identified the importance of reshaping educational preparation and the professional training of health care professionals. There is clear evidence that demonstrates that improved interprofessional and intraprofessional communications, information sharing and collaboration can reduce medical error and improve patient safety and patient/health outcomes. IPE has been identified internationally and nationally as a fundamental policy initiative to respond to the increasing demands on health and community services systems and enhance the quality and safety of care through increased coordination, communications, information sharing and collaboration between health and human services providers.

[9] Accreditation Council for Pharmacy Education. (2006). Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (adopted January 15, 2006). http://acpe-accredit.org/pdf/ACPE_Revised_PharmD_Standards_Adopted_Jan152006.DOC
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Appendix A:

The Safety Competencies
Enhancing Patient Safety Across the Health Professions
Canadian Patient Safety Institute (CPSI)

The Safety Competencies

Enhancing Patient Safety Across the Health Professions

DRAFT Framework, August 2007

Patient safety, defined as the reduction and mitigation of unsafe acts within the healthcare system, as well as through the use of best practices shown to lead to optimal patient outcomes,[1] is a critical aspect of quality healthcare. Increasingly, patient safety issues are being recognized as arising from problems with care systems rather than acts by providers. What is needed is a new structure to guide health professionals to incorporate patient safety into their daily work.

The Safety Competencies provide a framework of 7 core domains of abilities for all health professionals to incorporate into their work. By enhancing health professions education, The Safety Competencies will enhance patient care.

Domain 1: Creating a Culture of Patient Safety
The ability of health professionals to contribute to healthcare organizations, large or small, in ways that promote patient safety in their structure and function.

A patient safety culture is an essential ingredient to effectively implementing safer care. All health professionals require some expertise in contributing to such environments in the organizations in which they work. These organizations can be large or small, physical or virtual, but all can benefit from an effective safety culture. Content in this domain could include, but is not limited to:

- Understanding of patient safety concepts, epidemiology, and basic theories
- Awareness of healthcare error
- Promote systems approach to care and safety
- Promote staff empowerment to resolve unsafe situations
- Role model and demonstrate a commitment to leadership in safety
- Ensure feedback on safety issues
- Integration of safety practices into daily activities
- Commitment to communication, teamwork, and quality
- Adverse Event reporting

[1] Davies, J., Hebért, P. & Hoffman, C. 2003. Canadian Patient Safety Dictionary. Royal College of Physicians and Surgeons of Canada. p.11.

- Commitment to just, non-punitive, culture
- Appropriate professional accountability
- Commitment to continuous learning and improvement
- Patient advocacy
- Commitment to best practices
- Engagement of all stakeholders in safety
- Promote non-punitive approaches to recognizing error
- Participate in patient safety education
- Promotion of self assessment and reflection on practice outcomes

Domain 2: Working as a Team
The ability of health professionals to effectively collaborate with others to maximize patient safety and the quality of care.

All health professionals need to be able to effectively collaborate interprofessionally and intraprofessionally within their practice context to provide high quality patient-centred care. Content in this domain could include, but is not limited to:

- Awareness of team members, their competencies, roles, expertise, and scope of practice
- Respect and professionalism
- Conflict prevention and management
- Effective handovers, transfers, and care transitions
- Shared authority and decision making, as appropriate
- Team learning, including setting team goals and measuring them
- Continuity of care
- Appropriate and effective consultation
- Team dynamics and authority gradients
- Feedback
- Debriefing / team support
- Readbacks

Domain 3: Communicating Effectively
The ability of health professionals to effectively receive and convey information and facilitate the interpersonal and interorganizational relationships needed to support safe and effective patient care.

Effective communication is critical to many aspects of patient safety. Content in this domain could include, but is not limited to:

- Effective use of communication tools (e.g. “SBAR”) and technologies
- Informed consent and discharge
- Disclosure, reporting, and informing about adverse events
- Cultural competency
- Health literacy
- Describing risk
- Effective written and verbal communication regarding patient care
- Effective organizational communication systems

Domain 4: Using Safe Strategies to Enhance Practice
The ability of health professionals to incorporate best practices in patient safety into daily activities.

Safe practices have been identified and adapted from multiple domains of human endeavor to enhance patient care. Health professionals need to be able to incorporate those that are suited to their area of clinical activities and the organizational systems in which they work. Content in this domain could include, but is not limited to:

- Hand hygiene
- Sound alike medications
- Medication reconciliation
- Proper medication preparation
- Proper patient identification
- Sterile technique
- Standard infection control and prevention precautions
- Equipment maintenance and proper placement
- Equipment assessment and training
- Checklists
- Adoption of practice guidelines
- Safe patient transport, handling, and transfers
- Injury prevention
- Removing physical hazards
- Patient monitoring
- Readbacks

Domain 5: Managing Human Factors and Cognitive Processes
The ability of health professionals to recognize the relationship between human performance and human and cognitive factors that may lead to adverse events.

Inherent in this domain is an essential understanding of the concept of human factors, clinical decision-making and cognitive processes. While all human beings can make mistakes, all health professionals need the ability to recognize, prevent, and mitigate the human aspects of error. Content in this domain could include, but is not limited to:

- Fatigue
- Shiftwork
- Stress and burnout
- Memory
- Hazardous attitudes
- Authority gradients
- Critical thinking
- Self-awareness and limits of expertise
- Awareness of scopes of practice
- Cognitive biases
- Clinician health and well-being
- Environmental impact on health professionals and their work
- Effective ergonomics and appropriate design of equipment, space, and environments

- Types of errors (e.g. Procedural, affective, cognitive)
- Human factors engineering
- Interaction of humans with systems, designs and technology

Domain 6: Managing High-Risk Situations
The ability of health professionals to recognize, mitigate, and avoid common high risk clinical practices.

Researchers have identified some recurring, high-risk situations in patient care. Nosocomial infections and use of blood thinners are examples. Health professionals need to be able to recognize high risk situations and respond appropriately to prevent harm. Content in this domain could include, but is not limited to:

- Safe medication systems
- Blood products management
- Control of concentrated electrolytes
- Proper use of compressed medical gases
- Infection control strategies
- Effective emergency responses
- Prevention of falls, infections, and pressure ulcers
- Safe invasive procedures
- Protective devices and clothing
- Policies to incorporate new technology

Domain 7: Responding to an Adverse Event
The ability of health professionals to recognize an adverse event when it occurs and respond effectively to mitigate harm, ensure disclosure and prevent it from happening again.

All health professionals have a duty to recognize errors and adverse events, in their various forms, as they occur in their setting. They also have a duty to disclose adverse events and report events appropriately. Health professionals need to have the abilities needed to mitigate the impact of such events and prevent them from recurring. This requires an understanding of common causes of adverse events as well as near misses in systems of healthcare. This domain content could include, but is not limited to:

- Identification of adverse events
- Event analysis and response
- Adverse event/error reporting systems
- Incident analysis (e.g. Root cause analysis)
- Systems thinking
- Critical incident debriefing
- Commitment to continuous improvement
- Adaptability
- Hazard analysis
- Care of patients, families, and health professionals after an adverse event
- Communicating with media
- Disclosure
- Reporting of events including internal and external reporting structures

Appendix B:

Statement of Common Purpose for Subject Benchmark Statements for the Health and Social Care Professions

Statement of Common Purpose for Subject Benchmark Statements for the Health and Social Care Professions

1.1.1 Introduction

This new statement of common purpose builds on and replaces the emerging framework and, like the emerging framework, is designed to be associated with subject-specific benchmark statements in health and social care. It is set out under three main headings:

1 Values in health and social care practice

2 The practice of health and social care

3 Knowledge and understanding for health and social care practice.

The statement places the focus of students' learning on meeting the needs of clients and patients within an environment that requires effective team, interprofessional and inter-agency working and communication, as well as expert care. Its aims to encourage shared learning by students from a range of health and social care disciplines, both in practice and in classroom-based activities. Higher education institutions, in partnership with service providers, will make informed curriculum choices about the construction of shared learning experiences which promote improved collaborative practice and this statement is an important consideration in making those choices. It should not, however, be regarded as a national curriculum for shared learning in health and social care.

1.1.2 1 Values in health and social care practice

Health and social care professionals are personally accountable for their actions and must be able to explain and justify their decisions. They work in many different settings and practices and have to make difficult decisions about complex human situations which require the application of ethical principles. They seek to improve the quality of life for their patients and clients. All hold a duty to protect and promote the needs of their clients and patients and, in so doing, take into account any associated risks for the public.

1.1 Respect for clients' and patients' rights, individuality, dignity and privacy

Health and social care staff should:

- be open and honest with their clients and patients
- listen to clients and patients
- keep information about clients and patients confidential within the limits of duty of care
- ensure that their own beliefs do not prejudice the care of their clients and patients
- recognise and value cultural and social diversity
- ensure individualised care and treatment to combat discrimination and social exclusion.

1.2 Clients' and patients' right to be involved in decisions about their health and social care

Health and social care staff should:

- provide information about clients' and patients' health and social care options in a manner in which the clients and patients can understand
- gain appropriate consent before giving care and treatment
- enable clients and patients to make informed choices about care, including cases where those choices may result in adverse outcomes for the individual
- provide clients and patients with proper access to their health and social care records.

1.3 Justify public trust and confidence

Health and social care staff should:

- be honest and trustworthy at all times
- act with integrity and never abuse their professional standing
- never ask for or accept any inducement, gift, hospitality or referral which may affect, or be considered to affect, their professional judgement
- always declare any personal interests to those who may be affected.

1.4 High standards of practice

Health and social care staff should:

- recognise and work within the limits of their knowledge, skills and experience
- maintain and improve their professional knowledge, skills and performance
- be committed to enhancing standards of practice in health and social care
- make prompt, relevant, clear, legible and proper records
- must deliver the highest standards of integrity and competence.

1.5 Protection from risk of harm

Health and social care staff should:

- act properly to protect clients, patients, the public and colleagues from the risk of harm
- ensure that their own or their colleagues' health, conduct or performance does not place clients and patients at risk
- protect clients and patients from risks of infection or other dangers in the environment.

1.6 Cooperation and collaboration with colleagues

Health and social care staff should:

- respect and encourage the skills and contributions which colleagues in both their own profession and other professions bring to the care of clients and patients

- within their work environment, support colleagues to develop their professional knowledge, skills and performance
- not require colleagues to take on responsibilities that are beyond their level of knowledge, skills and experience.

1.7 Education

Health and social care staff should, where appropriate:

- contribute to the education of students, colleagues, clients and patients, and the wider public
- develop skills of responsible and proper supervision.

1.1.3 2 The practice of health and social care

Health and social care are applied academic subjects, where practice is underpinned by theoretical learning. In their practice, health and social care professionals draw from the values, knowledge and skills of their own discipline. This knowledge and understanding forms the basis for making decisions and judgements in a variety of contexts, often against a backdrop of uncertainty. Partnership working is essential to promote the wellbeing of individuals, groups and communities. Professional practice is essentially a process of problem solving. It can be characterised by four major phases:

- the identification and assessment of health and social care needs in the context of individual interaction with their environment
- the development of focussed intervention to meet these needs
- implementation of these plans
- critical evaluation of the impact of professional and service interventions on patients and clients.

2.1 Identification and assessment of health and social care needs

Health and social care staff should be able to:

- obtain relevant information from a wide range of sources, using a variety of appropriate assessment methods
- adopt systematic approaches to evaluating information collected
- communicate their evaluations effectively to their clients, patients and other members of the health and social care team.

2.2 The development of plans to meet health and social care needs

Health and social care staff should be able to use knowledge, understanding and experience to:

- work with clients and patients to consider the range of activities that are appropriate
- plan care, and do so holistically

- record judgements and decisions clearly.

2.3 Implementation of health and social care plans

Health and social care staff should be able to:

- conduct appropriate activities skilfully and in accordance with good practice
- assign priorities to the work to be done effectively
- maintain accurate records
- use opportunities provided by practice to educate others.

2.4 Evaluation of the health and social care plans implemented

Health and social care staff should be able to:

- assess and document the outcomes of their practice
- involve clients and patients in assessing the effectiveness of the care given
- learn from their practice to improve the care given in the particular case
- learn from the experience to improve their future practice
- participate in audit and other quality assurance procedures to contribute to effective risk management and good clinical governance
- use the outcomes of evaluation to develop health and social care policy and practice.

2.5 Communication

Health and social care staff should be able to:

- make active, effective and purposeful contact with individuals and organisations utilising appropriate means such as verbal, paper-based and electronic communication
- build and sustain relationships with individuals, groups and organisations
- work with others to effect positive change and deliver professional and service accountability.

1.1.4 3 Knowledge and understanding for health and social care practice

The education and training of health and social care professionals draws from a range of academic disciplines which provide the underpinning knowledge and understanding for sound practice. Each profession has an identifiable body of knowledge and will draw from this as appropriate. However, there are areas of knowledge and understanding that are common to all health and social care professionals, which include;

- ethical principles, values and moral concepts inherent in health and social care practice
- legislation and professional and statutory codes of conduct relevant to their practice, and understanding of health and social care delivery configurations
- research and evidence-based concepts and explanations from law, psychology, social policy and sociology

- physical and psychological human growth and development.

In addition, and to an extent determined by the nature of their practice, health and social professionals will be familiar with:

- the structure, function and dysfunction of the human body
- public health principles
- health education in their practice.

1.2 Annex A - List of NHS benchmark statements

Arts therapy
Audiology
Clinical psychology
Clinical sciences
Dental care professions
Dietetics
Health visiting
Midwifery
Nursing
Occupational therapy
Operating department practice
Orthoptics
Paramedic science
Physiotherapy
Podiatry
Prosthetics and orthotics
Radiography
Speech and language therapy

Submitted by

Clinidata

a division of Sykes Assistance Services Corporation Providers
of the Newfoundland and Labrador HealthLine

Submission

Task Force on Adverse Health Events

Government of Newfoundland and Labrador

Submitted by
Clinidata a division of Sykes Assistance Services Corporation
Providers of the Newfoundland and Labrador HealthLine
June 13, 2008

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Introduction

7.5% of patients admitted to acute care hospitals in Canada in the fiscal year 2000 experienced 1 or more Adverse Events. 36.5% of these patients were found to have highly preventable adverse events.[1]

In their study published in the Journal of the Canadian Medical Association in May of 2004 Ross Baker, Peter Norton and colleagues state that;

Efforts to make patient care safer will require leadership to encourage the reporting of AEs, continued monitoring of the incidence of these events, the judicious application of new technologies and improved communication and coordination among caregivers.2

At Clinidata we commend the Government of Newfoundland and Labrador for taking the necessary steps to answer the call of the Canadian Patient Safety Institute to look systemically at the management of adverse events and thereby create real systemic change which will lead to improved care for the citizens of Newfoundland and Labrador.

Founded in 1987, Clinidata has been a significant player in the Canadian health environment for over 20 years. During its first eight years, Clinidata focused all its energy on developing an electronic medical record (EMR) for primary care physician's offices, which integrated clinical record, scheduling, billing and a pharmaceutical support database. A second product, a self-directed medical continuing education program was built in partnership with the Canadian College of Family Physicians. In 1996 Clinidata participated in a landmark study called the Medical Office of the 21st Century (MOXXI) which demonstrated the role of the EMR in the prevention of adverse events in the elderly population.

In January 1997, Clinidata opened its first telehealth centre in Moncton, New Brunswick, where it has provided Telecare services on behalf of the New Brunswick Department of Health ever since. Since 1997 we have provided symptom management and health system referral services to over 9 million Canadians. Clinidata has grown from its New Brunswick roots to provide telehealth services for residents of New Brunswick, Ontario, The Northwest Territories, British Columbia, members of the Canadian Forces and since September 2006 the citizens of the province of Newfoundland and Labrador. The

[1] G. Ross Baker, Peter G. Norton et al JAMC • 25 MAI 2004; 170 (11)
[2] ibid

company also provides Canada-wide services to employees and participants in programs sponsored by Employee Assistance Programs and Canadian pharmaceutical companies.

At the current time, Clinidata is Canada's leading provider of patient-centred telehealth advisory and nursing triage services. It is generally recognized within the Telehealth Industry in Canada that Clinidata has set the benchmark for effective and efficient telehealth service delivery.

With over 450 professional nurses on staff, Clinidata is one of North America's largest telehealth companies. Nurses help patients choose the most appropriate source of care, using clinical guidelines that have been reviewed and approved by a multidisciplinary team of Canadian healthcare experts including Dr. ken Jenkins the VP of Medical Services for the Western Health Region in Newfoundland and Labrador. . Clinidata's telehealth services are continually monitored and improved through an innovative Quality Services program that measures outcomes and ensures compliance with established clinical protocols.

The Newfoundland and Labrador HealthLine has been in operation from three sites in St Anthony, Stephenville and Corner Brook since September 2006. In the year ending May 30th 2008 the service managed over 48,000 calls from across the province.

At the present time the nurses do not capture the aetiology responsible for the symptom or problem leading to the call to the service. While a broad descriptive history is taken to support the nurse's assessment which might include a recent experience with the health system or the use of a particular medication, the nature of the triage service to date does not include creating a link between cause and effect. The role of the triage nurse is to provide the best advice possible based on the symptom acuity being presented. This might include advice regarding self care, a potential visit to a family physician or in the most acute cases a visit to the emergency department or a transfer to an ambulance service dispatcher.

The team at the HealthLine believes strongly that we could have a significant role to play in the transformation of the Newfoundland and Labrador healthcare system including the creation of a system wide culture of safety.

Managing Adverse Events at the HealthLine

Clinidata's quality program incorporates the concepts of risk management, utilization management and quality improvement. Clinidata's Quality Services framework is supported by individual provincial and national legislative acts that provide the building blocks for policy and process development. Our philosophy regarding quality and risk management is that every staff member has an obligation to ensure that services are provided to clients with the highest quality possible and in such a way as to consistently meet established standards.

Processes that have been developed and used by Clinidata include recording, investigating and reporting of unusual incidents.

On a monthly basis, the we review and monitor an extensive list of quality elements (see Appendix A). Seven major quality categories are addressed: safety, staff competence, acceptability, accessibility, efficiency, appropriateness and effectiveness.

We also believe that quality and safety must encompass those elements which impact the staff operating the service as well as the usual practices to protect clients of the service. Without providing a safe environment for staff it would be impossible to ensure quality programming for the users of the HealthLine.

The Clinidata team has developed a database and system to record comments /concerns /complaints of callers. All staff are expected to receive complaints of any nature in a respectful manner and to gather all information possible from the caller so that a comprehensive investigation can be initiated as soon as possible.

The process of investigating a complaint from a caller has numerous steps and involves a number of staff. The Manager of Quality Services is responsible to ensure that all complaints are properly and fully investigated. In the case of a complaint, the staff member involved is interviewed; relevant polices are reviewed and the caller's chart is audited. The person who complained is contacted and provided with a preliminary report within one working day and is given a final report within ten days which details any corrective actions taken.

All unusual occurrences are investigated immediately and brought to the attention of the Manager of Quality Services within one working day. One hundred percent of complaints from healthcare professionals are responded to verbally within three working days to indicate receipt of the concern and within ten working days to provide written results of the investigation and any follow up actions initiated.

An example of a complaint is customer service issues. These are not frequent complaints; however, Clinidata has received occasional calls from users of the service that were dissatisfied with a PAR or nurse's response. A quality issue (QI) report is generated and forwarded to the staff's supervisor. The appropriate follow up is done, which may include additional coaching sessions related to verbal communication and customer service. The supervisor also follows up with the caller once the QI has been investigated.

In the following sections we will identify areas where we believe the HealthLine could support the development of a culture of safety within the Newfoundland and Labrador healthcare system.

Identifying Adverse Events

As noted in the section above the majority of adverse events and complaints are the result of a contact by a caller or a healthcare provider. When the call is received either by a registered nurse or a patient assistant representative (PAR) either staff member can complete a quality issue (QI) within the electronic decisions support application used by the service. This QI is then transmitted to the quality team to initiate the quality review process as described in Appendix A. In addition to issues identified by third parties any staff member can submit a QI for a quality or risk issue that they identify while working for the HealthLine service. Nurses can also submit a Clinical Comment form to identify any area within their practice that they believe might lead to a quality or risk management problem. These Clinical Comment forms are shared with the Quality and Clinical practice teams for review with our Medical Advisors and in some cases directly with the authors of the Clinical guidelines used to support the service.

Potential HealthLine Interventions

There has been much discussion regarding the creation of a "blame-free" quality, risk management or patient safety program. At Clinidata we have adopted the notion of a "Just and Fair" system which supports an open quality review process while acknowledging that members of the healthcare system must have accountability for their actions. In many jurisdictions hospitals and other providers have implemented sophisticated paper based or even electronic adverse event monitoring systems. The paper based system can be very difficult to manage due to the sheer number of reporting requirements. The electronic versions often need significant customization and an almost full time person to manage reporting and evaluation of the effectiveness of the application.

There are several areas where the HealthLine could help in the identification of adverse events.

Post Discharge Follow Up

One of the ways to prevent and or monitor adverse events and complaints is to check in with patients after they have had an interaction with the health system. Many patients do not have the best experience through the discharge process and may not adhere to suggested therapies or self care activities. This can lead to complications, unplanned visits to their physician, the emergency department or even readmission to hospital. The HealthLine could be used to perform systematic surveys of patients who have been discharged from care. The nurses could also coach patients regarding their ability and or willingness to follow discharge plans. The surveys would capture possible adverse events such as reactions to medications or surgical wound infections. This systematic approach

would ensure that all patients were tracked and given the opportunity to provide data to support an early clinical intervention and or review process.

Patient and Family Information/ Adverse Event and Reporting Line

Accreditation Canada (formerly CCHSA) has identified client feedback and response to complaints as a key deliverable for the accreditation process. Many institutions have implemented a complaint line as a part of their quality assurance programs. The HealthLine could be used as a province wide mechanism to capture client complaints and adverse events. This would ensure standardization across the province as well as remove any perception of conflict of interest from individual institutions. The Department could use the data to support a patient safety and satisfaction report card or as a tool to support the mandate of the NL Health Quality Council.

Whistle Blower / Adverse Events Reporting Line for Employees

Once a system wide culture of safety and quality has been created there would be no need for a "third way" to report on adverse events. However, given the existing healthcare culture across North America many institutions have created whistle blower policies for such things as patient privacy and safety concerns. To implement such a policy the Quality Council or the Department could use the HealthLine as a confidential, risk free mechanism for health system employees or stakeholders to report adverse events when they were concerned about the repercussions if they used the normal process to do so. This program would enhance the credibility of the normal reporting system in the eyes of the public.

Assessing Adverse Events

A discussion regarding the methods used by Clinidata to assess adverse events can be found in Appendix A. The HealthLine team would be pleased to share its experience from ten years of practice in this area as well as benefit from the outcomes from the task force. We are particularly interested in any tools that could be implemented to support root cause analysis (RCA).

Disclosing Adverse Events

At Clinidata we support the concept that the provider involved in an incident when possible should be involved in the disclosure of the adverse event to key stakeholders and especially the patient and their family. One of the issues faced by lay people is in understanding the technical nature of this information. For a patient and their family this can mean unnecessary anxiety regarding the severity of the incident or poor compliance

with proscribed interventions if they do not understand the actual severity of the event that occurred.

HealthLine Clinical Interpretation Service

As mentioned above many patients have trouble understanding the information that is provided to them by healthcare professionals. Evidence suggests that this can be due to the stress that they face when communicating with their doctor, their concerns about not embarrassing themselves by identifying poor health literacy or due to the variability in the communication skills of their provider. One of the key roles that our nurses could play would be to help patients and their families interpret the information that is provided to them by the health system.

In a recent health system issue in the Province of New Brunswick, Clinidata was asked to implement an information line to support callers who were concerned about pathology services provided by one of the province's regional health authorities. In that instance the Tele-Care team worked with various stakeholders to develop scripts which could be used to support callers. A special purpose toll free line was advertised so that people could call at any time to speak to a registered nurse about their concerns. Callers, who were sometimes patients who had been affected by the issue, were given information about the re-evaluation process as well as instructions regarding who to contact at the RHA for further information. This allowed the region and the Department of Health to provide anxiety reducing information to those affected as well as ensuring that the message provided was accurate and standardized across all callers.

Acting on Adverse Events

One of the biggest issues facing patient safety advocates is their ability to disseminate learning from analysis of sentinel or adverse events. Most institutions have a capacity to perform review of an adverse event and to make a recommendation. One of the key problems of the process is that even within the same institution there is no guarantee that recommendations will be disseminated to everyone who might benefit. In the case of a province wide health system there is a very good chance that informal communications processes are relied on to share the results or experience from one setting to another. As it exists today the HealthLine does not have an existing service which would aid in this dissemination. The Canadian Patient Safety Institute, the US based Institute for Healthcare Improvement, and organizations like the US Veterans Health Administration's National Centre for Patient safety have all developed tools to aid in dissemination. Clinidata would recommend a provincial patient safety web site developed under the mandate of the proposed Health Quality Council which would be a repository of anonymized recommendations from quality review processes such as Root Cause Analysis (RCA) or Failure Mode Effects Analysis (FMEA). Clinidata would be pleased to contribute to this project as well as use the results to help disseminate the evidence to providers and consumers alike.

Communicating

The Newfoundland and Labrador HealthLine operates in a high availability redundant 24/7 environment. It is supported by registered nurses and patient assistant representatives who would be available to support the communication goals of the Province. Through the advent of technology such as voice recognition and response the service could support the wide spread dissemination of critical time sensitive alerts. During the SARS crisis in 2003 Clinidata's Telehealth Ontario call volume jumped from an average of 3500 calls per day to a one day spike of 13,000 calls. During that day the service also delivered 1700 automated voice recordings of information on the public health emergency. These automated messages can be created and launched within a matter of hours and have proven to be very effective way to provide "information only" services to large populations.

Evaluation

As mentioned in section one above the HealthLine has the capability to rapidly survey large populations of people for opinions and experiences within the health system. The service could be used to review the implementation of policy based standards for quality processes, to check on the implementation of disclosure policy and finally to gauge the attitudes, opinions and knowledge of providers and health system stakeholders with regards to the implementation of a culture of safety within the Newfoundland and Labrador healthcare system.

Summary and Conclusion

The Task Force on Adverse Health Events is a very important step along the road to creating a culture of safety and guaranteeing a feeling of confidence in the Newfoundland and Labrador healthcare system. As the providers of the NL HealthLine Clinidata and the entire Sykes organization is please to participate in the process. We trust that the information provided in this document will be of use to the task force team and could provide some food for thought. In closing we would be very pleased to help in any way that we can. If you would like any clarification of information provided in this brief document please contact Marlene Penney RN, Director of Client Relations, Province of Newfoundland and Labrador at (709) 454-4133 (mpenney@clinidata.com) or Dr. ken Jenkins, Medical Advisor NL HealthLine at (709) 637-5000 ext. 5168 (kenjenkins@westernhealth.nl.ca)

Appendix A

Corporate Quality Services Program Policy (Excerpt)

Objective

To monitor, measure, and evaluate clinical and operational variances and outcomes to deliver quality telehealth services that meet or exceed established benchmarks. To utilize concepts of risk management, utilization management, and quality improvement to ensure patient safety and staff compliance to clinical and service standards.

QUALITY DIMENSION	QUALITY INDICATOR	QUALITY STANDARDS	QUALITY MEASUREMENTS	PRIME RESPONSIBILITY OF
Acceptability	Patient Satisfaction and Compliance	Patient satisfaction surveys are completed on a daily basis by telephone. Patients or callers are asked to comment on service elements such as communication and customer service skills of the nurse or receptionist, compliance with the nurse's instructions, reason for non-compliance, wait time to have call answered or receive call back and suitability of the information provided.	Patient satisfaction and compliance will be greater than 95%	Manager of Quality Services VP of Operations/Clinical Services Manager
Acceptability	Patient Satisfaction and Compliance	All caller/patient complaints are documented in the Complaint Module.	All caller/patient complaints will be followed up within 1 working day to indicate receipt of the concern and within 7 working days to provide results of the investigation. All high-risk incidences will be investigated immediately and brought to the attention of the Manager of Quality	Manager of Quality Services VP of Operations/Clinical Services Manager

QUALITY DIMENSION	QUALITY INDICATOR	QUALITY STANDARDS	QUALITY MEASUREMENTS	PRIME RESPONSIBILITY OF
			Services within 1 working day.	
Acceptability	Client Satisfaction	Corporate Feedback Surveys request feedback from the clients who fund the services provided to callers. Categories include client relationship issues, reporting and communications issues and providing valued advice issues.	Greater than 90 % of respondents fall in the “raving fan” category. Areas of dissatisfaction are addressed with the client within one working day.	Manager of Quality Services VP Operations
Acceptability		Health Care Professional Feedback forms are available at major health facilities for staff to report any concern they have related to the HealthLine, Telehealth Ontario, THAS or the New Brunswick Call Centre. The Medical Advisors review all comments received from physicians and the Quality Services Manager considers all comments from nurses and other professionals. Investigation includes considering the appropriateness of the clinical guidelines, responds to the person who initiated the enquiry and corrective action is taken.	100% of complaints from healthcare professionals will be responded to verbally within 3 working days to indicate receipt of the concern and within 10 working days to provide written results of the investigation and follow up.	Medical Advisors, Manager of Quality Services VP of Operations Director of Client Relations
Acceptability	Cooperative Planning	Staff will elect representatives to serve on the Corporate and Site Quality Services Committees as well as the Corporate Clinical Advisory, Clinical Practice, Human	100% of staff positions will be filled at all times. Thirty days (30) will be allotted for replacements.	Manager of Quality Services VP of Operations

QUALITY DIMENSION	QUALITY INDICATOR	QUALITY STANDARDS	QUALITY MEASUREMENTS	PRIME RESPONSIBILITY OF
		Resources, and Information Services Committees. Staff will participate on external telehealth boards and committees.	Clinidata will have a minimum of 4 members participating on telehealth boards or committees and 4 members actively involved with professional nursing organizations.	Clinical Services Manager
Accessibility	Language of Choice	Callers receive service in the language of their choice.	100% of callers will be served in the language of their choice.	VP of Operations
Efficiency	Wait Times	The average time for a call back from a nurse is 30 minutes or less. The actual average time per month is compared to the standard time. If the standard is not being met, corrective action is initiated.	90 % of callbacks are completed within 30 minutes or a minimum of 3 attempts within 2 hours	VP of Operations Clinical Services Manager Senior Nurse
Staff Competence	Position Description	There is a position description for each category of staff. The position descriptions for clinical staff include sections on clinical, education, professional and other responsibilities.	The Corporate Operations Committee will review the position descriptions for each staff member on an annual basis.	Director of Human Resources
Staff Competence	Hiring Criteria	Qualifications of staff reflect the HMCC industry norm which includes appropriate recent Acute Care nursing experience and good previous work record. The interview reflects the nurse's understanding of the	A profile of the education and experience of each staff member is maintained in a Human Resources file.	Human Resources

QUALITY DIMENSION	QUALITY INDICATOR	QUALITY STANDARDS	QUALITY MEASUREMENTS	PRIME RESPONSIBILITY OF
		triage process and demonstration of basic computer skills.		
Staff Competence	Credentials	Clinidata employs nurses in good standing, currently registered with the appropriate provincial nursing body.	Nurses must provide proof of registration to the CTM. A photocopy of the nurse's registration is kept in their Human Resources file.	Human Resources
Staff Competence	Orientation	All nurses receive 3-4 weeks of structured orientation prior to answering telephone triage calls. Additional orientation is provided if recommended by the preceptor, Staff Educator and/or the Staff Development Manager. Staff returning from an extended leave of absence will be provided with additional orientation as needed.	A checklist of all orientation activities is completed during each day of the orientation period. The checklist and a preceptor's report of the nurse's performance during the orientation is reviewed by the Staff Development Manager and then placed in the HR file.	Staff Development Manager Staff Educators Clinical Services Manager Human Resources
Staff Competence	Coaching	**Nurse Associate:** FT Probationary **(**up to 3 months) PT Probationary (up to 6 month)	The CTM will complete: 10 direct call/chart audits + 2 taped call/chart audits in the first 12 shifts following preceptorship. There will be 3	Clinical Services Manager Clinical Team Lead

QUALITY DIMENSION	QUALITY INDICATOR	QUALITY STANDARDS	QUALITY MEASUREMENTS	PRIME RESPONSIBILITY OF
			per month for the remainder of the probationary period.	(CTM)
		Ongoing coaching for FT & PT NAs	The CTM will complete 3 call/chart (direct or taped) audits per month. The CTM will use the Call/Chart Audit Form and Mastery Program frontline tactics as coaching tools.	
Staff Competence	Continuing Education	A staff educator or delegate will develop one case study/month that incorporates at least 2 of clinical, quality, policy and customer service issues.	All CTMs will complete 12 case studies/year. The Site Educator will review these. All nurses will complete 12 case studies/year. The team Senior Nurse will review these.	Clinical Services Manager CTM Staff Educator
		A minimum of 2 education sessions will be offered at each site per month. Education sessions will be based on the staff's learning needs. Internal and external clinicians will provide these formal and informal presentations.	All staff will attend a minimum of 2 new sessions/year or as requested by the education department. Each site Educator will maintain a record of attendance.	Staff Development Manager Site Educators
		A minimum of 10% of staff/site/year will be selected to attend appropriate conferences, teleconferences, and workshops.	Staff attending a conference or workshop will be expected to give a formal presentation to other staff based on their learning objectives.	Staff Development Manager Site Educators

QUALITY DIMENSION	QUALITY INDICATOR	QUALITY STANDARDS	QUALITY MEASUREMENTS	PRIME RESPONSIBILITY OF
		Administration and support staff (excluding NAs and PARs) will complete 4 hours of continuing education/ month	100% of staff will meet this standard.	
Appropriateness	Clinical Guidelines	Only clinical guidelines approved by the Medical Advisory and Clinical Advisory Committees will be used for clinical practice. Clinical guidelines will be reviewed with each new version release from the software vendor, annually, or as required	New guidelines will be updated within 25 working days of receiving the new version from the authors. If a modification is recommended by Clinidata's Medical and Clinical Advisory Committees, the database will be updated within 2 working days and immediately if the modification has a patient safety risk. In clinical situations where a high risk Quality Issue report is generated, the Clinical Practice Consultant will convene a meeting of the Clinical Advisory Committee within 2 working days.	Clinical Advisory Committee Medical Advisory Committee Clinical Practice Consultant
Appropriateness Effectiveness	Clinical Appraisal	Call/Chart audits are completed by members of the site Quality Services Committee to determine if there are variances in guideline dispositions based on a specific disposition statement within a protocol. Discrepancies are noted and strategies are implemented by the committee to resolve the issue if possible or suggestions are brought to other clinical committees for review.	A 5% variance in disposition may occur based on the nurse's clinical judgement. A minimum of 15 call/charts will be audited per site/month. A minimum of 0.1% of calls will be monitored remotely. Compliance of call process and documentation will be greater than 95%.	Manager of Quality Services VP of Operations Clinical Services Manager

QUALITY DIMENSION	QUALITY INDICATOR	QUALITY STANDARDS	QUALITY MEASUREMENTS	PRIME RESPONSIBILITY OF
Effectiveness	Outcome Surveys	1% of callers registered by site will be surveyed within 48 hours to determine their compliance with the nurse's recommendations.	95% of callers will comply with the nurse's recommendation	Manager of Quality Services
Safety	Health and Safety	Workstations and chairs are especially designed for Call Centre use. Adequate lighting and ventilation is available.	Incidents of Staff Absence due to ergonomic origin such as muscle fatigue, lower back pain, and wrist pain will be 1 incident or less in NL / New Brunswick per month and 5 incidents or less in Ontario per month	Human Resources
		Occupational Health and Safety Guidelines for New Brunswick and Ontario are followed. A fire and evacuation plan is developed for each site and communicated to staff. The building landlord provides security and staff are aware of how to contact the security staff.	The number of staff on short term and long term disability will be less than 5% of scheduled staff One fire drill/year will be conducted in conjunction with building fire drill. There will be an annual inspection by the fire department. Evacuation plan will be tested as paper exercise biannually. Random audit of staff awareness.	Director of Human Resources VP Operations

QUALITY DIMENSION	QUALITY INDICATOR	QUALITY STANDARDS	QUALITY MEASUREMENTS	PRIME RESPONSIBILITY OF
Safety	Patient Information Security	Access to all call centres is secured at all times and entry can only be accessed via use of an access card The computer room at all sites will be locked at all times. Weekly backup tapes will be transported off site to a secure location.	The site receptionist will keep a log of all access cardholders. The log will be updated on an ongoing basis. Only the site Information Associate will have access to the computer room. A log will be maintained by the Information Associate and reviewed annually by the Technical Support Specialist.	VP of Operations Clinical Services Manager Director of Information & Communication Technology
		Policies are in place in regards to release of patient information to other agencies. The patient's consent is required to release or transfer personal information. A preventative equipment maintenance program has been established.		Director of Quality Services Director of Information and Communication Technology
Risk	Risk Management	Administrative and Clinical Policies, Guidelines and Procedures are current and communicated to staff via email.	All changes to policy documents are made in the NL/ New Brunswick and Ontario shared drive as well as in all hardcopies of the Guideline and	Manager of Quality Services

QUALITY DIMENSION	QUALITY INDICATOR	QUALITY STANDARDS	QUALITY MEASUREMENTS	PRIME RESPONSIBILITY OF
		All unusual incidences are reported in the Complaints Module. The Manager of Quality Services and Medical Advisor will be notified of all high-risk incidences. All Quality Issue reports will be investigated and action plan for rectifying the problem will be initiated by the Senior Nurse and/or Clinical Services Manager. All completed Quality Issue reports will be forwarded to the Quality Services Manager for review.	Procedure Manual. Measured and reported monthly.	Clinical Services Manager, CTM,

Submitted by

College of Licensed Practical Nurses
of Newfoundland and Labrador

College of
Licensed
Practical
Nurses
of Newfoundland
& Labrador

Submission to the Task Force on Adverse Health Events

June 2008

College of Licensed Practical Nurses of Newfoundland and Labrador

Submission to the Task Force on Adverse Health Events

June 2008

Introduction

The College for Licensed Practical Nurses of Newfoundland and Labrador (CLPNNL) welcomes the opportunity to provide input into the Task Force on Adverse Health Events. The following submission provides our perspective regarding the requirements for achieving a blame-free culture that supports the timely reporting of incidents, near misses and adverse events in our Health Services System. Then, we have also commented on the suggested principles to guide adverse health event management and disclosure. Lastly, we have commented on the mandate and structure of the proposed Health Quality Council for the province.

CLPNNL, in accordance with the *Licensed Practical Nurses' Act*, has the legislative responsibility for regulating the practice of Licensed Practical Nurses in Newfoundland and Labrador. The mission of the CLPNNL is to promote safety and protection of the general public through the provision of safe, competent and ethical nursing care.

In fulfilling its role of protecting the public, the CLPNNL assumes the responsibility of determining standards for the education and practice of Licensed Practical Nurses (LPNs) to ensure they have the knowledge, skills, judgements and attitudes required to provide holistic nursing care to a diverse clientele in a variety of settings. The CLPNNL is also responsible for the investigation of all written complaints alleging negligence, incompetence, or professional misconduct by LPNs and any necessary disciplinary measures. As well, the CLPNNL recognizes the need to address mandatory competencies and issues related to maintaining these competencies.

Currently, CLPNNL has 2535 LPNs who work in a variety of acute care, long term care, and community-based settings. LPNs constitute the 2nd largest health professional group in the health care system, both here in the province and throughout the country.

Creating a Blame-Free Culture for Reporting

Despite the best prevention and most rigorous quality management processes, incidents will occur that could potentially place individuals and property at risk. Only through proper and timely reporting of incidents is the opportunity provided for investigation and implementation of actions to prevent further occurrences. This can best be achieved by developing a "blame-free" reporting system which is well understood by both health care professionals and by their patients and clients.

In our view, incidents occur generally as a result of some combination of human error and systems failure. Without consistent and timely reporting of incidents, it is virtually impossible to discover patterns that could point to systems failures that require attention and remedial action. Otherwise, imperfect systems can perpetuate to create the inevitable conditions for

significant adverse health events that cause harm to patients and clients. Near misses, incidents, unsafe acts and conditions are often not reported at all, yet learning from these conditions is really the best opportunity to continuously improve the quality and safety of care.

A significant factor that discourages reporting is the perception that to do so may result in blame for the reporter or a colleague resulting in consequential sanctions. Thus, the difficulty of ensuring complete reporting is, in part at least, a function of culture of an organization, system or society.

If health care providers are to report incidents and near misses they must not feel that they will be personally blamed or disciplined as a result of their reporting. However, we recognize that there will be instances where disciplinary action must be taken against an individual, such as for conscious or deliberate violation of a procedure, and/or in carrying out care that is inconsistent with established professional competencies and standards of practice. However, even in such cases, it is still important to understand why it took place; and whether the procedure was workable; and correct and whether there were extraneous pressures that may have contributed to the individual act. The role of professional regulatory bodies and of health care organizations in these cases is well understood and is working well.

In our view, the requirements for creating a blame-free culture include at least the following:

Unrelenting attention to ongoing education. Education regarding the incident and adverse health event reporting system during orientation is necessary, but not sufficient. Ongoing education is required to ensure there are clear and consistent awareness of what must be reported, the process of reporting, and the expected outcomes of reporting, including how reporting is linked to the organization's quality and risk management system. To facilitate this, it is recommended that one set of policies and procedures be developed and used throughout the province. An additional aim of education programs should be to achieve consistent use of terminology regarding what constitutes an incident, an occurrence, a near miss, and an adverse health event. Educational preparation must also be concrete, including for example how to complete an incident reporting form.

We have also noted that public and patient/client education are also required to raise awareness and confidence in the health system's processes for incident and adverse health event management. We suggest that patients/clients and their family members should also be part of the reporting system and that they too should be equipped to complete incident reports.

In addition to ongoing education, we believe there should be ongoing interdisciplinary, work unit forums that focus on prevention and safety. We believe these forums must be skilfully facilitated to ensure participants are encouraged to challenge the status quo and to overcome attitudinal and professional hierarchical barriers which are still very much prevalent among professional disciplines.

Visible leadership and work unit stability. LPNs are telling us that the visibility and presence of leadership at the work unit level throughout all nursing care settings has significantly diminished over the last decade, and particularly since the establishment of the four regional health authorities. Leadership presence is a vital ingredient to creating work unit environments that are conducive to open and honest communication and trusting relationships. This constitutes a prerequisite for a blame-free culture and for optimal use of reporting systems.

It is well understood that nursing staff within the province's health care system is under constant pressure resulting in high rates of casualization (versus permanent positions) and increased use of float positions. This creates a great deal of staffing instability on work units and significantly diminishes staffs' experience of open, trusting and honest communication. Furthermore a sense of belonging, of being an integral part of a team, and of mutual accountability for safe, quality care is jeopardized. This too is an essential component of a blame-free culture that supports timely and accurate reporting of incidents, near misses and adverse events.

Focus on the cause and not the person. As noted previously, most incidents are the result of a systems failure. Thus, a blame-free culture must focus on discovering the root cause and not on the person(s) who were involved. This also requires effective leadership and communication skill to ensure the focus is on discovery, investigation and action and not on individual blame.

Timely feedback, involvement and action. Unfortunately, staff does not consistently receive timely feedback regarding the incident reports they complete. This breeds skepticism regarding the utility of reporting, and especially so if corrective, systems-oriented action is not taken. It is critically important to ensure this follow-up is in place on a consistent basis.

In formulating corrective action, we believe it is important to directly involve work unit personnel. These personnel should be equipped to meaningfully participate through timely training in root cause analysis and systems problem-solving.

Provider support. Regardless of the care and attention paid to focusing on the cause rather than a person, a staff member who is involved in an incident, near miss or adverse health event will inevitably bear the burden of guilt and self-blame. Thus, provider support is necessary to ensure staff receive the necessary debriefing, counselling and other opportunities to assist them in resolving feelings of self-blame. Here again, training of leaders is necessary to ensure the effective and sensitive communication and resolution of incidents.

Patient and client support. Patients/Clients/Residents are often aware that an incident, near miss or adverse health event has occurred. A system of patient and client support must be available, including policies regarding who should communicate incidents and occurrences to patients and clients.

Changing Health Care Practices

Speciality areas in acute care settings such as critical and emergency care are well understood and supported by specialty education and systems support, including for incident and adverse event reporting. However, other areas of speciality have emerged including in mental health and addictions, elder care and community care. As these systems evolve, professional training has also evolved, for example LPN core education now includes areas such as health assessment, medication administration, intravenous therapy, blood and bloods products, and leadership skills. However, systems and reporting practices have lagged behind, resulting in inconsistencies and potential areas of risk for underreporting of incidents.

For example, in some practice settings, LPNs have full accountability for reporting incidents and near misses, and in settings there is only an expectation that LPNs verbally report these occurrences to a supervisor. Generally LPNs are not part of peer review processes and other review and evaluation processes. This represents a significant change in the management and cultural change that must be addressed if all health care professionals are to fulfill their role in the timely, accurate and complete reporting of incidents, near misses and adverse health events. Indeed, unresolved scope of practice issues and the intimidation that results in some settings is likely to encourage under-reporting as it impedes the ability to engage in open and honest discussion regarding incidents. We suspect this also extends to other professional groups where there are entrenched mindsets regarding scope of practice and hierarchy.

Guiding Principles for Adverse Health Event Management and Disclosure

Based upon the above discussion, CLPNNL offers the following guiding principles for the further development of adverse health event management and disclosure:

1. Focus on safe, quality patient/client care
2. Ongoing education and training of health professionals regarding reporting processes and policies
3. System wide, uniform reporting policies and procedures
4. Blame-free culture that fosters openness and transparency
5. Respect for scope of practice, professional autonomy and accountability
6. Inclusive peer review and other review processes
7. Clear, consistent documented processes that articulate roles and responsibilities
8. Focus on continuous quality improvement and learning; not on placing blame
9. Focus on root causes and systems rather than on individual actions
10. Timely feedback and action
11. Involvement of staff in designing processes and in designing remedies for areas of risk
12. Provider support
13. Patient/client support

14. Timely, direct, and ongoing communication of adverse health events and of measure being taken

Proposed Health Quality Council

We have noted that the Task Force on Adverse Health Events will also propose a mandate, structure, and budget for the establishment of a health quality council in Newfoundland and Labrador. In that regard we are offering the following commentary regarding the mandate and membership of such a quality health council.

Mandate:

Promote quality, accountability and transparency of the province's health system through:

- Monitoring the impact of population health approaches to health services investments and system-wide changes, including delivery models, technology, etc.;
- Developing a system of key performance and quality indicators as a basis for assessment, monitoring and reporting;
- Overseeing the development of strategies to restore public trust in the health system including the publishing of an Annual Public Report Card; and
- Facilitating discussion regarding the future development of the health care system to meet the needs of Newfoundlanders and Labradorians.

Membership:

CLPNNL believes the Health Quality Council should not consist of more than 12-15 members. Members should be selected on the basis of their expertise in areas such as research, quality and risk management, communications, and public administration. We strongly believe that members should be non-partisan and have the ability to take a 'whole system' view rather than a specific organizational view. Finally, we believe that there should be substantial public representation, likely constituting 25-30% of the Council's membership.

Conclusion

Open and transparent adverse health event management and disclosure can only exist when a blame-free culture exists at every level of the health system, especially at the work unit level. This culture can flourish when mutual trust, respect and open communication is the norm, when accountability and respect for professional autonomy and scope of practice exists and when organizational support and investments are made that result in visible and present leadership and staff education and training. Health care professionals must receive active support for reporting incidents. Where adverse health events result in harm, both health

professionals and those patients/clients directly affected must know that there will be open and ongoing communication and support that is immediately available to meet patient/client and family needs. Under these circumstances, the potential for achieving timely and accurate reporting of incidents and for reaping the quality benefits of organizational learning and improved safety are immense.

Thank you for the opportunity to provide input into your Task Force deliberations. The CLPNNL would welcome the opportunity to provide additional input as your work continues and we are ready partners as you commence implementation of recommendations.

Submitted by

College of Physicians and Surgeons
of Newfoundland and Labrador

Submission to the Task Force on Adverse Health Events

June 2008

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I. Introduction

In any human activity, events will occur that adversely affect the desired outcome. These events may occur for a variety of reasons. They may be foreseen or unforeseen. In either case, they must be addressed.

Health care is no different from any other human activity. As with any other complex human activity, health care involves many components, each of which has a role to play in preventing or avoiding adverse events or outcomes, identifying when they occur and setting a course of action to mitigate the impact they may have on the desired outcome.

The following submission provides observations on the role played by the College of Physicians and Surgeons of Newfoundland and Labrador in adverse events or outcomes as they relate to the practice of medicine. The submission includes recommendations which the College believes the Task Force should bear in mind as it fulfills its mandate.

II. Task Force on Adverse Health Events

The Task Force on Adverse Health Events was appointed in May 2007 to examine how the health system in Newfoundland and Labrador identifies, assesses, discloses, takes action, communicates and evaluates with respect to adverse events.

To fulfill its mandate, the Task Force is responsible for assessing current practices within Newfoundland and Labrador, examining best practices across Canada, identifying case studies, interviewing experts, and consulting closely with regional health authorities and stakeholders.

The Task Force is also responsible for proposing a mandate, structure and budget for the establishment of a health quality council in Newfoundland and Labrador.

III. College of Physicians and Surgeons of Newfoundland and Labrador

The College of Physicians and Surgeons of Newfoundland and Labrador regulates the practice of medicine in the province, in the public interest.

It continues the Newfoundland Medical Board which was established, by legislation in 1893. The mandate and powers of the College are established in the *Medical Act, 2005*.

The College fulfills its mandate in several ways:

1. The College assesses qualifications for registering and licensing medical practitioners.
2. The College sets professional standards for the practice of medicine in the province.
3. The College sets practice policies and guidelines for medical practitioners, including on disclosure of adverse outcomes.
4. The College participates jointly with the Colleges of Physicians and Surgeons in Atlantic Canada in a peer assessment to monitor the practice of medical practitioners through peer assessment review.
5. The College investigates allegations made against medical practitioners which raise a question of breach of professional standards. The results of investigations are presented to a Complaints Authorization Committee (CAC) which determines the disposition of the allegation. In certain cases, the Committee may refer a matter to a hearing before an adjudication tribunal. This is in cases where the CAC has reasonable cause to believe that a medical practitioner has engaged in conduct deserving of sanction including professional misconduct, professional incompetence, conduct unbecoming a medical practitioner, incapacity or unfitness to engage in the practice of medicine, and acting in breach of the *Medical Act, 2005* and the regulations and the code of ethics made under the *Medical Act, 2005*.
6. The College is required to maintain registers for medical practitioners, specialists, medical students, and professional medical corporations.

Given its mandate, the College has a significant interest in adverse medical events or outcomes.

The College's approach starts with the ethical considerations. The practice of medicine in Newfoundland and Labrador is based on the principles expressed in the Canadian Medical Association Code of Ethics which have been adopted by the College. The Code establishes the role of a physician and his or her professional obligations in practicing medicine.

The Code is founded on the belief that health care is best provided in a context in which patients are directly involved in making decisions about their own care. Care is founded on a relationship of trust and confidence between the physician and the patient. The well-being of the patient is paramount.

The Code recognizes that patients have a fundamental right to be informed about their care. They have a right to provide informed consent to care, including being advised in advance of any risks associated with a particular course of treatment.

They also have a right to know of any adverse events. As the Code of Ethics provides:

> 14. Take all reasonable steps to prevent harm to patients: should harm occur, disclose it to the patient.

The College, in the fulfillment of several aspects of its mandate identified above, has as one of its aims the identification and correction of practices and conduct which, if left uncorrected, could lead or contribute to adverse medical outcomes. To the extent possible, the College participates in the Atlantic Province's Medical Peer Review program.

The Medical Act, 2005 provides for peer review with clearly defined goals:

> **54.** (1) The peer assessment committee shall, subject to the approval of the college, develop and administer a peer assessment program that shall include
>
> (a) assessment standards of practice for medical practitioners including
>
> (i) standards for the clinical assessment and care of patients, and
>
> (ii) standards for the maintenance of records of care administered to patients;
>
> (b) procedures and requirements for the selection and education of assessors;
>
> (c) standards and methods of communication with physicians to be assessed;
>
> (d) budgetary and expense arrangements;
>
> (e) requirements and methods respecting the preparation of assessment reports;
>
> (f) the development of policies and procedures for the peer assessment committee and the delegation of these to subcommittees, assessors or employees as the peer assessment committee considers appropriate; and
>
> (g) the determination of further activities including the establishment of other committees and subcommittees to better administer the peer assessment program.

As well, the College has established a policy on adverse events or outcomes to give guidance to physicians on the appropriate response to an adverse event or outcome. The complete policy is included with this submission as Appendix A.
Under the policy, an adverse outcome is defined as "a non-trivial adverse outcome or consequence of health care treatment, which adverse outcome or consequence is not solely related to the course of the illness or condition being treated but has resulted at least in part from the health care treatment itself or from the manner in which the health care was delivered. Adverse outcome includes a situation where the possibility of the adverse outcome may be a recognised risk of the treatment."

The adverse outcomes policy recognizes explicitly that "patients have a right to know their present medical status, not only as an intrinsic right but also so that they may make informed decisions about their health care. Patients have a right to know when an adverse outcome of health care treatment has affected their present medical status."

In addition, other aspects of the College's legal mandate to regulate the practice of medicine may be related to an adverse event or outcome, depending on the nature of the event. In the investigation of an adverse event, authorities other than the College may become aware of issues that fall under the College's mandate. For example, investigation of an adverse event may properly involve the College's complaints and discipline process.

IV. The Task Force Questions and the College of Physicians and Surgeons

The Task Force has requested that written submissions address three specific questions:

Question 1. How can we improve the current approach used by our health and community services system to manage adverse events?

Question 2. In particular, are there gaps in how the system identifies, assesses, discloses, and takes action on adverse events?

Question 3. Are there gaps in how the system coordinates and communicates when it is managing an adverse event?

Following are general observations which can be made on the role of the College and which may be useful in developing a system for responding to adverse events within the health care system.

The essence of the relationship between a physician and patient as envisaged by the Code of Ethics, and the College's policy on adverse outcomes, is open communication. This has been discussed above.

Given that health care is delivered in the province through a system of agencies, professions and individuals, any policy on adverse events or outcomes should be founded

on a relationship among agencies which includes the same exchange of necessary information as should occur between a physician and patient.

That is, there must be a relationship of trust and confidence which recognizes the roles each agency, profession and individual plays in the health care system. The regional health authorities may have an undoubted and critical role based on their size and the scope of their responsibilities. However, other organizations, including the College have a role to play in preventing adverse events or in responding to them.

Licensing: The College's role in regulating the practice of medicine is intrinsic to the provision of health care, especially through the College's role in assessing the qualifications of physicians for licensure.

Assessments and reporting requirements: As well, assessments of physician competence through peer review either conducted through the Peer Review program of the College or through a review internal to the regional authorities may reveal issues related to the licensing of physicians that should be communicated to the College promptly so that necessary changes can be made.

It is the understanding of the College that, by current law, the College cannot be apprised of the detailed results of peer reviews. However, the College believes it is important that regional health authorities be able to provide sufficient information to permit the College to act upon its mandate, in particular where such reviews give rise to questions of professional misconduct or competence, without compromising the integrity of the peer review process.

Section 36 of the Medical Act, 2005 presently requires medical practitioners to report to the College circumstances where they have knowledge of conduct deserving of sanction by a medical practitioner. The College suggests that consideration should be given to whether other agencies, such as the regional health authorities, should also have a statutory requirement to report such circumstances to the College, and that further consideration be given to whether and how information learned in the course of peer review, peer assessment and other quality assurance processes could be included in such reporting to the College.

Complaints and Discipline: The regional health authorities acknowledge the role of the College in addressing complaints about professional practice, typically, through the medical by-laws under which the authorities operate.

It should be understood that, in many respects, the complaints and discipline process often functions as a form of quality assurance. The investigation of allegations and the discipline process are also integral to quality assurance in the delivery of health care, including by the identification and correction of practices and conduct which cause or contribute to, or have the potential to cause or contribute to, adverse outcomes.

This may be most apparent in those cases which proceed to a hearing before an adjudication tribunal. The hearings are presumptively public. Where there is a finding of serious misconduct, the tribunal decision must be published, and thereby serves an educational function for the whole of the profession. Even where there is not a finding which requires publication, the issues arising from the hearing may form the basis for a notice to the profession on professional conduct and practice.

Even where there may not be reasonable grounds to proceed to a hearing, as determined under the Medical Act, 2005, the Complaints Authorization Committee, comprising a minimum of two medical practitioners and one lay person, follows a practice (a continuation of one developed by the Newfoundland Medical Board) of providing detailed reasons for the Committee's decision and where appropriate issuing advice, caution or counsel to the medical practitioner. Receiving such advice, caution and or counsel may carry considerable weight in the mind of the practitioner and there may be occasions when this is more valuable than a peer review as most would understand that term.

While many observers may view the allegation investigation and discipline process of the College as being solely punitive, in practice, it is most often positive and corrective in the fashion akin to that of a peer review. Regional health authorities and others should bear this in mind as they develop procedures to deal with adverse health events.

Further Initiatives: The College is also pursuing other initiatives which are aimed at assuring professional standards, and by extension serve to identify and correct practices and conduct which could cause or contribute adverse outcomes. One of these initiatives is the recent making of a Code of Ethics By-Law of the College. Another is the College's participation in the development of a Provider Registry as part of an electronic Pharmacy Network. The College has also corresponded with the Department on the subject of quality assurance, and in particular revalidation of the credentialing of practicing physicians. A copy of the College's correspondence to the Department on this issue is attached as Appendix B.

Conclusion: In responding to an adverse health event, regional health authorities and other authorities should be mindful of the full spectrum of response. There are aspects which are entirely within the mandate of the authority. However, other aspects may fall to the College as a result of responsibilities set out in law. The College also has explicit or implicit obligations to others, including its counterpart Colleges across the country.

It is with those ideas in mind, that the College makes the following observations.

While immediate action may be taken to address an adverse event, in the overall process, certain issues can and should be referred to the College for assessment of the medical component of any incident. The College can provide professional advice to physicians and administrators individually or collectively on the medical regulatory (ethical and policy) aspects of any issue. These sorts of consultations currently take place, however, it

is timely to remind those who are not physicians that the College is available to provide this assistance.

Where adverse events trigger an investigation or review within a regional health authority, College should be advised of results of investigation so that it may take its own action, if needed, based on its own legal responsibilities to public.

In many instances, the result may not involve the College's complaint and discipline process even though this may sometimes be the one aspect of the College's role which comes foremost to some minds

There may be regulatory or policy direction to be given as a result of adverse events that would be beneficial to all physicians. The College may wish to review and amend some aspect of its credentialing process, in some instances. There is no way of anticipating all the possible ramifications of every event, however, as a general principle, the College can only take action to fulfill its mandate if it is properly informed.

Appendix A: Disclosure of an Adverse Outcome

The purpose of this guideline is to affirm the College's position that patients are entitled to be informed of all aspects of their health care. This right to be informed includes the right of a patient to disclosure of an adverse outcome in the course of receiving health care.

The disclosure of an adverse outcome, in accordance with this guideline, is not about attributing or admitting any fault or blame. In the view of the College, an adverse outcome will not necessarily be the result of negligence or incompetence.

Scope

This guideline applies to all medical practitioners, and all medical students and residents whose names are entered on the Educational Register, who become aware, while treating a patient, that the patient has suffered an adverse outcome in the course of receiving health care.

Meaning of "adverse outcome"

Of course, medical practitioners have always been expected, and should continue, to disclose adverse outcomes which can be said to be one of the possible consequences of an illness.

However, for the purpose of this guideline, adverse outcome means a non-trivial adverse outcome or consequence of health care treatment, which adverse outcome or consequence is not solely related to the course of the illness or condition being treated but has resulted at least in part from the health care treatment itself or from the manner in which the health care was delivered. Adverse outcome includes a situation where the possibility of the adverse outcome may be a recognised risk of the treatment.

"Adverse outcome" should be understood to mean not only a non-trivial adverse outcome or consequence of health care treatment which manifests itself in the course of or following health care treatment, but also an incident in the course of health care treatment which results in a recognized potential risk of a non-trivial adverse outcome or consequence at some future time. Such potential future adverse outcome may require the arrangement for appropriate follow-up surveillance, and perhaps other departures from the usual care plan. An example of such a potential adverse outcome would be the disclosure to a patient that an earlier test had detected a carcinoma, but that the information had apparently not been acted upon. Another example would be where damage is accidentally caused to tissues in the course of surgery, which damage is repaired in the course of surgery, but where even with such repair there is a recognized potential risk of future complications from the damage and/or repair

Patients' right to disclosure

Patients have a right to know their present medical status, not only as an intrinsic right but also so that they may make informed decisions about their health care.

Patients have a right to know when an adverse outcome of health care treatment has affected their present medical status.

Leaving it to a patient, a substitute decision maker or another health care provider to discover or act upon an adverse outcome is not consistent with the rights of patients outlined above, and in some circumstances the resultant delay may do harm to the patient.

The responsibility to disclose

The medical practitioner who was the most responsible physician for the health care treatment during the course of which the adverse outcome occurred, should disclose the adverse outcome to the patient.

In some circumstances, it may be that more than one medical practitioner was responsible for the health care treatment, which resulted in the adverse outcome. In such circumstances, each responsible medical practitioner has an individual responsibility to ensure that disclosure is made to the patient of the adverse outcome. In such circumstances, the responsible medical practitioners should consult as to who among them will make the disclosure to the patient.

Where another medical practitioner believes there has been an adverse outcome from health care treatment for which that practitioner was not responsible, that practitioner should advise the most responsible physician in relation to that treatment of the practitioner's belief that there may have been an adverse outcome and that this guideline may apply to the situation.

A medical student or resident should disclose an adverse outcome to his or her clinical teacher or supervisor. If the clinical teacher or supervisor is not the most responsible physician for the affected patient, then the clinical teacher or supervisor should ensure that the most responsible physician is informed of the adverse outcome. Upon becoming aware of the adverse outcome, the most responsible physician should disclose the adverse outcome to the patient.

In addition to this guideline, hospitals and health care facilities may have their own procedures for disclosure of adverse outcomes or similar situations to patients, which procedures should also be followed. Where it appears that this guideline may conflict with procedures established by a hospital or health care facility, medical practitioners are encouraged to contact the College to discuss how such apparent conflict may be resolved.

Persons to whom disclosure should be made

Whenever possible, disclosure of an adverse outcome should be made directly to the affected patient.

Where the patient is not competent or where meaningful disclosure of the adverse outcome directly to the patient may not be possible due to the medical condition of the patient, disclosure of the adverse outcome should be made to the patient's authorized substitute decision maker.

The time for disclosure

Where harm or deterioration of condition may result unless there is immediate disclosure of the adverse outcome, the medical practitioner should disclose the adverse outcome with the according urgency, to either the patient or an authorized substitute decision maker

Where the disclosure of an adverse outcome is not as urgent, the medical practitioner may consider whether it is appropriate to wait until a patient's condition has stabilized sufficiently so that he or she can be expected to reasonably understand the information, provided any delay is in the best interests of the patient.

A medical practitioner may wish to seek the advice of colleagues, of the College or of the medical malpractice protection provider before disclosing an adverse outcome to the patient. Such advice should be sought promptly and should not result in undue delay in disclosing the adverse outcome to the patient.

The manner of disclosure

Disclosure to the patient directly should first be considered. The setting for the disclosure should afford the patient privacy. The patient should be offered the opportunity to be accompanied by a support person. The medical practitioner himself or herself may want to have a support person present.

The adverse outcome should be factually described, with care taken to explain medical terminology so that it is understandable by the patient. Speculation or conjecture should be avoided, and the practitioner may respectfully decline to respond to questions or comments from the patient which invite speculation or conjecture.

Options for treatment to address the adverse outcome should be raised. The patient should be told when such treatment or a second opinion may be able to be provided, or should be provided, by another practitioner.

If upon commencing disclosure, it becomes evident that the patient is unable or unwilling to continue the discussion, the medical practitioner should offer to continue or resume the discussion at another time. In some circumstances, the patient may want to have the

disclosure made to an authorized substitute decision maker or in writing, and the practitioner should give due consideration to such requests.

Details of the adverse outcome and of its disclosure to the patient should be documented in the patient's record. Where necessary for the observation or treatment of the patient, the patient's family doctor or other treating physicians should also be informed of an adverse outcome.

Disclosure of an adverse outcome is not an admission of fault or liability

Findings of fault and liability are subject to legal principles of proof and causation. These issues cannot be resolved in a discussion between doctor and patient.

While a medical practitioner should be factually candid in describing the adverse outcome, the practitioner should also be prepared to be equally candid with the patient that the disclosure should not be considered an admission of fault. Should the patient raise questions of fault or liability in the course of the disclosure of an adverse outcome, the patient should be advised that such questions should be discussed with the patient's own legal advisor.

Comments to a patient which may be taken as attributing blame to other health professionals should be avoided.

In circumstances where questions of fault or negligence may give rise to a claim for damages or litigation, a medical practitioner may wish to first seek the advice of the medical malpractice protection provider as to how disclosure of an adverse outcome may be made without it being taken to be an admission of fault or liability.

Within the foregoing context, an expression of regret for the adverse outcome may be appropriate, and should not be taken as an admission of fault or liability.

A patient to whom an adverse outcome has been promptly, candidly and sensitively disclosed may be less likely to pursue litigation or other means of redress.

Summary

- Consider who is the "most responsible physician" for the health care treatment during the course of which the adverse outcome resulted.
- Where more than one medical practitioner is a responsible physician for such care, consultation amongst those practitioners should take place.
- Disclosure should be made promptly.
- The advice of colleagues, of the College, and/or of the medical malpractice protection provider may be sought prior to disclosure, provided this does not result in undue delay.
- The adverse outcome should be factually described; speculation should be avoided.

- Options for treatment to address the adverse outcome should be raised with the patient, including the possibility of obtaining a second opinion from another medical practitioner
- Details of the adverse outcome and of its disclosure should be documented in the patient's record.
- Be prepared for a patient being unable or unwilling to continue with a discussion of adverse outcome, and offer the option of resuming the discussion at another time.
- Be prepared to be frank that disclosure of the adverse outcome is not an admission or attribution of fault or liability.

THE COLLEGE OF PHYSICIANS AND SURGEONS
OF
NEWFOUNDLAND AND LABRADOR
Continuance of the Newfoundland Medical Board 1893

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October 26, 2007

Dr. Edgar Wilson Hunt
Dept. of Health & Community Services
Belvedere Site, 57 Margaret's Place
St. John's, Newfoundland & Labrador
A1B 4J6

Dear Dr. Hunt:

Re: Quality Assurance Initiatives: Non-Hospital Surgical Practice and Physician Revalidation

With reference to the undersigned's recent meeting with yourself, Dr. Cathi Bradbury and Dr. Blair Fleming of your Department, the College is writing at this time in furtherance of two quality assurance initiatives that are being considered by the College. The quality assurance initiatives under consideration are the regulation of non-hospital surgical practice (including, but not limited to, plastic surgery and cosmetic surgery performed outside of the hospital setting) and physician revalidation (the maintenance and demonstration of ongoing competence to practice).

The College's review to date indicates that, at minimum, regulations, requiring the Minister's approval, will be necessary to implement these quality assurance initiatives. It may also be necessary or desirable to amend the *Medical Act, 2005*, to more clearly delineate the College's authority to regulate on matters of quality assurance. Therefore, the College believes it to be important to consult with your Department, at this early stage in the development of these initiatives.

We discuss below the proposed quality assurance initiatives.

Non-Hospital Surgical Practice

Other Canadian Colleges of Physicians and Surgeons are regulating, or are considering regulating, non-hospital surgical practice. The recent death of a patient who underwent cosmetic surgery in a non-hospital setting in Ontario received national media attention, and has led to calls for greater regulation in this area of practice.

The College is aware that the College of Physicians and Surgeons of Alberta (CPSA) is already extensively involved in accrediting non-hospital surgical facilities. In Alberta, all non-hospital diagnostic and treatment facilities, in which medical and surgical procedures are deemed by the CPSA as having a sufficient risk of potential harm to a patient, must register and maintain accreditation by the CPSA as a non-hospital surgical facility.

The College at this time has no effective means of regulating the practice of fully licensed physicians who offer non-hospital surgical services, short of being able to consider egregious breaches of standards of practice as professional misconduct. In the view of the College, the discipline process is neither appropriate nor sufficient to address quality assurance issues in relation to non-hospital surgical services which may fall below the threshold of conduct deserving a sanction, but nonetheless deserve regulatory attention for the better protection of the public. In the view of the College, quality assurance should be a matter of being proactive in identifying problems and potential problems, before they rise to the level of conduct deserving of sanction.

Effective regulation of non-hospital surgical practice would require that the College be provided with the means to accredit and audit non-surgical hospital practices. As the accreditation and auditing of non-hospital surgical practices engages areas of public policy including not only regulation of the profession, but also regulation of commercial activity (many of the non-hospital surgical services offered are non-insured), access of the public to non-hospital surgical services, and the confidentiality of patient information, the College believes that it is necessary that amendment to the *Medical Act, 2005* be considered, to provide the College with clear authority to regulate in this area.

The issues arising out of regulation of non-hospital surgical practice are many, and we will not attempt to summarize them all here. However, the College does propose that a working group be established, with representation from the College, your Department, and possibly other stakeholders as may be identified, to be tasked with developing a regulatory regime for non-hospital surgical practice.

Physician Revalidation

The College has previously made reference to this quality assurance initiative, in the College's 2006-2007 Annual Report to the Minister.

Professional revalidation of physicians is an issue which has been reviewed by the Federation of Medical Regulatory Authorities of Canada (FMRAC), culminating in FMRAC's Position Paper of July 4, 2007. The Position Paper defines revalidation as a quality assurance process in which physicians are required to provide satisfactory evidence of their commitment to continued competence in their practice.

The FMRAC Position Paper identifies the issues in relation to physician revalidation as follows:

> *The public places its trust in the medical regulatory authorities to license physicians who, in turn, are expected to remain competent throughout their practice lifetimes.*
>
> *The practice of medicine, including the treatment and prevention of illness, is in constant evolution. Therefore, physicians must be committed to participating in lifelong practice reflection and continuing professional development.*

The demonstration of ongoing competence and performance of physicians is a pillar of professional self-regulation

The FMRAC Position Statement on physician revalidation is as follows.

All licensed physicians in Canada must participate in a recognized revalidation process in which they demonstrate their commitment to continued competent performance in a framework that is fair, relevant, inclusive, transferable and formative.

While the FMRAC Position Statement is not binding on FMRAC's members (which include all of the Canadian Colleges of Physicians and Surgeons), this College does support the Position Statement, and we believe that it is also supported by most, if not all, of the other Canadian Colleges of Physicians and Surgeons.

As identified in the 2006-2007 Annual Report to the Minister, work remains to be completed to build a consensus around the concept of revalidation. To that end, it is the intention of the College to release its own Position Statement on revalidation in early 2008, for the information and comment of the profession and other stakeholders. As part of that Position Statement, the College would intend to give notice of its intention to develop, in consultation with your Department, regulations regarding revalidation. Naturally, however, we do not wish to embark on such a process without preliminary consultation with your Department to confirm that there is a consensus between the College and your Department on this quality assurance initiative.

While it might be ambitious, it is the College's goal to seek to have in force the necessary regulations, and any necessary amendments to the *Medical Act, 2005*, by the end of 2008, so that the revalidation process will begin to be applicable to new licensures and renewal of licensures in 2009

Final Comments

As has been adverted to above, the College believes it will be necessary or desirable to make amendments to the *Medical Act, 2005*, to be able to effectively carry out these quality assurance initiatives. We note that the amendments to the *Act* in 2005 focused almost exclusively on the discipline process, and were made with the understanding that further amendments with respect to licensing and other regulatory matters still remained to be considered.

While the final form and shape of these quality assurance initiatives may take some time to develop, the College also recognizes that amendments to legislation can be a protracted process. Therefore, the College believes that the process of identifying necessary or desirable amendments to the *Medical Act, 2005* should be started as soon as possible, so that the necessary drafting and introduction of the appropriate Bill or Bills in the House can be reasonably expected to coincide with the proposed timeframe for implementation of these initiatives by the end of 2008. The College, therefore, hopes to hear from your Department in the near future regarding the above-proposed

initiatives. As always, we would be pleased to meet with you or other Department representatives, at your convenience.

Sincerely yours,

Robert W. Young, MD. FRCPC
Registrar

RY/co

Submitted by

Eastern Health

EASTERN HEALTH

Submission to the Task Force on Adverse Health Events

July 2, 2008

Introduction:

The Eastern Regional Integrated Health Authority (Eastern Health) was established in 2005 from the merger of seven legacy health care boards in the province of Newfoundland and Labrador. Eastern Health is responsible for the operation of community –based services, public health, institutional health care facilities and medical clinics. There are 871 acute care beds, 87 critical care beds and 1. 684 long term care beds, in addition to numerous community based services. There are approximately 12,000 employees, 600 physicians, over 3, 000 volunteers providing services. It serves a regional catchment area of approximately 292. 000 residents over a large geographic area comprised of urban and rural sites, as well as the whole province for select services.

The development of best practices in healthcare is paramount to patient safety. Patient Safety is defined by the Canadian Patient Dictionary (2003) as the reduction and mitigation of unsafe acts within the healthcare system, as well as through the use of best practices shown to lead to optimal outcomes. Patient safety initiatives have been increasingly on the national and international agenda in recent years. In 2002, Health Canada established the Canadian Patient Safety Institute in an effort to coordinate best practices and national standards in the area of patient safety. In 2004, the report of Baker and Norton's Adverse Events study emphasized the need to improve patient safety in Canadian hospitals. The study reported the incidence of adverse events to be at a rate of 7.5% of acute care hospital admissions. Of these, it is estimated that 70,000 were

preventable adverse events. This research supports the development and implementation of initiatives to improve patient safety.

Eastern Health adheres to the philosophy of providing high quality service and care that is evidence based and consistent with its strategic plan. In keeping with patient safety this submission to The Task Force on Adverse Events will highlight the issues that impact the coordination and management of adverse events. An adverse event is defined by the Canadian Patient Safety Dictionary as an unexpected and undesired incident directly associated with the care or services provided to the patient; an incident occurs during the process of providing health care and results in patient injury and death; or an adverse outcome for a patient, including an injury or complication.

There are many components related to patient safety of which the management of adverse events is only one. This submission will focus mainly on the issues related to the management and prevention of adverse events.

While Eastern Health is responsible for the management of adverse events, there are related issues that require provincial involvement and/or coordination:

1. Coordination of the management of adverse events that involve more than one health authority
2. Development of consistent definitions, policies and procedures related to adverse events throughout the province

3. Development of mechanisms to share information from adverse events throughout the province's healthcare system
4. Development of public notification guidelines
5. Review of relevant legislation such as the *Evidence Act, Public Inquires Act, Access to Information and Protection of Privacy Act, Child and Youth Advocate Act, Citizen's Representative Act*, to identify the implications for Quality/Peer Review processes
6. Support for the development of a " just and trusting culture" and to improve the reporting of adverse events and learning's from them to prevent re-occurrences
7. Funding for the provision of increased resources for information technology and human resources for the management of adverse events
8. Physician engagement

1. Central Coordination for Management of Adverse Events:

When an adverse event involves multiple patients and/or more than one Health Authority, the degree of complexity multiplies in managing the adverse event. Challenges in the areas of accessing and sharing information, identifying roles and responsibilities of each Authority, disclosure, documentation and ongoing monitoring of progress towards effective resolution must be addressed, if not, there is the potential to increase the negative impact on patients and families .

Eastern Health recommends the designation of a person or monitoring committee to provide provincial coordination and/or assistance in the event of adverse events that involves more than one Health Authority depending on the complexity.

2. Development of Consistent Definitions, Policies and Procedures:

There is a need to have consistent policies related to adverse events throughout the province. These policies include, but are not limited to, Sentinel Event, Occurrence Reporting, Just and Trusting Culture and Disclosure of Adverse Events. These policies should have a common language so they are applied consistently throughout the province. The use of common definitions is necessary if there is information that can be used for comparative analysis and trending.

A key development in the patient safety movement in the past decade has been the call for a common taxonomy for categorizing adverse events. This would guide the principles of classification and aid in understanding why an event happened, how it happened and what the impact of the event is on patient and providers. A consistently applied taxonomy is an important part of any comprehensive patient safety program by providing the structure for the organization's occurrence reporting system.

The World Health Organization (WHO) is in the process of developing an internationally acceptable taxonomy for this purpose. Eastern Health is in the planning stages of introducing a standardized electronic occurrence reporting system and as part of that process is developing a taxonomy reflective of current national/international standards. It is the intent to incorporate the WHO classification where possible.

Eastern Health recommends development of standardized policies and procedures and a standardized taxonomy throughout all provincial health authorities and supports a consistent interpretation of adverse events throughout the province.

3. Development of Mechanisms to Share Information from Adverse Events:

In an attempt to standardize provincial patient safety policies and develop a way to share information across the province a mechanism is needed. The primary purpose would be to share information throughout the province on risk management and adverse events and to provide a forum for education. A provincial network would also be an opportunity to have provincial safety conferences and training in quality improvement tools. However, there may be greater acceptance throughout all key stakeholders, such as Educational Institutions, Regulatory Bodies and Medical staff if this critical need was a government coordinated activity.

Eastern Health recommends that there be provincially sponsored mechanisms to build a forum to share information and learning's related to adverse events.

4. The Development of Public Notification Guidelines:

In 2008 the Canadian Patient Safety Institute released the Canadian Disclosure guidelines. The purpose of these guidelines "is to support and guide health care providers in these communications and to encourage organizations to develop policies and processes to effectively support the communication between the patients and providers." This document is very useful to organizations in the development of their patient disclosure policies however there is little in the document to assist with public notification of adverse events.

Sherry Espin recently reviewed the literature regarding disclosure in healthcare for the Commission of Inquiry on Hormone Receptor Testing. In her paper, she states

"healthcare organizations have to balance the privacy of patients and the public's right to know." This literature review is useful in assisting organizations in the development of guidelines and policies for public disclosure, and Health Authorities would benefit from a consistent approach.

Eastern Health recommends the development of a discussion document to support provincial public notification guidelines. .

5. Review of Relevant Legislation and Regulations:

Currently, Eastern health interprets the *Evidence Act* in this province as protecting quality and peer review documents and processes. This is critical protection in the investigation of adverse events as it supports a just and trusting culture by allowing open discussion of opinions. Many internal patient safety processes, such as quality reviews, mortality and morbidity rounds have developed under the protection the Act provides; that the opinions expressed cannot be disclosed. Since facts are not protected, the legislation does not inhibit the key patient safety activity of sharing adverse events.

Over the past several years, there are many legislative statutes in this province that have implications for quality processes. Those statutes have legislative authority to protect evidence, provide information, produce documents, compel evidence and investigate .In addition Judge Dymond's decision in the Supreme Court of Newfoundland and Labrador raised concern about whether Eastern Health had properly constituted quality committees in place. The *Public Inquires Act* has the power to compel evidence in relation to quality review documents. Section 5 of the *Access to Information and Privacy Act* regulations provides that the *Evidence Act* shall prevail over access to information requests. There are

investigative powers under the *Citizen's Representative Act* and it has the power to request any records for review, however records will not be released from their office. The *Child Youth Advocate Act* has the right to information respecting children and youth and may compel the release of quality review reports; only solicitor-client documents are protected. Health Authorities in this province require clear direction to move the area of quality review forward.

As well, it is necessary to review the language in the Board and Medical Staff By-laws so that there are consistent approaches provincially with respect to language.

Eastern Health recommends that there be a review of all relevant legislation that has implications for the protection of quality review processes and that there is provincial direction in relation to the implications of provincial legislation;

Eastern Health also recommends that there be provincial direction on the Medical and Board by –laws with respect to language and standard mechanisms for recording and sharing of information as it relates to quality and peer reviews.

6. Support for the Creation of a "Just and Trusting Culture"

The consensus of the researchers conducting patient safety related studies such as Brennan et al, 1991, and Wilson et al in Australia in 1995 was that the largest issue in patient safety was system error rather than individual error. In other words, it was the way a task was performed by a provider in health care, rather than the provider performing the task.

Other researchers such as Wiegman & Wiegman (2004) explain that this focus on the system within healthcare is the preferable method to prevent errors in medicine. This is further expanded by Ralston & Larson (2005) who discuss that the system approach is the fundamental premise in transforming a health care organization to one, which ensures patient safety.

In Canada, the Canadian Adverse Events Study by Baker and Norton in May 2004 found "that the greatest gains in improving patient safety will come from modifying the work environment of health care professionals, creating better defenses for averting [adverse events] and mitigating their effects" (Baker et al, 2004, p. 1685).

While critical in promoting a safer system, it is imperative that this focus does not dismiss, or dilute, professional or personal accountability. A balance has to be made by the organization to support the focus on the prevention of system error while at the same time not decreasing the individual level of accountability. In the promotion of a just culture, the consistent application of tools such as the National Patient Safety Agency *Incident Decision Tree*, allows Authorities to consistently and fairly make this balance between system error and individual accountability. Unfortunately, the creation of a just and trusting culture is a challenge for many organizations, particularly in our current climate where the actions of individuals are publicly criticized.

Eastern Health recommends that the province recognize the importance of developing a just and trusting culture and assist in creating an environment conducive to this philosophy.

7. Funding for the provision of increased resources

Management of adverse events involves the investigation of actual adverse events including such activities as chart reviews, interviewing, data analysis, contacts with patients and report writing. It can require significant resources especially when it involves more than one patient. Current resources tend to be consumed mostly on these reactive activities. The best approach to adverse events would be to prevent their occurrence in the first place. There are numerous initiatives which must be put in place to assist in the reduction of adverse events. Examples of this include expertise in data management, involvement in national campaigns such as Safer Health Care Now, education in adverse event management and quality improvement tools. There is also a need for positions dedicated to health system re-design and more quality and risk management positions and infection control practitioners.

It is critical to have expertise and resources in data management to assist with the coordination and analysis of data, which allows organization to focus resources on areas of concerns.

There has to be dedicated human resources to support national initiatives such as Safer Health Care Now a campaign supported by the Canadian Patient Safety Institute. Eastern Health has five active teams enrolled in three strategies. These strategies include:

- The improved care of acute myocardial infarction
- Prevention of ventilator associated pneumonia
- Prevention of surgical site infection

It is necessary to have funding for education initiatives for Quality and Risk Management staff to be trained in areas of patient safety. Examples if this include the Patient Safety Officer course that is delivered through the Canadian Patient Safety Institute. Funding is also needed for Quality and Risk Management staff to be trained and then deliver the training to staff in quality improvement tools such as Failure Mode Effect Analysis (FMEA), Root Cause Analysis (RCA), and Plan Do Study Act (PDSA) .

The funding for the addition of new resources is needed in the area of Health System Design and Management. The Conference Board of Canada has established a Centre for Health System Design and Management which provides a forum for health care decision makers to focus on system design and overall quality and efficiency. It conducts research on how current health care system can be improved.

The addition of resources in the area of Infection Control is also important. It is noted that healthcare acquired infections (HAI's) pose a serious threat to patient safety. According to the Canadian Patient Safety Institute, healthcare acquired infections constitute a major category of adverse events in Canadian hospitals. In Canada each year 222,000 patients get a HAI and 8000 of these patients die from their infection. These infections increase hospital stay about four days and cost the health care system one billion dollars per year. This is also a concern in long term care facilities and community care settings. It has been suggested that resources in this area for education, monitoring and developing best practice guidelines up to one half of health-care acquired infections can be prevented. Therefore, it is crucial to have sufficient numbers of Infection Control Practitioners for prevention initiatives, education and the implementation of infection control recommendations.

Eastern Health recommends strategic funding in this area for human resources and data management systems to improve the management of adverse events and enhance prevention initiatives in patient safety.

8. Physician Engagement:

Physicians are a core element in the provision of health care to the people of our province. It is essential that physicians are actively engaged and enabled to participate in patient safety and quality/risk management activities. Physicians receive little training and education in the basic principles of patient safety and quality activities. Furthermore, many physicians are independent practitioners who provide service in both community and in an institutional setting. The considerable workload carried by most physicians and their limited involvement in administrative practices make it very difficult for physicians to participate and play a leadership role. It is critical for physicians to understand how, when, and with whom to participate in the disclosure process when information pertaining to an adverse event is necessary.

Eastern Health recommends the following:

- Institute patient safety and quality within the curriculum of the medical school
- Invest in physician leadership skills and ability including providing appropriate remuneration for leadership and administrative activities; provide clear and precise job descriptions with expectations/goals/objectives; providing ongoing education in management and leadership skills including change management and engage and empower physician leaders to make improvements.

- Provide ongoing physician education specific to the areas of patient safety principles and practice.
- Review provincial legislation both here in Newfoundland and other provinces to look for best practice legislation that will promote active participation in quality initiatives such as mortality and morbidity rounds and provide the highest level protection to the quality assurance committee process.
- Consider developing a new position of physician champion in patient safety and quality with the appropriate investment and remuneration for that position
- Provide appropriate support personnel and tools to enable promotion of quality principles and practice throughout the medical staff organization and activities.

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Submitted by

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Adverse Health Event Management in Newfoundland and Labrador: Avoiding Engineering Error

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Introduction

In accordance with the Government of Newfoundland and Labrador's Task Force on Adverse Health Events mandate to examine the current approach of the health and community service systems in handling adverse health events, the eHealth Research Unit, housed in Memorial University's Faculty of Medicine, offers the following submission. As the mission of the eHealth Research Unit is to engage in research related to the development, use, and impact of information systems in health care in Newfoundland and Labrador, the unit is uniquely positioned to contribute to the discussion. The eHealth Research Unit submits that the scope of consideration for adverse events should be expanded to include a broad spectrum of occurrences of which adverse events are simply the most obvious outcome. Further, the approach to avoiding and remediating such incidents should include Human Factors Engineering practices.

Discussion

Policy evaluation regarding reactions to adverse health events is an essential component in the successful management of critical incidents. However, to develop effective strategies for adverse health event management in community service and health sectors, it is important to consider the full spectrum of circumstances that can culminate in an adverse event. An effective risk management methodology should recognize the continuum of occurrences, with identification and reporting of hazards, near misses, and close calls as well as full-blown adverse events. Patterns of cause precede adverse events.

Industries such as aviation, nuclear power technology, and petrochemical processing have instituted procedures for reporting and investigating near misses or close calls as a vital way to prevent adverse events. By focusing on such warning signs, many more opportunities for learning about and improving management strategies are presented than would be the case if only a relatively small number of adverse events were considered (Barach & Small, 2000). The greater volume of data allows these industries to implement mitigation strategies that prevent rather than react to an adverse event.

Health care systems must address this omission by introducing hazard, near miss, and close call reporting strategies that are confidential, non-judgmental, and non-punitive to provide consistent means to evaluate current practice. As well, increasing the attention paid to human factors in medical environments will better equip health care settings to accommodate the people who work within them and how they work.

Another critical component in efforts to improve patient safety and avoid adverse health events is the implementation of Human Factors Engineering (HFE). HFE seeks to include in the design of work environments mechanisms that support improved provider performance as well as identify means to eliminate factors inherent in the workplace that predispose to error. Therefore, HFE strives to identify and understand the human performance requirements of a work environment and then design systems and practices that accommodate to

those needs. Consideration of human capabilities and limitations is integral in the development of safe, effective, and efficient products, processes, and systems. In practice, human factors engineers design products, technologies, equipment, or procedures to fit the people who live and work in a given environment. The objective is to have the tools and technologies in a given system fit the people working in it, not the other way around (Scanlon, Karsh, & Densmore, 2006). HFE focuses on designing systems to support performance, safety, and efficiency, while reducing predisposition to error.

Despite the maturity of the field of HFE in other industries, it remains under utilized in health care delivery. The irony is that HFE is particularly relevant to health care. That health systems such as community services, hospitals, and clinics must be designed to support performance of providers as well as the safety of patients is clear. Traditional thinking in health care organizations emphasizes the need for health care providers to conform to new work systems through a series of educational opportunities, in-service training, and professional development (change management). In some cases, this change management underestimates the complexity of health care and the considerable experience of the provider that has lead to the behaviour to be changed. In an effort to address this, some health care organizations are now embracing HFE and incorporating its practices into their risk management processes (Karsh, Holden, Alper & Or, 2006). By implementing HFE principles and methods into health care delivery, some health care organizations have begun a proactive shift towards designing

and selecting technologies and practices that best suit system needs rather than imposing the limitations of ill matched initiatives.

In recent years, information technology has been advocated as a solution to errors, specifically in health care. Use of information technology to improve the efficiency of information exchange between providers and the quality of the information exchanged has been touted by some to be the answer to the problems created by a system that still relies predominantly on paper and pen for much of its documentation. This line of thinking presumes that the interaction between the human and the technology will facilitate information efficiency and will suit provision of health care. While in some cases this will be true, evidence is beginning to emerge that poorly designed technology can in fact increase the volume of and efficiency by which errors occur. Empirical evidence demonstrates that errors facilitated by the software can actually increase the potential for mistakes in drug prescriptions and administration (Koppel et al, 2005). It cannot be taken as a given that information technology will be the panacea that some propose in avoiding the spectrum of behaviors that can culminate in an adverse event.

To ensure that information technology use will facilitate prevention of those behaviors that could result in adverse events, the processes through which information technology procurement decisions are made must include explicit evaluation of human factor engineering considerations. In addition to assessing the technology to determine if it meets the needs for which it is being acquired, a

formal evaluation of the technology to ensure that it conforms to the pattern of practice of healthcare providers for which it is intended and that it does not predispose the practitioner to error must be performed. Otherwise, we may find that information technology increases the efficiency and volume of adverse events rather than desired goal of decreasing such outcomes.

Summary

In summary, it is important that the consideration of adverse health events in Newfoundland and Labrador recognize the full continuum of events and include strategies for identifying and reporting hazards, near misses, and close calls as well as full-blown adverse events. In addressing and developing policy to handle adverse events it is imperative that HFE practices are considered so that community and health care systems are equipped to enable our health care providers to deliver quality services in a safe and efficient manner from within a respectful and supportive work environment. Finally, HFE guidelines should be an integral part of future software acquisitions to ensure a good fit with workplace environments as well as to reduce risk of future adverse events within community and health service systems.

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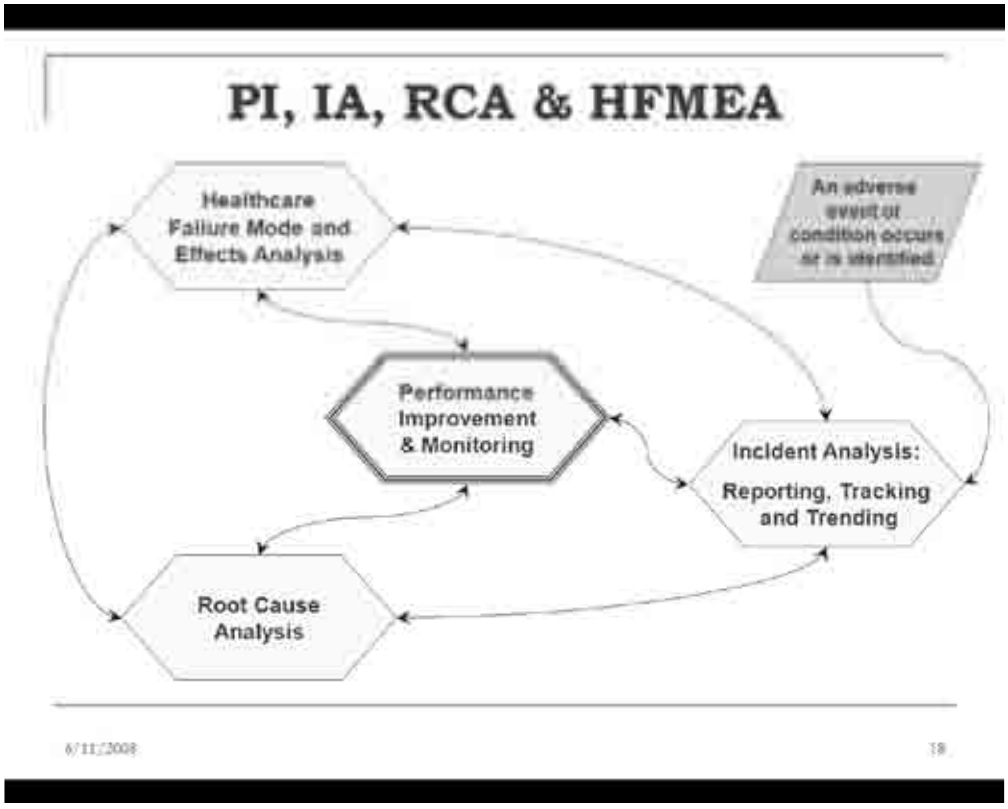
Submitted by

Nevil Ghadially

When considering adverse events, it is important to do so in the context of quality improvement more so than in the context of risk management. The reporting and investigation of an adverse event should be the start of the improvement process and not an end in itself. The most important part should be the tracking and subsequent sharing of the interventions, and the results of the interventions, designed to prevent reoccurrence. Unfortunately, only Saskatchewan (I believe) has mandated root cause analysis on all serious events and failure mode effects analysis gets very little focus in our health system, yet root cause and failure mode hold the greatest opportunities for system improvement.

If I were to express an opinion as to the direction it would be:

1. Electronic collection of adverse events at the point of care – including identification of process failure points
2. Some method of rewarding, rather than penalizing, reporting
3. Export of de-identified events to a provincial data warehouse for research and analysis
4. Root Cause Analysis on all serious events with the causes and action plans monitored for efficacy and shared among all regions – this may require provincial support/training as RCA requires some expertise that may not be available in all locations
5. FMEA's conducted at both the local and provincial level based on analysis of events in the data warehouse.
6. Over time the integration of the DAD (discharge abstract database) combined with collecting of clinical information (diagnosis and procedure) within the adverse event would provide direction for either FMEA or process re-engineering depending on the scope of the issue.



Submitted by

Mary Goss-Prowse

FROM: Mary Goss-Prowse

DATE: June 5, 2008

SUBJECT: Chronology of Katie's Appendectomy

I feel that our daughter's experience with a ruptured appendix due to slow diagnosis would fit your terms of reference. We met with Eastern Health a few months after the event for the sole purpose of bringing their attention to the issue and hoping that procedures would be changed or improved. The representatives of Eastern Health were sympathetic and appeared to want to make changes. We received a letter soon after thanking us for the meeting but did not receive any further follow-up to let us know whether the change occurred. The chronology of the event is attached.

Chronology of Katie's Appendectomy:

Date	Description	Comments/Concerns
2006-02-15	Katie called home from school due to pain in stomach – teacher sent her home because he saw her lying down on her back across 2 desk chairs.	
2006-02-16	Mom left on business trip to Gander – Katie still home – about the same. A bit nauseous then diarrhoea	
2006-02-17	Mom got back from Gander. Katie still home from school – diarrhoea continues	
2006-02-18	(Saturday) Dad working. Both concerned as no improvement. Mom had looked up dehydration and appendicitis on the internet – aware of danger through child care training. Mom took Katie to the Janeway in the afternoon. Dr. Enriques saw her in ER – put her on IV fluids and sent for bloodwork. Confirmed severe dehydration. Kept her on IV fluids till 8 p.m. when second full blood workup would be done. Enriques finished shift at 4 – female doctor from 4 – 6 then Dr. Cooper from 6 onwards. At 8 p.m. after blood drawn, Dr. Cooper suggested going home – that the results might take an hour or more and he anticipated that she would be fine. He suggested that we leave the hep block in so that if she needed fluids the next day we would not need to "re-stick" her. Just come back the next day and if she did not need more fluids the IV could be removed in ER. He wanted her to drink Gatorade. Mom and Katie slept semi-reclined on the couch in the living room (Katie leaning back onto Mom) as Katie was more comfortable in that position.	Neither the female Doctor nor Dr. Cooper came over to examine Katie from 4:00 to 8:00 … not even to introduce themselves. Overheard Dr. Cooper in a conversation with a nurse at the observation room desk – when asked what he was doing on-call on a Saturday evening he replied that he was getting too old to be doing this (on-call). When he came to us at 8:00 to send us home he barely looked at Katie – pressed on her stomach once – brought tears to Katie's eyes – and proceeded to tell us it was dehydration due to severe gastro
2006-02-19	(Sunday) Woke in the morning feeling sicker than the day before. Throwing up bile and bits of Gatorade.	

	Took her back to the Janeway. Triage nurse in ER remarked that Katie had an "appendix walk". She was placed in observation and seen by a resident and an intern. On consultation with the on-call Doctor on Medicine – Dr. Bridger – she was admitted for further observation. Had an x-ray. The resident and intern asked whether she had eaten any nuts or other hard round objects as they had seen two round objects in one position on the standing x-ray and they moved on the lying down x-ray[1]. We told them she hadn't. Given a private room on the Medicine floor. She was very uncomfortable. Diarrhoea continued.	Did not appear to know about Saturday visit. [1]Could these have been appendix "stones" prior to rupture – not recognized because her appendix was not situated in the "so-called" normal place?
2006-02-20	Woke in agony. Said it hurt so much she didn't know what she was going to do. Buzzed a nurse and I think it was Dr. Bridger that saw her. They gave her IM Demerol which eased the pain and helped her sleep. Abdomen distended. Had a decent afternoon. Dr. Akhtar (Medicine) saw her (I think around lunchtime or earlier) and ordered x-ray and ultrasound. She did not appear to know about the Saturday ER visit. This persisted with several doctors. She said that she had called someone from surgery to have a look at her. She had an x-ray (no ultrasound). Had to help her stand up for the standing x-ray. A surgical resident came and looked at her mid-afternoon and Dr. Akhtar (Surgical) saw her later afternoon. Both determined she was non-surgical – severe gastro – even with the distended and taut abdomen. I asked the nurses about the ultrasound on at least 2 occasions – it was never done. Early evening started hurting again. Gave more Demerol. Prior to shot Katie wanted to go to the washroom (she knew that after the shot it was hard to walk). Struggled to the washroom with my support then had the shot and slept.	I am sure this is when the appendix ruptured. Once we were home in March I looked up appendicitis on the internet again … it states that there is extreme pain upon rupture then a period of felling better followed by pain again … textbook for what she went through.

2006-02-21	Woke again in agony. Buzzed the nurse who brought 2 tylenol in a cup. I basically said that she had Demerol all day yesterday – do you think that Tylenol is going to work? She left and sent Jan H (nurse who gave the Demerol the night before) in to give the shot. Again, Katie felt like she was going to have diarrhoea. Jan asked if she wanted to go to the washroom before the shot (as usual). Katie said she was just going to do it in the bed. After the shot Jan went out and the next person we saw was Dr. Mograbi (surgical resident). He asked Katie if he could check her belly. She pleaded with him not to touch it. He promised he wouldn't hurt her. True to his word he laid his hand gently on her belly, looked at Jan and asked her what she (Katie) was doing up here. He left and came back in with a stretcher and Dr. Bridger (surgical resident) – they (and Jan) accompanied us to ultrasound and x-ray. Dr. Bridger was so helpful with Katie – kept her from worrying – joking and telling stories about her appendectomy. Ultrasound first – Dr. Mograbi told them what to look for. Went and brought back Dr. Bridger (chief of radiology) to look at the ultrasound. From there to x-ray. Moving her for the x-ray was torture for her. X-ray wanted a standing up x-ray to complete the series – Katie was terrified that they would make her stand up. Dr. Mograbi refused to make her stand – he said they had enough documentation. Back to her room – met by ICU staff. Started hooking her up to multiple IV lines. Dr. ? (Chief – ICU) pulled me aside – expressed concern – said she was shocky – they wanted to stabilize her before surgery. Once hooked up they took us to ICU where she was prepped for surgery. On the way to ICU the big heavy double doors on ICU shut and banged the stretcher from both sides – with a ruptured appendix this was incredibly painful and Katie started crying and panicing. Instead of allowing us a minute to calm her down they tried to hustle us away so that they could get their stuff done. It was the one time that I lost it … forced them to give me a minute to hug her and	On several occasions both while in the hospital and since discharge, a number of nurses (many paediatric) have stated that it's unheard of to give Demerol for 24 hours to a child for gastro – no matter how severe the gastro. In addition, whether her appendix was situated normally or not, her distended painful belly was clearly an acute abdomen and required – at the least – exploratory surgery. The same surgeon who did her surgery on Tuesday had looked at her on Monday and determined she was not surgical. Noone asked if her belly was always big … she was a flat bellied dancer – she looked 5 months pregnant. Her new family doctor also said the circumstances were highly unusual. Even when time is of the essence, it is sometimes necessary to allow a parent to calm a child – particularly after they just caused her such pain. Katie is still afraid of automatic doors! The waiting area for PICU is woefully

	settle her down and tell her what was happening. Went into surgery at 4 pm – we were shown the waiting room by ICU – pitifully small! One family was already in there. Needed more privacy. Jan offered use of Katie's room upstairs until the surgery was finished or they needed the room. Dr. Mograbi let her know about 1 – 1.5 hours later that things were going well. The anaesthetist wanted to speak with us about the same time. We went downstairs to meet with her. She stated again how well things were going. She had handed off to another anaesthetist as her shift had ended. She made a point of commending Greg and I on our ability to put Katie first and to be very cooperative. The surgery ended about 7 p.m. and Katie was brought to ICU. Dr. Akhtar spoke with us and diagrammed where her appendix was and what the procedure followed had been – involving removal of the appendix and 3 internal rinses of the abdomen to try to get rid of as much infectious material as possible. As he explained there could still be a pocket of infection hidden in the many folds and cavities in the abdomen but he felt that they had done a good job of cleaning the area. He stressed the positioning of her appendix as one of the main reasons for missing the diagnosis. Katie was intubated and sedated when we got to see her. She had a huge amount of fluid retention. ICU staff were great about allowing us to visit as much as possible within the parameters of their work.	inadequate. Far too small and only one phone. This is a time when families need a little space and the ability to use a phone. The night Katie's intubation was removed the nurses arranged a room for us in NICU as there was a storm and nowhere to sleep. What a difference! Clearly the priority for the Janeway is NICU not PICU – the room was at least 3 times larger, painted in a nicer color, chairs, couches and tables along with phones and intercom for the unit. PICU has 2 pull-out chairs wedged side by side with a table between and one extra chair; one phone and a TV mounted high on the wall. There was not room for 2 families (all that was there when Katie was in PICU) … what if PICU was full? Where would the families go???
2006-02-22 to 2006-02-26	In PICU – Dr ? was great about keeping us completely informed of Katie's condition and progress. Was a few days before urine kicked in – had 2 doses of diuretic then began producing on her own. Had the breathing tube removed (big storm day). Had a very rough night the first	

	night – sats very low. At one point needed 50% oxygen. OT regularly visited to use a "thumper" on her chest to prevent pneumonia. Regular x-rays. Lots of antibiotics. Had IVs in both arms and a carotid IV.	
2006-02-27 to 2006-03-03	Moved to constant care room on surgical floor. Same day moved to another constant care room. Nurses commented on the number and high dosage of numerous high quality antibiotics being given IV. Started liquids then solids.	Multiple moves were very disturbing … very difficult for children who need stability and consistency. It is understandable when the level of care changes but not at other times.
2006-03-04	Moved to a private room – told to start getting up and moving as much as possible. Same day around lunchtime they came in to take out the IV in her carotid – which would necessitate lying flat for 12 hours! Not great planning. We suggested taking it out in the evening so that the majority of the "flat"ness was overnight and the nurses agreed.	
2006-03-06	Moved to a 2-bed room	
2006-03-07	Moved to another 2-bed room	
2006-03-08	Discharged	Very little information given about things to watch out for etc. Still have not had any information about possible long-term effects of multiple high dose antibiotics, multiple x-rays; high O^{2}; internal organ effects from the rupture and bile; etc.
2006-03-23	Out-patient check up with Dr. Akhtar. Removed 12 of the 24 staples (every second one). Told to come in to ER if anything was concerning us and to have him paged.	
2006-03-25	Numb area on belly and raised hot and itchy area on both thighs. Dr. Akhtar was in surgery. A surgical resident looked at her and did not think there was anything to be concerned about – the numbness was likely due to nerves cut in surgery. The raised patches appeared to be reactions to injection sites.	Questioned delayed reaction to Demerol injections (over 3 weeks before) – no answer readily available.
2006-03-28	Out-patient – Dr. Mograbi removed remaining staples. Pleased with progress. Confirmed numb area and reason. Discharge chart not transcribed – had been dictated by Dr. Bridger (surgical resident)	Could an ongoing lag in transcription have contributed to the problems with diagnosing appendicitis? There seemed to be a lack of connection
2006-04 (last	Called Dr. Akhtar's office to get a note re inability to complete ballet exam in May.	

week)	Nurse (first day back from mat leave) pulled up Katie's file on the computer – did not even see log of surgery! Actually asked was I sure that the surgery was done on the date I indicated! Transcription clearly behind. Had a record of our original Saturday visit prior to admitting Katie on Sunday.	between the Saturday visit and the Sunday visit with admitting. Were other things not entered in a timely fashion?
2006-08-03	Out-patient check up with Dr. Akhtar. File officially closed.	I wonder if it's transcribed yet?

2008 – May

Two years later Katie is just getting her abdominal strength back – she is a dancer (6 days a week) and I credit that with her getting through this as well as she did.

What did it cost her?

- Loss of a year's exam ballet work – had to take 2 grades together and do 2 exams the following year to catch up with her group.
- A very large and visible scar on her abdomen and stretch marks on stomach and thighs due to water retention after surgery
- She had major surgery and life threatening outcomes for something that should have been diagnosed before the rupture occurred.

Stars in the system: I credit Jan H (nurse) and Dr. Mograbi with saving my daughter's life. Dr. Bridger (intern at the time) was wonderful. These three actually listened to us. Jan saw Katie as a patient, not a chart, and saw the decline in our daughter's status; Dr. Mograbi stood up for us in x-ray and made sure she was seen by those who needed to see her. Dr. Bridger was Katie's friend – she brightened up everytime she came around (even on her days off she stopped in to visit).

Submitted by

Health Canada

FROM: Annette Daley

DATE: June 12, 2008

SUBJECT: Submission to the NL Task Force on Adverse Health Events

Thank you for the opportunity to contribute information to the Task Force that we hope you will find useful in your examination of the management of adverse events in the health system.

Background:
As Canada's federal authority responsible for regulating health products, Health Canada's Health Products and Food Branch (HPFB) evaluates and monitors the safety, quality and effectiveness of the thousands of human and veterinary drugs, vaccines, medical devices, natural health products and other therapeutic products available to Canadians. Within HPFB, post-market surveillance is the responsibility of the Marketed Health Products Directorate (MHPD). With more than 22,000 pharmaceutical products, 42,000 natural health products and 80,000 medical devices on the market, MHPD's creation in 2002 was driven by:

- The need for independent monitoring of health product safety--a distinct function from the pre-market approval process;
- Patients wanting to take more responsibility for their health product decisions;
- The need for more rigorous monitoring of marketed health products as a result of regulatory developments, increased international standardization and cooperation, advances in access to information, and public expectations; and
- The increased potential for adverse reactions and interactions among drugs, health products and food products.

Working collaboratively with other HPFB directorates, MHPD coordinates the monitoring of health products on the market for prompt action when safety risks are identified. It investigates the link between adverse reactions and health products, and determines cause-and-effect relationships. The link between medication incidents and safety concerns with the naming, packaging and labelling of health products are also investigated. Taking the risk tolerance of Canadians into account in its risk management decisions, it then takes appropriate action, ranging from informing the public and health care professionals of new product safety information, to recommending labelling changes or removal of a product from the market altogether.

At this time, we would like to submit three pieces of information

on MHPD's work that we feel may be relevant to the Task Force's investigation:

1. A Health Products and Food Branch (HPFB) working document i) outlining the overall relationship between patient safety related terms from a federal regulator perspective; and ii) clarifying the differences between the terms adverse reaction and medication incident.

(See attached file: Patient Safety Terminology February 2008_v4.doc)

2. Background information on Health Canada's discussions with the provinces and territories on the development of a mandatory adverse reaction reporting requirement for health care institutions for federally regulated health products. Preliminary discussions with all provinces and territories on this issue were completed in May 2008. (See attached file: hospital-based AR reporting bilateral document.pdf)

3. We would also like to provide information about a pilot that is being initiated within our marketed medical device bureau looking at a new pro-active surveillance mechanism to adverse event reporting for devices within health care facilities. This sentinel system approach (soon to be named) would engage a subset of reporters to provide high quality reports of any adverse event encountered with a medical device to Health Canada directly. They, in turn, would be provided feedback which would help them with their quality improvement activities.

(See attached file: Government of NL Task Force on Adverse Health Events. Sentinel project.doc)

MHPD would be happy to provide more information or participate in further discussions with the Task Force on any of these pieces. For additional information on either the patient safety terminology document or on the mandatory reporting issue you can contact Cindy Evans at cindy_evans@hc-sc.gc.ca. For the medical devices pilot project please contact Colleen Turpin at colleen_turpin@hc-sc.gc.ca.

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Health Canada Santé Canada

Your health and safety... our priority. Votre santé et votre sécurité... notre priorité.

MARKETED HEALTH PRODUCTS DIRECTORATE

Patient Safety Terminology*

*This draft document has not been vetted with referenced external organizations

Supersedes:
New Document

Date issued:
Draft: February 27, 2008

Date of implementation:
N/A

Ce document est aussi disponible en français.

Canada

Purpose

A Health Products and Food Branch (HPFB) working document,

1) outlining the overall relationship between patient safety related terms from a Health Canada perspective; and

2) clarifying the differences between the terms adverse reaction and medication incident.

Patient Safety Terms from a Health Canada Perspective

Understanding patient safety key terms is critical as different sources define terms differently resulting in inconsistency and confusion.

As stated by the Royal College of Physicians and Surgeons of Canada (Jan M. Davies, Philip Hébert and Carolyn Hoffman) "If we, as professionals, and as members of society, are to learn from less than optimal events in the health system, then we need to have a common language and understanding of the terms that are central to the enterprise of patient safety."[1]

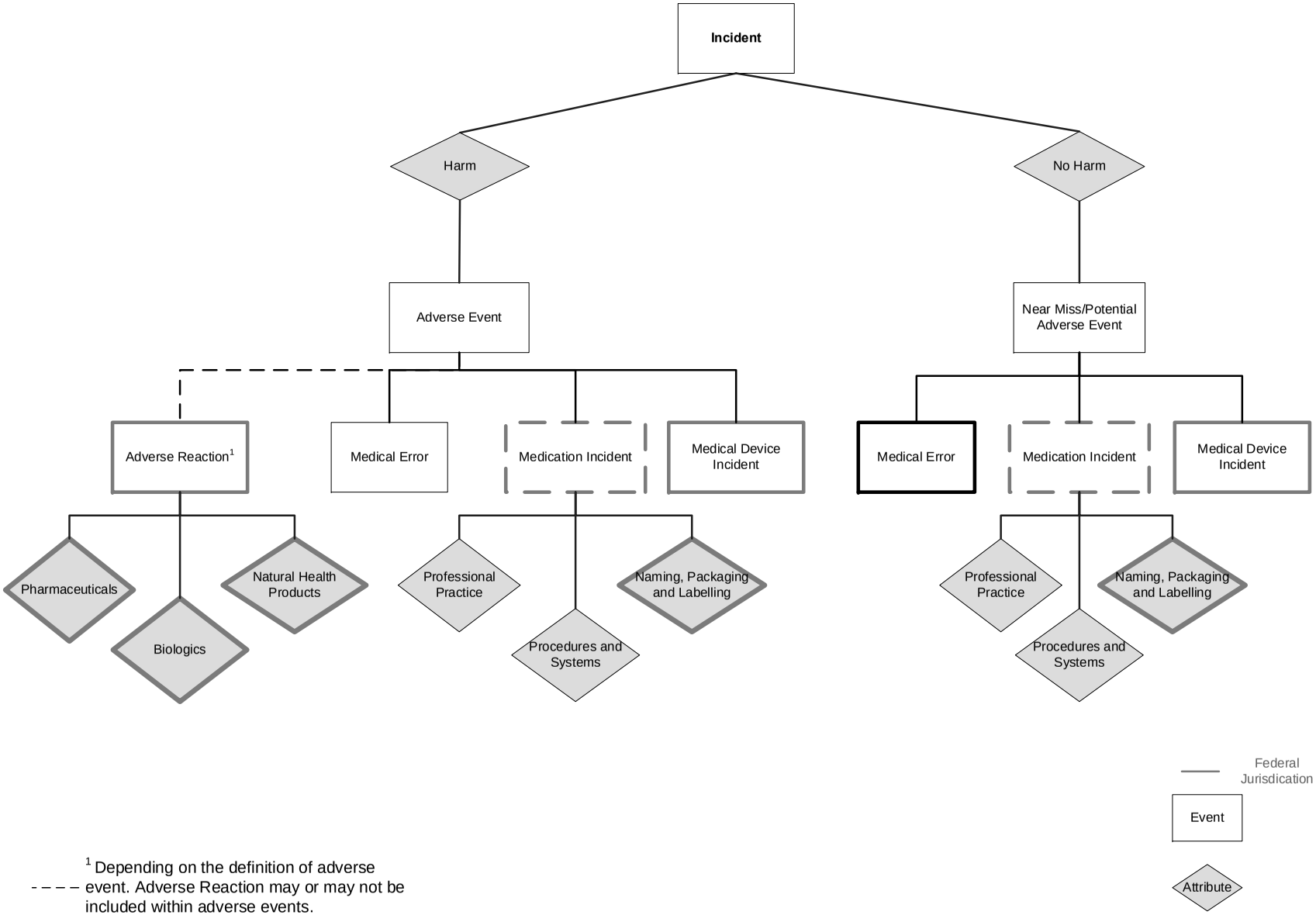
Yu, Nation and Dooley (2005) conducted an electronic search of websites of 160 organizations associated with medication safety, and found 25 different medication safety terms and 119 definitions from 33 organizations. Twenty-one different definitions alone were found for "adverse event".[2] (Refer to appendix 4 for specific examples)

Figure 1 illustrates the overall relationship between patient safety-related terms as they are used by Health Canada. Although this diagram is highly simplified and an adverse event can have more than one cause, it provides an understanding of the responsibilities that fall within the federal jurisdiction. The diagram starts with an "incident" which is defined as an event, process, practice, or outcome that is noteworthy by virtue of the hazards they create for, or the harms they cause patients. For consistency, it is suggested that the definitions of the terms following the diagram be used.

[1] Royal College of Physicians and Surgeons of Canada (Jan M. Davies, Philip Hébert and Carolyn Hoffman, Canadian Patient Safety Dictionary, October 2003, http://rcpsc.medical.org/publications/PatientSafetyDictionary_e.pdf; accessed February 11, 2008

[2] Yu, K.H., R.L. Nation, and M.J. Dooley, *Multiplicity of medication safety terms, definitions* and functional meanings: when is enough enough? Qual. Saf. Health Care, 2005. **14**(358-363).

Figure 1: Overall Relationship between Patient Safety-Related Terms From Health Canada Perspective



Defining Key Terms

Incident	Events, processes, practices, or outcomes that are noteworthy by virtue of the hazards they create for, or the harms they cause patients. (Adapted from the Royal College of Physicians and Surgeons of Canada (Jan M. Davies, Philip Hébert and Carolyn Hoffman, Canadian Patient Safety Dictionary, October 2003, http://rcpsc.medical.org/publications/PatientSafetyDictionary_e.pdf; accessed February 11, 2008)
Harm	An outcome that negatively affects the patient's health and/or quality of life.
Adverse Event	In Health Canada guidelines, policies and procedures, the term adverse event is used as defined in ICH E2D as meaning any untoward medical occurrence in a patient administered a medicinal product and which does not necessarily have to have a causal relationship with this treatment. An Adverse Event can therefore be any unfavourable and unintended sign (for example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to this medicinal product. (International Conference on Harmonization, Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting E2D, November 2003, http://www.ich.org/LOB/media/MEDIA631.pdf, accessed February 11, 2008)
Near Miss	An incident that could have resulted in unwanted consequences, but did not because either by chance or through timely intervention, the event did not reach the patient. Sometimes referred to as potential adverse event. For example, a nurse reports that there are two medications used for refractive eye surgery, both made by the same pharmaceutical company, and both come in similar packaging and the labels are very similar (same colours blue and white) which could easily be mistaken for each other because of similar packaging. This is reported without any harm actually occurring. (Canadian Medication Incident Reporting and Prevention System. Key Definitions for the Canadian Medication Incident Reporting and Preventions System. Ottawa, 2005)
Medical Error	Failure to complete a planned action as it was intended, or when an incorrect plan is used in an attempt to achieve a given aim. For example, wrong site surgery, wrong patient. (Adapted from the Canadian Patient Safety Institute, Canadian Patient Safety Dictionary, October 2003, http://rcpsc.medical.org/publications/PatientSafetyDictionary_e.pdf; accessed February 11, 2008)
Medical Device Incident	Any occurrence involving a medical device which encompasses actual or potential occurrences of device failure. *(Health Canada Guidance Document, Mandatory and Voluntary Problem Reporting for Medical Devices, July 2001)*
Adverse Reaction	Adverse drug reaction as defined in the *Food and Drug Regulations* is a noxious and unintended response to a drug, which occurs at doses normally used or tested for the diagnosis, treatment or prevention of a disease or the modification of an organic function. For example, (1) A patient who

experiences a hypersensitivity reaction to penicillin who was not previously known to be allergic to penicillin; (2) A patient who experiences rhabdomyolysis following treatment with a cholesterol lowering agent (statin).

Adverse reaction as defined in the *Natural Health Products Regulations* is a noxious and unintended response to a natural health product that occurs at any dose used or tested for the diagnosis, treatment or prevention of a disease or for modifying an organic function.

Adverse reaction as defined in the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* is an undesirable response in the recipient to transplanted cells, tissues or organs, including the transmission of a disease or disease agent.

Medication Incidents

Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Medication incidents may be related to drug products, professional practice, procedures and systems including, prescribing, order communication, product naming, packaging or labelling, compounding, dispensing, distribution, administration, education, monitoring and use. The term "medication incident" is synonymous with medication "error", but less "punitive" in its connotation. (Adapted from the National Coordination Council on Medication Error Reporting and Prevention, What is Medication Error?, http://www.nccmerp.org/aboutMedErrors.html; accessed February 11, 2008)

Critical Incident*

A serious adverse health event including, but not limited to, the actual or potential loss of life, limb or function related to a health service provided by, a regional health authority or health care organization. (Saskatchewan, *The Critical Incident Regulations.* 2004, Government of Canada.)

Sentinel Event*

Any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a person or persons, not related to the natural course of the patient's illness. Sentinel events specifically include loss of a limb or gross motor function, and any event for which a recurrence would carry a risk of a serious adverse outcome. (The Joint Commission, Sentinel Event Policy and Procedures, July 2007, http://www.jointcommission.org/NR/rdonlyres/F84F9DC6-A5DA-490F-A91F-A9FCE26347C4/0/SE_chapter_july07.pdf; accessed February 12, 2008)

* Term not included in diagram, but defined for additional clarity

Table 1 further illustrates the differences between the terms adverse reaction and medication incident.

	Adverse Reactions	Medication Incident
Focus	Primary focus of regulatory agencies and post-market surveillance	Primary focus of patient safety organizations and healthcare system stakeholders such as the Canadian Patient Safety Institute and the Institute for Safe Medication Practices Canada
Scope	• Harm directly caused from an administration of a drug. An adverse event of which nature or severity is not consistent with the product information. • Mostly unpreventable, unintended response to an approved health product given at usual doses; result not from an error but from the intrinsic properties of the product	• Inappropriate use of product that may or may not result in harm. • Preventable; a result of the care provided. Prevention results from improvements in the medication use system
Regulatory Applications	Under the *Food and Drug Regulations:* Adverse Drug Reaction Reporting C.01.016, C.01.017; New Drugs C.08.007, C.08.008 *Natural Health Products Regulations:* Reaction Reporting Section 24 (see appendix 1 Adverse Reaction Regulatory Requirements) *Safety of Human Cells, Tissues and Organs for Transplantation Regulations Section 47and 48*(see appendix 1 Adverse Reaction Regulatory Requirements)	Primarily non-regulatory, voluntary (see Appendix 2 – Regulatory considerations relating to health product naming, packaging and labelling) Saskatchewan , Manitoba and Quebec: Mandatory critical incident reporting (see Appendix 3 Provincial Activities)
Nature of reports	• Identifiable information for reporter is required (but not for the patient). • Could be used in a legal proceeding, parts of the report are subject to Access to Information	• Anonymity of reporter is assured. • Reporting of all events are encouraged including near misses • Focussed on systems issues
Management	• Successful management relies upon compliance and enforcement potentially through standards/accreditation process • Benefit-Risk Assessment • Updating labelling can highlight potential adverse reactions and approximate frequency to reduce their occurrence in the future.	• Successful management including changes to health care delivery within institutions relies on building a culture of safety, the development of standards and accreditation through for example the Canadian Council on Health Services Accreditation (CCHSA) • Management of risks due to product naming, packaging and labelling • Root Cause Analysis (RCA) or Failure Mode and Effects Analysis (FMEA)

Examples of Medication Incidents that fall under the Federal Jurisdiction:

Naming, Packaging or labelling

- Manufacturer's label design inhibits proper product recognition and selection. Example: Print size too small, font style is too ornate, expiry dates are unclear.

- Manufacturer's packaging or container design elements that look similar to those of another drug product and inhibit the proper selection

- Sound-alike drug names: The brand or generic name of a drug product is similar in pronunciation (it is phonetically similar) to another drug product. Example: hydromorphone and morphine

- Look-alike (Spelled-alike) drug names: The brand or generic name of a drug product is similar in spelling to another drug product name. Example: Losec and Lasix

More specific examples:

(1) Medication Incident relating to Look-Alike Sound-Alike Health Product name confusion - A patient in labour was administered epinePHRINE instead of epheDRINE. The patient experienced severe hypertension and nausea.

(2) A patient with known allergy to penicillin receives penicillin instead of amoxicillin and experiences a hypersensitivity reaction to penicillin.

Examples of Medication Incidents that fall under the Provincial/Territorial Jurisdiction:

Professional practice, Procedures and Systems

- Abbreviations: Written miscommunication due to the use of abbreviations for information pertaining to the drug product. Example: drug name, dosage rout of administration, latin abbreviations for frequencies such as QD (daily) or OD (once daily)

- Leading zero omitted: Absence of a leading zero in front of a fractionated amount. Example: ".5" may be interpreted as "5"

- Increased workload: Increase in the volume of work that a healthcare provider is assigned or expected to do in a specified time period

- Physical environment: Distractions/frequent interruptions, lighting, noise level, room temperature, workflow design, workspace design

More specific examples:

(1) A physician used the letter “u” for “units”, which was misinterpreted as “0” (zero) by a nurse resulting in a 10-fold overdose error.

(2) Drug D was ordered to infuse at 100 ml/hr, but was administered at 40 ml/hr

Appendix 1: Adverse Reaction Regulatory Requirements

Adverse Drug Reaction Reporting – *Food and Drugs Act and Regulations*

The Food and Drug Regulations (C.01.016, C.01.017, C.08.007, C.08.008), set forth regulatory requirements for manufacturers to report adverse drug reactions and to report unusual failure in efficacy of new drugs to Health Canada.

C.01.016.

(1) No manufacturer shall sell a drug unless the manufacturer, with respect to any adverse drug reaction or any serious adverse drug reaction known to the manufacturer that occurs after this section comes into force, furnishes to the Director
   (a) a report of all information in respect of any serious adverse drug reaction that has occurred in Canada with respect to the drug, within 15 days after receiving the information; and
   (b) a report of all information in respect of any serious unexpected adverse drug reaction that has occurred outside Canada with respect to the drug, within 15 days after receiving the information.

(2) The manufacturer shall, on an annual basis and whenever requested to do so by the Director, conduct a concise, critical analysis of the adverse drug reactions and serious adverse drug reactions to a drug referred to in subsection (1) and prepare a summary report in respect of the reports received during the previous twelve months or received during such period of time as the Director may specify.

(3) Where, after reviewing any report furnished pursuant to subsection (1) and any available safety data relating to the drug, the Director considers that the drug may not be safe when used under the recommended conditions of use, the Director may, for the purpose of assessing the safety of the drug, request in writing, that the manufacturer submit
   (a) case reports of all adverse drug reactions and serious adverse drug reactions to that drug that are known to the manufacturer; and
   (b) a summary report prepared pursuant to subsection (2).

(4) The manufacturer shall submit the case reports and summary report referred to in subsection (3) within 30 days after receiving the request from the Director.

C.01.017.

The manufacturer shall maintain records of the reports and case reports referred to in section C.01.016 for auditing purposes.

New Drugs (C.08.007, C.08.008)

C.08.007.

Where a manufacturer has received a notice of compliance issued in respect of a new drug submission or abbreviated new drug submission or a supplement to either submission, the manufacturer shall establish and maintain records, in a manner that enables an audit to be made, respecting...

(h) any unusual failure in efficacy of that new drug.

C.08.008.

No manufacturer shall sell a new drug unless the manufacturer has, with respect to all the manufacturer's previous sales of that new drug, furnished to the Minister...

(c) within 15 days after the receipt by the manufacturer of information referred to in paragraphs C.08.007(g) and (h), a report on the information received.

Adverse Reaction Reporting – *Natural Health Products Regulations*

The Natural Health Products Regulations under section 24 set forth regulatory requirements for licensees (as opposed to manufacturers).

Reaction Reporting (Section 24)

Section 24.

24.(1) A licensee shall provide the Minister with

(a) a case report for each serious adverse reaction to the natural health product that occurs inside Canada, within 15 days after the day on which the licensee becomes aware of the reaction; and

(b) a case report for each serious unexpected adverse reaction to the natural health product that occurs inside or outside Canada, within 15 days after the day on which the licensee becomes aware of the reaction.

(2) A licensee who sells a natural health product shall annually prepare and maintain a summary report that contains a concise and critical analysis of

(a) all adverse reactions to the natural health product that have occurred inside Canada; and

(b) all reactions for which a case report is required to be provided under subsection (1), that have occurred

(i) during the previous 12 months, and

(ii) at a dose used or tested for the diagnosis, treatment or prevention of a disease or for modifying organic functions in humans.

(3) If after reviewing a case report provided under subsection (1) or after reviewing any other safety data relating to the natural health product, the Minister has reasonable grounds to believe that the natural health product may no longer be safe when used under the recommended conditions of use, the Minister may request that, within 30 days after the day on which the request is received, the licensee

(a) provide to the Minister a copy of any summary report prepared under subsection (2); or

(b) prepare and provide to the Minister an interim summary report containing a concise and critical analysis of

(i) all adverse reactions to the natural health product that have occurred inside Canada, and

(ii) all reactions for which a case report is required to be provided under subsection (1), that have occurred

(A) since the date of the most recent summary report prepared under subsection (2), and

(B) at a dose used or tested for the diagnosis, treatment or prevention of

Adverse Reaction Reporting – *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*

Pursuant to the Safety of Human Cells, Tissues and Organs for Transplantation Regulations, establishments and "source establishments" are required to:

47. (1) Subject to subsection (2), an establishment that is not a source establishment and that has reasonable grounds to believe that an unexpected adverse reaction has occurred must immediately take all of the following steps:

(*a*) determine the donor identification codes of the transplanted cells, tissues or organs;

(*b*) identify and quarantine any other cells, tissues and organs in its possession that could potentially cause an adverse reaction in the same way as the transplanted cells, tissues or organs; and

(*c*) notify the following establishments:

(i) the relevant source establishment, and

(ii) if the cells, tissues or organs were imported, the establishment that imported them.

48. (1) A source establishment that has reasonable grounds to believe that an unexpected adverse reaction has occurred that involves cells, tissues or organs for whose processing it is responsible must immediately take all of the following actions:

(*a*) quarantine any implicated cells, tissues and organs in its possession;

(*b*) send a notice described in subsection (2) to all of the following establishments:

(i) if the implicated cells, tissues or organs were imported, the establishment that imported them,

(ii) any source establishment from which it received the donor referral, if applicable,
(iii) any source establishment to which it made a donor referral, and
(iv) any establishment to which it distributed implicated cells, tissues or organs; and

(*c*) initiate an investigation into the adverse reaction.

Mandatory Problem Reporting – *Medical Devices Regulations*

Pursuant to Part 1, section 59 of the Medical Devices Regulations, manufacturers and importers of medical devices are required to:

59. (1) Subject to subsection (2), the manufacturer and the importer of a medical device shall each make a preliminary and a final report to the Minister concerning any incident that comes to their attention occurring inside or outside Canada and involving a device that is sold in Canada and that
(a) is related to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its the directions for use; and
(b) has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so were it to recur.

Pursuant to PART 2, Section 77 of the Medical Devices Regulations (Custom-made Devices and Medical Devices to be imported or sold for special access) health care professionals are required to:

77. The health care professional referred to in subsection 71(1) shall, within 72 hours after the occurrence of an incident described in section 59 involving a medical device for which an authorization has been issued pursuant to section 72, report the incident to the Minister and to the manufacturer or importer of the device, and specify the nature of the incident and the circumstances surrounding it.

Appendix 2:
Regulatory Considerations Relating to Health Product Naming, Packaging and Labelling

Pre-market:

a) Product naming

Authority is considered to be present to refuse to issue a Drug Identification Number (DIN) (new drugs and drugs other than new drugs) and/or Notice of Compliance (NOC) (new drugs only), as applicable. [see subsection C.08.002.(1), C.08.002.(2), C.08.002.(3) and C.01.014 to C.01.014.3 of the *Food and Drug Regulations*]. Section 9 of the *Food and Drugs Act* may also confer authority. It states *(1) No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.*

b) Product labelling

The *Food and Drug Regulations* require that the written text of all labels and package inserts to be used in connection with a drug be provided in a drug submission as part of the information required to assess the safety and effectiveness of a product.

Specifically, subsection C.01.0141(2)(m) of the *Food and Drug Regulations* states that: *(2) An application under subsection (1) shall be made to the Director in writing and shall set out the following information (among other items):*
(m) The written text of all labels and package inserts to be used in connection with the drug and of any further prescribing information stated to be available on request.

In additions, subsection C.01.014.2 (2) (b) states that: *(2) Where the Director believes on reasonable grounds that a product in respect of which an application referred to in section C.001.014.1 has been made (b) is a drug but that its sale would cause injury to the health of the consumer or purchaser or would be in violation of the Act or these Regulations, he may refuse to issue the document referred to in subsection (1)* (ie. a DIN).

C.08.002(2)(j) of the *Food and Drug Regulations* states that: *(2) A new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following: (j) a draft of every label to be used in conjunction with the new drug.*

C.08.002.1(2)(a) of the *Food and Drug Regulations* states that: *(2) An abbreviated new drug submission shall contain sufficient information and material to enable the Minister to assess the safety an effectiveness of the new drug, including the following: (a) the information and material described in paragraphs C.08.002(2)(a) to (f) and (j) to (l).*

The list of items explicitly set out in the above sections of the Regulations regarding what must be included in the submission is not a *finite* list. The Regulations make it clear, through the use of the word 'including' in the sections quoted above, and by provisions such as that in sections C.08.002(3)(d) and C.08.002.1(3)(d), that the Minister can request any additional information or material respecting the safety of the drug.

Specifically C.08.002(3)(d) (for a new drug) and C.08.002.1(3)(d) (an abbreviated new drug) state that: (3) *The manufacturer of a new drug shall, at the request of the Minister, provide the Minister, where for the purposes of a new drug submission/abbreviated new drug submission the Minister considers it necessary to assess the safety and effectiveness of the new drug, with the following information and material: (d) any additional information or material respecting the safety and effectiveness of the new drug.*

Based on the above, authority is considered to be present to refuse to issue a DIN and/or NOC, as applicable, if proposed labels lead to confusion with another drug, are lacking important safe use information, if confusing/unclear label presentation could result in safety concerns when the product is put to use post authorization, or if any other label-related patient safety issues are uncovered during the assessment of a submission.

c) Product packaging

On a pre-market basis, the authority of the *Food and Drug Regulations* which permit the Minister to request any additional information or material respecting the safety and effectiveness of a new drug, may enable assessment of a product's packaging from a safe use perspective. [Refer to C.08.002(3)(d) and C.08.002.1(3)(d) cited above under labelling].

It is much easier to use the above noted regulatory authorities on a proactive, pre-market assessment basis to the extent that safety issues can be anticipated prior to a product actually being marketed, than retrospectively post product approval. However, since not all safety issues related to product naming, packaging or labelling (NPL) can be foreseen, it stands to reason that some will have to be addressed on a post-marketing basis as well.

Post-market:

Section 9 of the *Food and Drugs Act* which states: *(1) No person shall label, package, treat , process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety. (2) A drug that is not labelled or packaged as required by, or is labelled or packaged contrary to, the regulations shall be deemed to be labelled or packaged contrary to subsection (1),* may confer authority to mandate changes to an approved drug's packaging or labelling if related safety issues come to light post marketing.

The *Food and Drug Regulations* state in section C.01.013: *(1) Where the manufacturer of a drug is requested in writing by the Director to submit on or before a specified day evidence with respect to a drug, the manufacturer shall make no further sales of that drug after that day unless he has submitted the evidence requested.*
(2) Where the Director is of the opinion that the evidence submitted by a manufacturer, pursuant to subsection (1), is not sufficient, he shall notify the manufacturer in writing that the evidence is not sufficient.
(3) Where, pursuant to subsection (2), a manufacturer is notified that the evidence with respect to a drug is not sufficient, he shall make no further sales of that drug unless he submits further evidence and is notified in writing by the Director that further evidence is sufficient.

(4) A reference in this section to evidence with respect to a drug means evidence to establish the safety of the drug under the conditions of use recommended and the effectiveness of the drug for the purposes recommended.

Regulatory authority to mandate change to a drug's NPL once an NOC and/or DIN has been issued by Health Canada is more limited on a post-marketing basis. Upon becoming aware of and assessing a safety concern to determine actual or potential risk associated with the NPL of a drug following issuance of an NOC and/or DIN for a drug, HPFB can use section C.01.013 of the *Food and Drug Regulations* to require the manufacturer to establish the safety of the drug under its recommended uses by submitting, by a specified date, evidence sufficient to establish the safety of a drug under the conditions of use for which the drug is recommended. When sufficient evidence is not so provided, the Director may direct the manufacturer to make no further sales of the drug.

Appendix 3:
Provincial Activities

Saskatchewan

The government of Saskatchewan requires the reporting and investigation of critical incidents in healthcare as of September 15, 2004.[3] A regional health authority or a healthcare organization must report any critical incident within 3 business days after the day of occurrence or it becomes aware of the incident. A critical incident is defined as "*a serious adverse health event including, but not limited to, the actual or potential loss of life, limb function related to a health service provided by, a program operated by, a regional health authority(RHA) or a healthcare organization (HCO)*".[4] The authority or the organization also has to investigate the incident and submit a written report that describes the incident, contributing factors, actions taken and recommendations to the minister of health.

In February 2003, Saskatchewan Health delivered the first Root Cause Analysis (RCA) workshop to facilitate its efforts to promote patient safety in the province. Workshops held in subsequent three years ensured that RCA is exposed all regions. In 2005, increasing demands for the RCA workshop prompted Saskatchewan Health to approach the Canadian Patient Safety Institute (CPSI) for promoting the tool nationally. In collaboration with Saskatchewan Health and the Institute for Safe Medication Practices Canada (ISMP Canada), the CPSI developed the Canadian Root Cause Analysis Framework in 2006.[7]

Manitoba

The Regional Health Authorities and Manitoba Evidence Amendment Act, which became effective of November 1, 2006, requires a health corporation or organization to report any critical incident to the regional health authority, and the authority to notify the minister. A critical incident is defined as "*an unintended event that occurs when health services are provided to an individual and results in a consequence to him or her that*

> *(a) is serious and undesired, such as death, disability, injury or harm, unplanned admission to hospital or unusual extension of a hospital stay, and*
>
> *(b) does not result from the individual's underlying health condition or from a risk inherent in providing the health services*".[5]

In March 2005, Manitoba provided support to its regions to attend the Canadian Root Cause Analysis Framework workshop. Health authorities have begun to implement the method to better investigate and prevent critical incidents. The health authorities in the province are learning from aggregated patient data using Root Cause Analysis and Failure Mode Effects And Analysis (FMEA) to improve patient safety and quality of care.[6] The Winnipeg Regional Health

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[3] Saskatchewan, *The Critical Incident Regulations*. 2004, Government of Canada.
[4] Hoffman, C., et al., *Canadian Root Cause Analysis Framework*. 2006: CPSI, ISMP Canada and Saskatchewan Health.
[5] Canada, *The Regional Health Authorities Amendment and Manitoba Evidence Amendment Act*. 2006, Queen's Printer.

[6] Beard, P. and L. Smyrski, *Reporting for Learning and Improvement: The Manitoba and Saskatchewan Experience.* Healthcare Quarterly, 2006. **9**(Special Issue): p. 61-64.

Authority's Patient Safety Team also had a Human Factors Leader in critical incident reviews and FMEA over the period of 2005-2006.[7]

Quebec

In December 2002, the Quebec government adopted Bill 113 which defines healthcare facilities' obligations on disclosure of incidents and accidents, creation of risk and quality management committee, and on the development of a local registry. The committee is responsible for identifying and analyzing incident or accident risks, ensuring support is provided to the patient, and establishing a monitoring system for the analysis and prevention of incidents and accidents.[7] The regulation also requires every institution in Quebec to transmit an annual report of its activities related to risk and quality management to the Minister.[8]

[7] Winnipeg Regional Health Authority. *Regional Integrated Patient Safety Strategy*. 2007 April [cited 2007 August 10]; Available from: http://www.wrha.mb.ca/healthinfo/patientsafety/ripss.php.

[8] Quebec, *An Act respecting health services and social services*. 2002, Government of Canada.

Appendix 4
Definitions of Adverse Event

Provided below are examples of inconsistencies in the definition of adverse event:

The landmark study on the adverse events among hospital patients in Canada by Baker et al. (2004) defines the "adverse event" as "an unintended injury or complication that results in disability at the time of discharge, death or prolonged hospital stay and that is caused by health care management rather than by the patient's underlying disease process".[9]

The World Health Organization defines adverse event as "Any untoward medical occurrence that may present during treatment with a medicine but which does not necessarily have a causal relationship with this treatment.[10]

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), USA defines "adverse event" as "an untoward, undesirable, and usually unanticipated event, such as death of a patient, an employee, or a visitor in a health care organization. Incidents such as patient falls or improper administration of medications are also considered adverse events even if there is no permanent effect on the patient.".[11]

The Royal College of Physician and Surgeons of Canada, Canadian Patient Safety Dictionary recommends "adverse event" to be defined in one of the following ways

1. An unexpected and undesired incident directly associated with the care or services provided to the patient;
2. An incident that occurs during the process of providing health care and results in patient injury or death;
3. An adverse outcome for a patient, including an injury or complication.

Not only do some definitions refer solely to adverse events relating to medication treatment, other definitions do not consider adverse reactions are included within adverse events. To further complicate matters, professionals and organizations may have their own interpretation of the term.

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[9] Baker, G.R., et al., *The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada.* Canadian Medical Association Journal, 2004. **170**(11): p. 1678-1686.

[10] World Health Organization. *Safety of Medicines - A Guide to Detecting and Reporting Adverse Drug Reactions – Why Health Professionals Need to Take Action*. 2002 [cited 2008 February 11]; Available from: http://www.who.int/medicinedocs/index.fcgi?sid=rQ6TWIlB9ee80ca700000000474e0a12&a=d&d=Jh2992e.

[11] The Joint Commission. *Sentinel Event Glossary of Terms*. 2008 [cited 2008 February 11]; Available from: http://www.jointcommission.org/SentinelEvents/se_glossary.htm.

Provincial/Territorial Bilateral Discussion Document:
A Hospital-Based Adverse Reaction Reporting System

Background

In 2005, Health Canada began consultations with provinces and territories, health professionals, industry, international regulatory bodies and the Canadian public on a set of preliminary issues associated with creating a mandatory adverse reaction (AR)[1] reporting system for health professionals. Health Canada's consultation discussion paper noted that the input received could be used to develop practical options, such as targeted mandatory reporting rather than an all-inclusive requirement, to assess and refine during subsequent phases of consultations.

During the first phase of consultations many stakeholders cited the inability of a broad regulatory requirement to directly address the principle barriers to reporting. However, the Department is currently examining the feasibility and advantages of a hospital-based reporting system as a better way to address the key reporting barriers and increase the reporting of serious adverse reactions to federally regulated health products.

Because health care services are delivered through the provincial and territorial programs, this initiative must be carefully integrated across jurisdictions. With this in mind, the Department intends to consult provincial and territorial governments prior to presenting a more detailed proposal to other stakeholders.

The principal questions at this time are (I) whether a system of hospital-based mandatory reporting would be best placed under federal or provincial regulation, and (ii) whether a non-regulatory approach could be effectively used (e.g. developing accreditation standards for healthcare facilities).

Meeting Objectives

To meet with health officials from provinces and territories (P/T) on a bilateral basis in order to:

- provide an update on results of our investigation regarding mandatory reporting (MR) of ARs by health professionals;
- introduce the plan to investigate a hospital-based AR reporting system;
- learn about whether P/T's have any mandatory reporting systems in place for their hospitals and if so for what issues;
- gage input and views into the feasibility of a hospital-based AR reporting system from P/T's perspective including dynamics such as administration/regulatory oversight,

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[1] An adverse reaction (AR) is a *non-preventable* adverse event and occurs when a patient experiences a noxious and unintended response to a drug, which occurs at doses normally used or tested for the diagnosis, treatment or prevention of a disease or the modification of an organic function. Health Canada collects reports of ARs to pharmaceuticals, biologics (including fractionated blood products as well as diagnostic and therapeutic vaccines), natural health products, and radiopharmaceuticals, in order to monitor inherent product safety, as opposed to errors in the medication process.

compliance and enforcement, and quality of reporting;

Meeting Outcomes

- synthesize P/T input into a discussion document to share for comment from the greater stakeholder community; and
- ensure P/T governments are included in the overall policy development process.

Approach

We suggest that officials be invited from both the Ministries and Regional Health Authorities, with a focus on the Ministries since they may be best positioned to comment on issues concerning regulatory oversight.

Format/Agenda:

A general guideline consists of the following:

- Summary of results for the investigation of MR by health professionals and continuing investigation of a hospital-based AR reporting system;
- Presentation of our hospital-based AR reporting system proposal and consultation plan;
- Posing of a series of questions to stimulate discussion and solicit P/T views on the feasibility of a hospital-based AR reporting system (see Appendix A); and
- Opportunity for P/T officials to ask Health Canada questions and share any experiences (e.g. AR reporting, hospital systems, mandatory reporting systems)

The meeting will be informal and about half a day (3 hours maximum).

Appendix A

Examples of Key Questions/Items for Discussion for Bilateral Meetings:

Introductory remarks

As part of Health Canada's ongoing efforts to improve adverse drug reaction (ADR) reporting, we are investigating the advantages of different models for mandatory reporting, including the feasibility of a hospital-based AR reporting system. An important part of our research involves consulting with provincial and territorial health regulatory authorities such as yourself, our partners in protecting the health of Canadians, to gain your feedback and insights on the feasibility of a hospital-based AR reporting system. Your views are extremely important in helping us determine the best course of action in the pursuit of this investigation.

Items for Discussion

Value and Impact of Proposal

- What is your initial reaction to our proposal for a hospital-based AR reporting system?
- Could you see your jurisdiction supporting this proposal?
- What features of a hospital-based AR reporting system might increase the likelihood of success (i.e. increasing quality and quantity of serious AR reports from health facilities)?
- From your perspective, what would be the key challenges in developing and implementing such a reporting system?
- What barriers might exist to implementing this system broadly and consistently across jurisdictions?

Linkages to Health Facilities

- What types of hospitals do you think should be included in such a system (e.g. all hospitals, acute care hospitals, hospitals with over x number of beds, other)?
- Do you see any opportunity in building our proposed system upon existing reporting infrastructures present in hospitals?
- Is there an opportunity to share with us any cost/impact assessments developed for existing reporting systems? (e.g. critical incident reporting)
- What are some of the problems we might encounter in clearly defining these facilities?

Regulatory Oversight and Administration

- In terms of regulatory oversight, in your opinion what would be the best approach (e.g. federal regulation, provincial regulation, a non -regulatory approach such as standards/guidelines or other)?
- In terms of administration, how would you see the role of provincial health authorities and the Ministries themselves? How about Health Canada (NCR and Regions)?
- What are the issues around promoting and monitoring compliance as you see them?

Quality of Reports

- Do you have any thoughts of how we could encourage high quality reports (e.g. accreditation)?

Final Thoughts

- What advice would give to us as we continue our investigation?

Prepared by: Derek Wade
October 29, 2007
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Government of NL Task Force on Adverse Health Events: Call for Submissions
Date: June 13th, 2008
Submitted by:
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Project Manager
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Task Force Questions:

1) How can we improve the current approach used by our health and community services system to manage adverse events?
The Task Force could investigate a new pro-active approach offered by Health Canada for reporting medical devices adverse events. A pilot to use a sentinel approach (subset of health care professionals who report and act as 'guards' for all) to post market surveillance for medical devices is currently being planned by Health Canada for 2008-2009.

We are looking for volunteer user facilities, acute or community based within Canada, to participate in reporting any adverse event or 'near misses' to Health Canada that occur with any medical device within your organization. This will help us better understand how organizations use devices, how problems are perceived and reported, and what characteristics of the system contribute to a particular event to potentially mitigate risk at an earlier stage.

Participation in such a pilot would help the facility by:

- further developing its quality management/risk management approach to medical devices safety
- learning from 'near misses'; incorporate into own quality assurance activities
- creating/further developing infrastructure/mechanisms/policies/communication tools for adverse event reporting that could be used for other health care products
- impacting manufacturing processes or licensing requirements or assisting in own purchasing processes
- having access to awareness campaigns/education; providing information to front line users about safe medical device usage and reporting
- avoiding duplication of reporting; report would be provided to manufacture/other governmental agencies as needed
- creating a communication link with Health Canada; being privy to early warnings and participating in auditing of devices prior to failure or events within your facility
- developing a sense of community with other Sentinel users, mechanism to share information with other facilities.

2) In particular, are there gaps in how the system identifies, assesses, discloses, and takes action on adverse events?

MHPD is unaware of any gaps that are particular to the NL health system but has identified a lack of standardized reporting infrastructures within other facilities across Canada.

A variety of different processes within facilities have been encountered while investigating the background for this project. Typically there is some structure on how serious adverse events, particularly medication errors or falls are handled within institutions and reported upwardly to the corporate organization. There are less formalized processes around other health products and particularly medical devices if the outcome of the event was not of a serious nature. The collection of similar events to identify potential wide spread problems and/or warnings to other departments as 'lessons learned' happens less frequently. The distribution of equipment recalls, advisories from Health Canada and development of associated action plans are inconsistent across organizations.

Participation in the sentinel pilot for reporting adverse events from medical devices may provide structure where none existed before, or support current mechanisms that are already in place. There are opportunities here to obtain the same goals but flexibility in how to obtain them.

3) Are there gaps in how the system coordinates and communicates when it is managing an adverse event?

Within facilities across Canada, the distribution of equipment recalls/device advisories and development of associated action plans are inconsistent across organizations. Some facilities do this well but use foreign reports more so than domestic information. This may result in needless work to prepare action plans to recalls/advisories that may not affect the Canadian marketplace.

Provincially there may be mechanisms to report centrally, but MHPD is unsure if there are processes to provide the facility with information back about the event that has been reported. Potential areas of feedback that are being considered for the sentinel systems are regular newsletters, early notification of recalls/advisories, and warnings about other reports received at other sentinel reporting sites to determine the magnitude of problem. This will provide methods to pro-active surveillance for medical device problems within your institution.

Participation in the sentinel pilot for reporting adverse events from medical devices will provide early access to information about potential issues with devices on the Canadian market. This coordinated effort in communication may assist in the safe use of medical devices within the organization.

Recommendation: Task Force to investigate NL's participation in the pilot project for a sentinel system for medical device adverse event reporting.

Background (from Sentinel Business Case/internal document Health Canada/2008):

Introduction

Canadians consume over $3 billion in medical devices annually. There are over 80, 000 devices currently licensed for sale in Canada (MDS, 2008). Medical devices are largely based on technology. As advances are made in technology, the number of devices and their complexity will increase. For these reasons, it is expected that the medical devices industry will continue to grow in the future, both in size and in importance.

The increasing complexity of medical technology, perhaps coupled with economic pressures and organizational change within health care institutions, increases the potential for unanticipated and unintended consequences. Adverse medical device events have found to occur 83.7 times per 1,000 US hospital admissions (Samore et al, 2004). Hospitals have internal reporting systems but the information is rarely shared with other institutions, so the impact on improving medical device safety is limited.

These changes demand that surveillance of marketed devices moves from a reactive to proactive stance. This proactive strategy includes an understanding of how organizations use devices, how problems are perceived and reported, and what characteristics of the system contribute to a particular event.

Problem Statement

Health Canada's Marketed Health Products Directorate (MHPD) has insufficient post-market surveillance tools and limited information sources to adequately monitor, assess and identify safety issues with marketed medical devices.

Current problem reporting for medical devices relies on a system of spontaneous reports from all sources, and mandatory reporting by manufacturers and importers of medical devices. Despite these measures, which may be characterized as 'all data' or universal reporting systems, there are recognized deficiencies in the quantity and quality of information gathered about the effectiveness and safety of marketed devices

Voluntary reporting rates for medical device adverse events have been historically very low in Canada (317 in 2007 compared to 4624 mandatory reports received in our Canadian reporting system- MDS) and, as a result, the Auditor General (2004) states that Health Canada is not able to adequately identify adverse events via this passive surveillance system.

In contrast to universal data systems, sentinel systems are an alternative strategy designed to increase the quantity and quality of problem reports from a subset of user facilities. Through training and education, sentinel reporters deliver high quality data which is more sensitive and timely, and which permits proactive interventions.

Current Situation

Currently, Health Canada requires that manufacturers and importers of devices make preliminary and final reports to Health Canada concerning any incident involving their device that:

a) is related to the failure or deterioration of the device or inadequacies in the labelling or directions for use; and

b) has led to the death or serious deterioration in the health of a patient, user or other person; or could have led to a death or serious deterioration in the health of a patient, user or other person.

The Inspectorate is responsible for compliance and enforcement activities such as monitoring recalls of medical devices as they pertain to the mandatory reports received. Medical Devices Bureau (MDB) is responsible for the pre-market evaluation and licensing of the medical devices. MDB also plays a role in safety surveillance; they have a health hazard evaluation unit comprising of a lab and evaluators.

MHPD evaluators monitor the recalls, mandatory and voluntary reports in the MDS database for emerging safety trends. This risk assessment activity is encumbered by receiving belated, vague and incomplete information.

What is a Sentinel System?

A Sentinel system uses a group of dedicated, trained user facilities to report high quality data about adverse events associated with medical devices to the regulator. Through the review of this rich data source, the post market evaluators will be able to look for emerging safety trends. The safety of Canadians will be impacted by better quality risk assessments and earlier regulatory interventions. Providing citizens with timely information to make informed health choices will help them maintain and improve their health.

A Sentinel system will be an important source of product safety evaluation and provide:

- this pro–active surveillance approach fulfills AG's recommendations for MDP program
- delivers high quality reports about adverse events of medical devices, creating an early warning system for emerging safety trends
- produces better quality risk assessments and earlier regulatory interventions; providing citizens with timely information to make informed health choices will help them maintain and improve their health
- creates awareness of hospital staff not to be complacent about device problems that stimulates reporting to HC and manufacturers
- quality improvement information gained from sentinel alerts could be transferable to institutions
- supports Branch objective to use similar approach to post market surveillance as other international regulators; opportunity to share information
- user 'clinical community' rather than manufacturer relationship driven process
- may provide for safer product development and licensing in the future

One major benefit of a Sentinel system is that this pro-active strategy will provide a better understanding how organizations use devices, how problems are perceived and reported, and what characteristics of the system contribute to a particular event to potentially mitigate risk at an earlier stage.

Scenario

This initiative would include an on-line report form for the users to enter adverse events, a repository for the reports and adequate evaluation resources to complete and code reports while looking for emerging safety trends to report potential post market signals to MHPD evaluation staff on a regular basis. These reports are transferred to the universal reporting system for medical devices (MDS) to share with our partners in Medical Device Program (MDP). The reports would also be shared with the manufactures eliminating the need for facilities to duplicate reporting. Various types of feedback could be trialed in the pilot so as to determine best value to provide incentive for reporting.

Conclusion:

MHPD would be happy to provide more information or participate in further discussions with the Task Force or any other group that is interested in this sentinel project in the future.

Annex A: Acronyms

AE- Adverse Event
AG -Auditor General
FDA- Food and Drug Administration
HC- Health Canada
HPFB-Health Products and Food Branch
HPFBI- Health Products and Foods Branch Inspectorate
IM/IT- Information Management/Information Technology
MDB- Medical Devices Bureau
MDP- Medical Device Program within Health Canada (pre market, post market, inspection/compliance & enforcement bureaus)
MDS- Medical Device System (Health Canada's Medical Device application/licensing/incident tracking system)
MHPD- Marketed Health Product Directorate
MPMDB- Marketed Pharmaceuticals and Medical Devices Bureau
OIMT- Office of Information Management and Technology
US- United States

Annex B: Glossary of Terms

Act

"Act" means the *Food and Drugs Act*.

Adverse Event (AE)

In Health Canada guidelines, policies and procedures, the term adverse event is used as defined in ICH E2D as meaning any untoward medical occurrence in a patient administered a medicinal product and which does not necessarily have to have a causal relationship with this treatment. An Adverse Event can therefore be any unfavourable and unintended sign (for example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to this medicinal product. (International Conference on Harmonization, Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting E2D, November 2003, http://www.ich.org/LOB/media/MEDIA631.pdf, accessed February 11, 2008)

Device

"medical device" means a device within the meaning of the Act, but does not include any device that is intended for use in relation to animals.

Evaluator

Person performing the evaluation of the post market signals; also reviewer.

Health Care Facility

"health care facility" means a facility that provides diagnostic or therapeutic services to patients. It includes a group of such facilities that report to one common management that has responsibility for the activities carried out in those facilities.

Health Care Professional

"health care professional" means a person who is entitled under the laws of a province to provide health services in the province.

Manufacturer:

"manufacturer" means a person who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

Post-Market Surveillance

The continued monitoring for, and the study of effects and other safety and effectiveness related aspects of health products that have been marketed to the public.

Recall

"recall" , in respect of a medical device that has been sold, means any action taken by the manufacturer, importer or distributor of the device to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device

(*a*) may be hazardous to health;

(*b*) may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety; or

(*c*) may not meet the requirements of the Act or these Regulations.

Signal

Refers to 'reported information on a possible causal relationship between and adverse event and a health care product, the relationship being unknown or incompletely documented previously'. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information

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Submitted by

Independent Living Resource Centre

Independent Living Resource Centre

ADVERSE HEALTH EVENTS

Submitted to: ***The Task Force on Adverse Health Events***
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Independent Living Resource Centre (ILRC)

The Independent Living Resource Centre (ILRC) is a resource centre designed by and for people with disabilities. The centre is open to anyone with any type of disability and of any ages. We offer a wide range of disability related information, services and resources. Our goal is to support people living with disabilities in making informed decisions about their lives.

Independent Living (IL) History

The Independent Living movement arose from the opposition to the institutionalisation that many people with disabilities once faced. The institution, born from a paternalistic impulse and an over-reaching medical view in which a person is transformed into a patient, provided a rigidly controlled life that was separate from the community. Simply stated, Independent Living can be understood to be the institution's exact opposite.

The Independent Living (IL) philosophy is based on the premise that all people with disabilities have skills, determination, creativity and a passion for life. The IL philosophy also acknowledges that many people with disabilities are still today unable to fully participate in the economic, political and cultural life of community because barriers to full citizenship persist in Canadian society – outdated attitudes, inflexible laws and regulations, and fragmented and uncoordinated approaches to everything from disability related supports, to housing, to public transportation, to access to health care services. The IL philosophy is not an abstract concept. Instead, it is about a "way of living" as a person with a disability in a society full of barriers, an ongoing dynamic process that addresses the intersection between barriers, gaps, skills and supports at both an individual and systemic level.

Pre-amble

One of the words that call us back to our existence within the institution is the word patient. We prefer to call ourselves consumers. The word consumer is, first of all, a word we have chosen. In opposition to the word patient, a word with overtones of dependence and passivity, the word consumer emphasizes our role as *active* and *informed* consumers of products, programs and services. We are consumers of disability related supports, and we are consumers of health care services.

Words are important. We are not only replacing one term with another, we are changing our role and our expected contribution. The first reality we are facing in the current health care system is simultaneously it's most challenging and promising reality – the changing role of the 'patient.'

There is a lesson to be learned from the story told by people living with disabilities (hereafter *consumers*). Its theme you will see in each of the areas of this report. As we have moved beyond definitions that confine us within our disability, so the 'patient' is moving beyond their limited role as receiver of care. In the eyes of a government that promotes an open and participatory citizenship, we need a cooperative approach that values everyone's place within the system. For alone, no one person can hope to make perfect decisions, but together, we can hope to make good decisions arrived at with transparency and respect.

Introduction

In preparation of this submission to the Task Force on Adverse Health Events the ILRC ensured that consumers had an opportunity for their voice to be heard. The ILRC facilitated a focus group of 27 consumers, to discuss how the health care system identifies, assesses, discloses and takes action on adverse events, as well as their experiences and recommendations of how effective communication can facilitate this process. The attached list of questions was used as a template to lead the discussions. Please see Appendix "A."

1. a) "I can usually identify a problem."

• Consumers want to have the opportunity to identify adverse health events.

b) "I want any problems dealt with by the person in my health care directive. After all, I've chosen that person because they are knowledgeable and I trust them."

• Consumers with advance health care directives have planned for the possibility that they will be unable to control the course of their treatment. Under these circumstances, they have selected a substitute decision maker that will identify adverse health events on their behalf.

c) Many consumers noted that they had identified an adverse health event – such as inappropriate treatment in the emergency room – but there was no record of it in their chart.

•Consumers often identify adverse health events to their health care providers. In this case, consumers want the identified adverse health event to be marked and noted in their charts. There needs to be a record or paper trail that draws attention to the adverse health event.

d) "My rehabilitation specialist is the 'only game in town.' I don't feel comfortable challenging him again and again. I need these services for life."

•Some consumers do not feel comfortable identifying adverse health events to their health care provider. Often in these cases the consumer is dependent on the service provided by that particular health care provider. It may be that the health care provider is the only specialist that provides that particular service to the consumer, the consumer lives in a rural area served by one main health care provider, or the consumer relies on treatment from that health care provider for the rest of their life.

e) Consumers need an alternate *safe* way of reporting adverse health events, especially when there is a dependence on the one health care provider.

•In these cases, it is still essential to give the consumer the opportunity to identify possible adverse health events, while allowing the consumer to maintain anonymity, at least in the eyes of the health care provider in

question. Again, there should be a record and paper trail of the identified adverse health event as said trait helps coordinate a response, and ensures that the consumer's identification of the adverse health event is acknowledged.

2. a) Consumers have indicated instances where secretaries for doctors have prevented a potential adverse health event.

•Adverse health events should be identified by whichever health care provider discovers it. If any health care provider identifies an adverse health event, they should notify the main health care provider immediately. Again, the identified adverse health event needs to be recorded and documented. The goal is to minimize harm to the consumer.

b) "...Nurses may be the ones to identify the problems but they have no say... doctors find it offensive that...nurses could even question their judgement."

•Some health care providers may not feel comfortable identifying adverse health events, especially if they work under the supervision of the main health care provider. A system that promotes identification of adverse health events by *any* health care provider, regardless of rank, is essential. Anonymity would ensure that the subordinate health care provider is protected and feels safe enough to identify adverse health events.

3. "I was perched high up, when they gave me a needle. They didn't make sure I was safe and I nearly fell."

•Consumers have identified that lack of accessibility has led to adverse health events or potential adverse health events. Exam tables are notoriously inaccessible. In particular, it can be difficult for wheelchair users to get on or off the tables. Add to that the increased difficulty consumers face when they have broken limbs or are experiencing dizziness. Consumers have indicated that it makes them feel unsafe.

4. "You have to be persistent."
"Yes, you have to be persistent in advocating for everything. Sometimes...I feel so tired."

•Consumers have had to repeatedly identify what they need if they are to avoid an adverse health event. Their required persistence implies that they are working against attitudes that are pervasive in the system.

These systemic attitudes endorse the belief that the health care provider always knows what is best for the consumer. The experience that the consumer has gained through living with their disability, and how that experience informs their knowledge of their required health care is not sufficiently valued.

Assessment & Adverse Health Events

1. a) "There is pressure placed on me to just get in a chair and give up trying to walk.

•Consumers' assessments of their health care delivery and the health care providers' assessments of the same often vary greatly. The gap between the two may lead to the suppression of an adverse health event as identified by the consumer. Health care providers should try to see the consumer's point of view.

b) "I think the provincial government should hire two or three 'patient' advocates, with the autonomy to report problems."

•Consumers who face this gap often feel frustrated, invisible and powerless. To overcome this obstacle and to help with the unpleasant feelings evoked by this dissonance, consumers indicate that they would like to have access to a 'patient' advocate. This advocate would represent the interests of the consumer and furthermore, should have knowledge of the independent living model and the disability rights movement. Supplying this advocate for the consumer is essential as it provides them with the support necessary to share what is often a difficult story.

c) When consumers have a contribution to make, and when that contribution is nurtured and valued, the system is improved.

•Involving consumers in the assessment of their health care delivery will not only increase the responsiveness of the health care system, but it will also increase the public sense of confidence in that same system. Ultimately, by providing support to consumers, they can share the wealth of knowledge they have with their health care providers. Consumers move beyond the role of patient and into the role of a contributing peer.

2. "I told my doctor the equipment was inappropriate, but my opinion was not valued. I only received new equipment after showing him the

sores."

•Often, a consumer's assessment of their treatment is only taken seriously when they have proof in the form of an adverse health event. In this case, the adverse health event is usually physically observable; if it were not so, the consumer would probably continue to endure the underlying cause of the adverse health event – the health care provider's reluctance to acknowledge the consumer's insight into what constitutes appropriate treatment.

3. a) "The doctor took one look at me and said my headache was because of my shunt, when I didn't even have one."

•A consumer's disability often skews the assessment of the health care provider. Often the assumptions of the health care provider put the consumer at risk for an adverse health event.

b) "Upon reporting to the ER with chest pains, I had to insist that they remove the mental health label from my chart, and then I had to insist they classify my insistence as something other than agitation brought on by my mental health concerns."

•Consumers of mental health services experience this time and again. They may present themselves to an emergency room with a concern unrelated to their mental health, but upon disclosure of the medications they are taking, "mental health" is written across their file as their reason for visiting the ER. The effect of this assessment is two-fold. First, the wrong focus may lead to inappropriate or delayed treatment that causes an adverse health event. Second, the consumers increased stress while confronting these assumptions is in itself an adverse health event.

c) "Because of my disability, my specialist may say that there is no treatment as the symptom is related to my disability. I discover later that there is a treatment and that more investigation could have shown it. "

•A consumer's disability can cause tunnel vision in the health care provider. Their assessment may relate many or any symptoms to the consumer's disability when another underlying cause may be responsible. Sometimes the health care provider may not treat the symptoms, as they believe the symptoms are caused by the disability, which may have limited treatment options. Again the consumer experiences an adverse health event, one filled with discomfort and pain.

Disclosure of Adverse Health Events

1. Most consumers have never had their health care provider disclose an adverse health event; however, most consumers have identified that they have experienced an adverse health event. This gap needs to be addressed if consumers are to regain their faith in the current health care system.

2. Consumers recognize that disclosure should occur as soon as possible, that it should be delivered by the most appropriate – often main – health care provider, and that it should be done face to face.

3. Consumers also acknowledge that an apology goes a long way. It lets the consumer feel human again.

4. Consumers realize that health care providers make mistakes and that the health care system may occasionally produce an adverse health event. It does not serve the health care provider or the health care system to deny this fact. Consumers would be more sympathetic towards their health care providers if they acknowledged their failures.

Evaluation & Response to Adverse Health Events

1. a) One consumer who had lost his leg because he received the wrong medication says he still does not know if he had to lose it. There was no evaluation after the fact.

•Consumers have noted that they often fail to see a response to their adverse health event. It may be that the current reporting system prevents the identification of the adverse health event in the first place. It is also possible that the response to the adverse health event and the system that evaluates what an appropriate response should be does not include the consumer as an active and important decision maker.

b) "I have had to walk in on consultations about me that were never meant to include me."

•At a more fundamental level, evaluations and multi-party consultations between health care providers about consumers have been carried out without the attendance of the consumer. If consumers are not included in their own evaluations, what chance is there that they will be involved in a more general and systematic review?

2. Transparency of the entire process is essential.

•The response should be observable and its rationale explained to the consumer it concerns. If the response has occurred 'behind the scenes,' then an explanation of how the response will help prevent similar adverse health events in the future is needed. In short, if you involve the consumer and respond to them, you create a health care system that is respectful and responsive.

3. "I had to bring a TV crew to my appointment to document the inaccessibility of the facility and the procedure. I received an apology, but nothing has changed."

•Some consumers have received written apologies for inaccessibility, only to discover that the facility they attended and the treatment they received are still inaccessible. Similarly, consumers have indicated that they have encountered the same adverse health event again and again (ex. continually being turned away from the ER when reporting as a consumer of mental health services). Consumers need to know that neither they nor their peers have to continually face the same obstacles over and over.

4. "Do you know what it is like to walk in my shoes?"

•The health care provider should have training that allows them to see the situation from the consumer's perspective. As well, the process for evaluating health care professionals should try to ascertain what role they believe the consumer should play. This evaluation itself needs to respect the consumer and allow them to play a role. Involving the consumer as an active and important member of a transparent evaluation process will lead to a more appropriate response to adverse health events.

Communication and Adverse Health Events

1. Communication plays a very important role. Effective channels of communication can;

- prevent an adverse health event
- ensure fewer adverse health events go unreported
- decrease the impact of an adverse health event by increasing the support provided to the consumer during the process

2. To ensure effective communication with consumers, health care providers should speak in plain language whenever possible, provide information in whatever format the consumer identifies and remember to speak to the consumer and not their attendant.

3. "They tried a brace and that didn't work, they tried popping it back in and that didn't work, they talked about surgery but nothing has happened. Now they don't say anything."

   •Health care providers do not handle failure well, and it is disappointing that communication often breaks down after an adverse health event occurs. Consumers want to feel that they matter and that they are important. Often all it takes to help the consumer feel respected is for the consumer and their situation to be acknowledged.

4. Sometimes adverse health events have happened due to language barriers. Readily available sign language interpreters are essential for persons who are deaf to ensure that what they are communicating is understood and the information they are receiving is accessible.

Appendix "A"

Adverse Health Events
Questions to lead discussion

1. Who ***identifies*** problems that occur during Health Care Delivery? You? Your family? Government? The media?
    1. Do you feel comfortable ***identifying*** a problem you have encountered during Health Care Delivery? Would you feel more comfortable identifying the problem after the fact?
    2. Do you feel comfortable with your family ***identifying*** a problem with your Health Care Delivery?
    3. Do you feel comfortable with the Provincial Government ***identifying*** problems during Health Care Delivery? Should they have a greater or lesser presence in the identification process?
    4. Do you feel comfortable with the role of the media in ***identifying*** problems that occur during Health Care Delivery?
    5. Are there appropriate channels through which one can ***identify*** problems occurring during Health Care Delivery?
    6. What would make ***identification*** of Health Care Delivery problems easier?

2. Does your ***assessment*** of your treatment match your health care provider's ***assessment***?
    1. If there were discrepancies between the two ***assessments***, were you taken seriously? Were there other channels to turn to?
    2. How could the ***assessment*** of problems that occur during Health Care Delivery be improved?

3. Has your health care provider ever ***disclosed*** a mistake or omission in treatment?
    1. Was this ***disclosure*** handled properly? Respectfully? Promptly?
    2. After this ***disclosure***, were you informed of your options? Did you feel that you had any options?
    3. How would you feel if this ***disclosure*** was not provided to you first?
    4. Whose responsibility is it to see that ***disclosure*** occurs?

4. Was there a ***response*** to the problem that occurred during your treatment?
    1. What was the ***response***?
    2. Was the ***response*** appropriate?
    3. Did the ***response*** come quickly?
    4. Was the ***response*** observable? If not, were the "behind the scene" ***responses*** explained? Was the process transparent?
    5. Do you think the ***response*** was effective? Do you think that someone else would still encounter the same problem? Have you ever faced the same problem again and again?

5. Do you think the lines of ***communication*** were open during your experience?
    1. Was information ***communicated*** to you effectively? Quickly? Completely?
    2. Did you notice failures of ***communication*** between health care providers? From nurse to nurse? From nurse to doctor? From doctor to nurse? From doctor to doctor? From doctor to lab? From lab to doctor? From doctor to rehabilitation specialist? Between specialists?
    3. What should be done when lines of ***communication*** fail?
    4. Whose job is it to ensure effective ***communication*** occurs?

6. Was there an ***evaluation*** of the entire process?
    1. Was it respectful? Effective? Transparent?
    2. Were your rights the central concern of the ***evaluation***, or did you feel left out of the process? Was it responsive to your input?
    3. Was there an opportunity to review the ***evaluation*** process? Was it unbiased? Was it done by a third party?

7. Why do you think these problems arise during Health Care Delivery?
    1. Was your input actively sought at each stage of the process?
    2. What questions/concerns would you address to the Premier? Minister Ross Wiseman (responsible for The Department of Health & Community Services)? The Task Force on "Adverse Health Events" (i.e. Problems that occur during Health Care Delivery)? Eastern Health and other Regional Health

Authorities? Doctors, Specialists, Nurses?

3. What needs to happen to ensure we have the best possible Health Care system?
4. Should there be a well defined "Quality Control System"?

Submitted by

Lorraine Michael, MHA
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Loretta:
Pls note as a submission.
Lf

JUN 1 2 2008

HOUSE OF ASSEMBLY
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June 11, 2008

Dear Mr. Thompson:

I am glad to have the opportunity to communicate with the Task Force on Adverse Health Events. I understand that the Task Force is looking at how the system identifies, assesses, responds to and communicates adverse events, and that it will identify gaps and recommend a new framework for managing adverse events

I also understand that the Task Force is reviewing best practices across Canada in governance, quality, risk and patient safety, and that your review includes Calgary Health Region, as described by its VP of Quality and Safety at your forum on May 26th.

It is interesting that Calgary Health policies grew out of their own experience of adverse events as well as a review of international best practices. They appear to have put in place excellent procedures for reporting, disclosure, patient support and communication, and established a culture of safety to minimize adverse events.

It is also impressive that they have become more supportive of patients, families and health care providers, for example, creating a disclosure team of doctors, administrators and a patient representative, offering counselling and financial aid for families, and setting up a system for supporting those who report hazards and adverse events.

These innovations are worth introducing in this province. I urge your Task Force to give them, and any comparable practices you may have encountered, serious consideration as the basis for your recommendations.

Sincerely,

Lorraine Michael

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Submitted by

Newfoundland and Labrador Association
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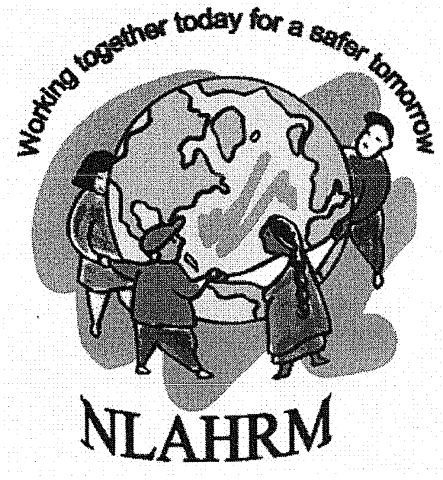

May 15, 2008

Mr. Robert Thompson
Chair
Task Force on Adverse Events
Government of Newfoundland and Labrador

Dear Mr.Thompson,

In response to your call for submissions to the Provincial Task Force on Adverse Events I am enclosing a copy of a Patient/Resident/Client Safety Manual that was completed by the Newfoundland and Labrador Association of Healthcare Risk Management in 2004.

The NL Association of Healthcare Risk Management is a Chapter of the American Society of Healthcare Risk Management and is currently comprised of clinical health professionals managing or coordinating patient safety/risk management programs and/or activities within the four provincial regional health authorities. Our association has been in existence for a number of years and began as an informal network to share ideas and develop common approaches to patient safety and risk management within the Province's health care boards. As our association predates the Canadian Patient Safety Institute and other provincial and national forums recently developed around patient safety, we formalized our network and obtained Chapter status with our American counterparts through ASHRM. We are pleased to note that our reliance on ASHRM has lessened in recent years with the establishment of the Canadian Patient Safety Institute.

2.

Using a template developed and shared by a chapter in the US, NLAHRM developed a manual that could assist organizations to move toward a culture of safety. The manual outlines the following tools and processes:

- incident/occurrence and adverse event data collection and reporting;
- hazard analysis and risk identification
- root cause analysis and failure modes and effects analysis
- disclosure
- fair and just reporting
- education and support

As frontline, clinical managers and coordinators, NLAHRM's goal was to provide a practical resource that risk management/patient safety health professionals and others could use (with their Board's approval) in the development of agency specific policies, procedures and programs. While we fully recognized that the document would need to be revised based on health systems research and new approaches, particularly relating to disclosure, it was a start. Our ultimate aim was that we would have a standardized approach to core patient safety principles within Newfoundland and Labrador's health organizations.

As an association we have long recognized that if we are to ***prevent*** adverse events and improve patient safety within health care, leaders and practitioners must have the necessary tools, resources, education and training. This continues to be our greatest challenge despite significant research which supports investments in patient safety initiatives, resources and technology to improve patient care.

I hope that this document and these comments will provide some assistance in achieving your mandate. On behalf of NLAHRM I wish you well and we look forward to attending the forum and the recommendations of the task force.

Sincerely,

Glenys P. Walsh

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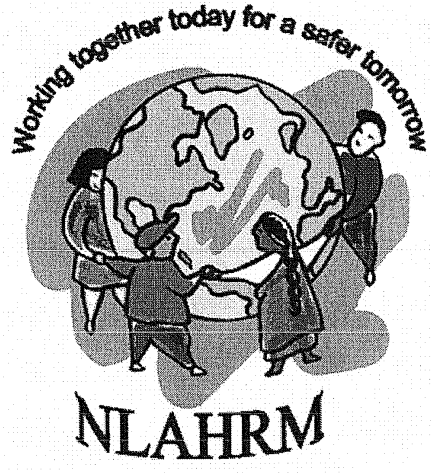

Newfoundland and Labrador Association of Healthcare Risk Management's
(NLAHRM)

PATIENT/RESIDENT/CLIENT SAFETY MANUAL

Completed Nov. 2004

NLAHRM PATIENT/RESIDENT/CLIENT SAFETY MANUAL

Acknowledgement:

Thank you to the Pennsylvania Association of Health Care Risk Management (PAHCRM) which won an American Society for Healthcare Risk Management (ASHRM) Chapter Recognition Program Award in 2001; and who willingly shared their patient safety document.

The following document is the result of the combined efforts of the members of the Newfoundland and Labrador Association of Healthcare Risk Management (NLAHRM). Members of NLAHRM include:

Susan Sullivan – President
Glenys Walsh – Secretary
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PATIENT/RESIDENT/CLIENT/CLIENT SAFETY MANUAL

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PATIENT/RESIDENT/CLIENT SAFETY PROGRAM

Introduction:

The Board of Trustees of **(Title of your Board)** is committed to creating an environment that encourages occurrence identification, remediation, non-punitive reporting, and prevention of recurrences through education, systems redesign, and/or process improvement.

Additionally, a proactive assessment of high-risk activities, identified through aggregate data collection and utilizing knowledge-based information for risk reduction will be implemented.

Orientation Programs will emphasize job-related aspects of patient/resident/client safety, an interdisciplinary approach to patient/resident/client care and the requirement and mechanism to report adverse occurrences. Staff involved in serious/sentinel occurrences will have access to resources for debriefing and support.

Emphasis will also be placed upon patient/resident/client safety in areas such as patient/resident/clients' rights, patient/resident/client and family education, continuity of care and management of human resources.

Full disclosure of serious medical occurrences or unanticipated outcomes will be made to patients/residents/clients/families and to accrediting and licensing bodies as per Regional Policy.

Responsibility:

Although all members of the organization have responsibilities as specified in the Culture of Safety Policy, the **(Performance Improvement Committees, Safety Committee, Risk Management Committee or Individual or Committee identified in your organization)** shall continually monitor and evaluate the implementation and effectiveness of the Patient/Resident/Client Safety Program. This will permit oversight of all components of the organization and will generate appropriate feedback and follow-up. The **(Performance Improvement Committees, Safety Committee, Risk Management Committee or Individual or Committee identified in your organization)** shall prepare an annual report to the **(Board of Trustees or Title of your Governing Body)** indicating adverse occurrences, remediation activities and proactive efforts to prevent future occurrences.

Risk Identification:

Trending of adverse occurrences, environmental safety issues, aggregate data collection and review of sentinel occurrences in similar organizations are part of proactive identification and management of risks to patient/resident/client safety to prevent such occurrences.

Analysis:

As needed, a "failure mode," "effect" and "criticality" review shall be conducted on a high-risk process, selected in part through Critical Occurrence (Sentinel Event) summaries. The "failure mode" identifies step(s) where there is, or may be, an undesirable variation. The "effect" of each "failure mode" on a patient/resident/client is assessed as to the seriousness or "criticality" of such an occurrence. The most serious effects will require a root cause analysis to determine the cause of the variation and a redesign of the process or system to minimize or prevent the risk to the patient/resident/client. The redesigned process will be tested, implemented and monitored for on-going effectiveness or modification, if necessary.

In addition, error-prone or high-risk processes are measured and analyzed. Corrective action is taken to rectify significant deviations. At any given time, the critical steps of at least one high-risk process is the subject of measurement and analysis to determine degree of variation from intended performance.

Processes for failure mode, effect and criticality review or other error-prone/high risk processes may by identified by the Performance Improvement Department, Risk Management or the Patient/Resident/Client Safety Committee.

Finally, patient/resident/client/family and staff opinions, perceptions of risk and suggestions for improving safety will be solicited and aggregated to identify opportunities for improvement. These suggestions should be solicited in a separate process from the occurrence reporting process.

See Appendix A – The American Society of Healthcare Risk Management (ASHRM) White Paper on Failure Mode & Effect Analysis (FMEA)

POLICIES

Policy on A Culture of Safety

(Use your own Organization's Policy here – or use this sample as a template for policy development)

It is the purpose of this policy to define the responsibilities of employees in relation to the culture of safety at all facilities of _____
Health Care Board Name

I. Policy

_____ is committed to providing a safe environment
Health Care Board Name
for all individuals. Promotion of safety and prevention of injury must be the first consideration in all actions, and is the responsibility of each employee, medical staff members, students and volunteers.

The culture of safety, and the ongoing promotion of a safe environment is achieved only through the capable, coordinated and efficient efforts of each individual's contribution toward these goals by promptly reporting errors/occurrences and "near misses" to enable identification and correction of system problems. To enhance increased reporting, this process de-emphasizes the "who" but focuses on the "how" of errors/occurrences, all the while underscoring individual accountability and responsibility.

II. Culture of Safety Philosophy

A. Individual employee responsibility
1. Know and follow policies and procedures applicable to assigned duties.
2. Use sound judgment and awareness of potential hazards before taking action.
3. Promptly report errors/occurrences or situations of actual or potential occurrence or harm.

B. Management responsibility
1. Educate staff regarding error/occurrence reporting and continuous safety improvement.
2. Involve staff in identification of system flaws and potential corrective action required.
3. Focus on the "how" of an error/occurrence – how did it occur, etc. – rather than "who" may have contributed to it.
4. Maintain compliance with all licensing/regulatory bodies by appropriate actions taken for violations.
5. Ensure that appropriate evaluation processes are implemented.
6. Establish a culture that encourages error/occurrence reporting.
7. Implement corrective measures and plans and educate all staff accordingly.

C. Administrative and medical staff responsibilities
   1. Promote improvements in safety by encouraging reporting, while avoiding "blaming," but emphasizing the "how" of errors/occurrences.
   2. Enlist assistance of persons in identifying real or potential hazards.
   3. Implement proven safety strategies throughout all areas of the facility.
   4. Provide for continual education of physicians and employees regarding safety issues and practices.
   5. Promptly reporting occurrences/errors or situations of actual or potential harm.

D. Governing Body
   1. Receive and monitor ongoing safety reports.
   2. Allocate adequate resources to support comprehensive patient/resident/client safety strategies.

Policy On Adverse Occurrences

(Use your own Organization's Policy here – or use this sample as a template for policy development)

These standards are intended as guidelines to assist in the delivery of patient/resident/client care or management of the organization's services. They are not intended to replace professional judgment in patient/resident/client care or administrative matters.

PATIENT/RESIDENT/CLIENT SAFETY:

_____ is committed to providing quality
Health Care Board Name
care to its patients/residents/clients and the communities it serves. Despite constant and committed efforts to provide and improve patient/resident/client care, it happens from time to time that patients/residents/clients are harmed rather than helped by the care they receive. While sometimes these outcomes of care are unavoidable, at other times they may result from errors in the provision of care.

_____analyzes such occurrences to prevent the recurrence of such
Health Care Board Name
events ("adverse occurrences", AOs). We are also committed to respecting the right of patients/residents/clients and their families to be informed about such occurrences.

POLICY:

_____ identifies and investigates all adverse
Health Care Board Name
occurrences and encourages the full and frank disclosure of adverse occurrences to patients/residents/clients.

PURPOSE:

- To address the issue of the disclosure of AO's to patients/residents/clients/families.
- To create a standardized mechanism for identifying, reporting, investigating, trending and resolving adverse occurrences
- To educate providers and patients/residents/clients/families concerning the many aspects of patient/resident/client safety.
- To provide a consistent mechanism for improving the patient/resident/client care process.

SCOPE:

This policy applies to all Patient/resident/clients cared for at any of the organizations of _____.
Health Care Board Name

DEFINITIONS:

Adverse Occurrence/Event (AO/AE) –
An unexpected and undesired incident/occurrence directly associated with the care or services provided to the patient/resident/client; or
An incident/occurrence that occurs during the process of providing health care and results in patient/resident/client injury or death; or
An adverse outcome for a patient/resident/client, including an injury or complication.
Based on the "Canadian Patient Safety Dictionary" Oct. 2003

Occurrences may result in or demonstrate a potential for an injury to an individual or damage to or loss of equipment or property. *(Canadian Council of Health Services Accreditation (CCHSA))*

Category of Adverse Occurrence/Event:
Error – The failure to complete a planned action as it was intended, or when an incorrect plan is used in an attempt to achieve a given aim. *"Canadian Patient Safety Dictionary" Oct. 2003*

Occurrence – Events, processes, practices or outcomes that are noteworthy by virtue of the hazards they create for, or the harms they cause, patients/residents/clients. *Based on the "Canadian Patient Safety Dictionary" Oct. 2003*

Critical Incident/Occurrence (Sentinel Event) – An occurrence resulting in serious harm (loss of life, limb, or vital organ) to the patient/resident/client or the significant risk thereof. Occurrences are considered critical when there is evident need for immediate investigation and response. *Based on the "Canadian Patient Safety Dictionary" Oct. 2003*

From the Joint Commission of Accreditation for Health Care Organizations (JCAHO)-USA: serious psychological injury would also be considered. Moreover, they state that the phrase "or risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

From the Canadian Council of Health Services Accreditation – they add that the occurrence is unexpected, and related to system or process deficiencies – leading to death or major and enduring loss of function

Hazardous Condition – Any set of circumstances (exclusive of the disease or condition in which the Patient/resident/client is being treated), which significantly increases the likelihood of a serious adverse outcome.

Near Miss – Used to describe any process variation which did not affect the outcome, but for which a recurrence carries a chance of an adverse outcome.

Minimal Reporting Requirements Include: Refer to Aggregate data collection tools & definitions on pages 73-78 In order to compare like data, all participating organizations should report these occurrences as a minimum-reporting requirement.

SEVERITY OF ADVERSE OCCURRENCE:

MINOR:
Level 1: An event occurred but the patient/resident/client was not harmed; or

Level 2: An event occurred that resulted in the need for increased patient/resident/client assessments and there is no resultant patient/resident/client harm and no treatment/intervention is required.

MODERATE:
Level 3: An event occurred that resulted in the need for treatment and/or intervention and caused temporary patient/resident/client harm; or

Level 4: An event occurred that resulted in initial or prolonged hospitalization, and/or caused temporary patient/resident/client harm.

SERIOUS:
Level 5: An event occurred that resulted in permanent patient/resident/client harm or a near death occurrence, such as anaphylaxis; or

Level 6: An event occurred that resulted in patient/resident/client death.

* Levels 3 through 6 shall be discussed with patient/resident/client and or families. Discussion will be as per the organization's policy on disclosure.

Handling the Occurrence

The first priority upon discovering an adverse occurrence is to have the patient/resident/client evaluated, have the adverse occurrence remedied, if possible, insure that others are not at risk and obtain and sequester all relevant information, equipment, products, etc. for future analysis. (i.e. Loss Control)

REPORTING OF THE OCCURRENCE:

Internal Reporting:

(Your organization may wish to continue to use the Incident Report/Occurrence Report Policy and Procedure currently in place. Otherwise, you may use or adapt the sample policy contained in the patient/resident/client Safety Manual). ***Customize for your organization and list your policies.***

Reporting To Outside Agencies:

Examples include: *insurers, legal advisors, adverse drug reactions, hazardous equipment etc.*

DISCLOSURE:

1. What occurrences ought to be disclosed?

   Occurrences in which patients/residents/clients are harmed, including Severity Levels 3 through 6. For example: unexpected admission to intensive care, unexpected patient/resident/client death, unnecessary treatment with burdensome impact on the patient/resident/client, return to OR.

   Errors that do not harm patients/residents/clients and do not have the potential to do so (insignificant or minor occurrences) do not require disclosure to the patient/resident/client. If there is a question concerning disclosure, contact **(Risk Management, Quality Improvement or the responsible individual in your organization.)** After hours, inquiries should be directed to **(responsible party in your organization).**

2. To whom should the disclosure be made?

   Disclosure of AO's should be made to the affected patient/resident/client, and when appropriate, the patient/resident/client's family or designated decision-maker.

3. When should disclosure take place?

   Disclosure of the AO should take place as soon as practical after the AO has occurred or been identified. Disclosure to the Patient/resident/client should occur when the patient/resident/client is stable and/or able to comprehend the information. Disclosure to the patient/resident/client's family or decision-maker may occur sooner depending on the occurrence's severity and his/her need to know this information.

4. Who ought to disclose occurrences to patients/residents/clients?

   There are several ways in which an AO may be disclosed, depending upon the occurrence. The responsibility usually rests with the attending physician/most responsible party. In some circumstances further investigation will be required to determine which individual(s) should be involved. The attending physician/most responsible party and the **(risk manager –*customize for your organization*)** will consider involving representatives from nursing, allied health professionals, pastoral care, social workers or staff members known to and trusted by the patient/resident/client/family.

   If the attending physician/most responsible party is unwilling or unable to disclose the occurrence, or if investigation determines that his/her involvement could exacerbate the problem, the **(risk manager –*customize for your organization)*** will work with administration ***(customize)*** to identify the appropriate person to handle this responsibility.

5. How to disclose an occurrence

   The nature, severity and cause (if known) of the AO should be presented in a straightforward and non-judgmental fashion. An expression of sympathy is often appropriate and not an admission of guilt. Speculation should be avoided and focus should be placed on what is known at the time of discussion. Answer questions and provide assurance that unanswered questions will be investigated further. Describe what, if anything can be done to correct the consequences of the AO. Offer a second opinion, the involvement of outside assistance, or transfer of care to another practitioner if applicable.

6. How is disclosure documented:

   Relevant information and the medical/client record should be on hand. A summary of the disclosure should be noted in the medical/client record. A notation of attendees should also be retained.

TRENDING AND ACTION PLAN:

Trending:

Trending of occurrences is an interdisciplinary process, which may be done by **(Performance Improvement teams, Department Managers, Safety Officers, Risk Managers or various other hospital committees as established in your Performance Improvement Plan).** Whichever mechanism is used, a trending tool must be in place. **(You may use or adapt the form contained in the patient/resident/client Safety Manual).**

Action Plans:

These are examples of some of the actions that you might consider when developing your plan:

a. Organizational Processes

- Communication flow changes
- Consultant services – e.g. legal, insurer, ergonomic reviews
- Organization structure changes
- Inventory changes
- Staffing adjustments
- Revision of job descriptions
- New/revised policies and procedures
- Equipment changes
- Work flow/structure/ergonomic changes
- Business process redesign

- Establishment of a process improvement team
- Signage

b. Human Factors

- Staff meeting discussion
- Educational training programs
- Counseling/guidance
- Adjustment in clinical duties, clinical privileges or staff status
- Employee improvement plan

Policy on Occurrence Reporting

*(Use your own Organization's Policy here – or use this sample as a template for policy development. **Note** – consider using the definitions on Page 9)*

POLICY -

It is the policy of _____ to document and report immediately
Organization Name
all occurrences or unusual occurrences as defined in the guidelines set forth in this policy. This policy shall, at all times, comply with federal, provincial and local regulations in addition to those applicable standards set forth by the Canadian Council of Health Services of Accreditation or the Department of Health and Community Services.

PURPOSE

The purpose of occurrence reporting is to enhance the quality of patient/resident/client care, to assist in providing a safe (risk-reduced) environment for that care, and to allow prompt response by the Risk Management Department to potential liability exposure. It is not designed to place blame on individuals.

The interests of patients/residents/clients and staff are best served by the consistent and uniform utilization of a program designed to discover and report all unusual occurrences within the organization.

The Occurrence Report provides a uniform procedure of informing the Risk Management Department of relevant information surrounding an occurrence. The occurrence reporting policy should be followed with all incidents occurring at
_____. Depending on the type or severity of
List name(s) of your organization
Occurrence, the Risk Management Department should be notified immediately by telephone and then as a follow-up measure, by the submission of an Occurrence Report. Early and accurate reporting is the objective.

Other policy purposes are: to achieve consistency in the method of reporting; to serve as an information base for devising corrective measures to preclude reoccurrences; to target problem areas through effective trend analysis; and to promote open channels of communication throughout all levels within the organization on an as needed basis.

SCOPE

_____
List services in your organization

PROCEDURE

The procedure governing reporting of occurrences or unusual occurrences follows:

I. Guidelines – Occurrences may be those involving Patient/resident/client care or those involving the operation of a department/facility.

A. Patient/resident/client Care – Reported via the Occurrence Report.

1) Adverse Occurrence/Event (AO/AE) –
An unexpected and undesired incident/occurrence directly associated with the care or services provided to the patient/resident/client; or
An incident/occurrence that occurs during the process of providing health care and results in patient/resident/client injury or death; or
An adverse outcome for a patient/resident/client, including an injury or complication.
Based on the "Canadian Patient Safety Dictionary" Oct. 2003

2) Error –The failure to complete a planned action as it was intended, or when an incorrect plan is used in an attempt to achieve a given aim. *"Canadian Patient Safety Dictionary" Oct. 2003*

3) Critical Incident/Occurrence (Sentinel Event) – An occurrence resulting in serious harm (loss of life, limb, or vital organ) to the patient/resident/client or the significant risk thereof. Occurrences are considered critical when there is evident need for immediate investigation and response. *Based on the "Canadian Patient Safety Dictionary" Oct. 2003*

From the Joint Commission of Accreditation for Health Care Organizations (JCAHO)-USA: serious psychological injury would also be considered. Moreover, they state that the phrase "or risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.
From the Canadian Council of Health Services Accreditation (CCHSA) also describes the occurrence as unexpected and relating to system or process deficiencies leading to death or enduring loss of function.

4) Hazardous Condition – Any set of circumstances (exclusive of the disease or condition in which the Patient/resident/client is being treated) which significantly increases the likelihood of a serious adverse outcome.

5) Near Miss – Used to describe any process variation which did not affect the outcome, but for which a recurrence carries a chance of an adverse outcome.

B. Department/Facility/Organization – Reported via the Security Department Incident/Occurrence Report.

1. Damage or loss of property owned by either the facility/organization or patient/resident/client/visitor.

2. Visitor behavior problem.

3. Failure to follow hospital/organization policies (non-patient/resident/client care related).

4. Unsafe environment.

C. Employee injuries are reported in accordance with the facility's/organization's Workers' Compensation Program (**or specify your organization's procedure**)

D. Example of Reportable Incidents – The following examples are intended to illustrate types of reportable incidents:

1. Patient/resident/client Care

a. Bodily Injury – An inpatient/resident/client or outpatient/resident/client suffers an injury while on the hospital/organization's premises.

b. Violation of Rights – A patient/resident/client does not give informed consent before a procedure is performed; confidential patient/resident/client information is released to the public.

c. Blood wastage or infection control issues.

d. Unexplained or unexpected medical or surgical outcomes or mishaps.

e. Equipment problems related to a particular patient/resident/client.

2. Department/Facility/Organization

a. Visitor Fall

b. Theft

c. Assault

d. Confiscated weapon, illegal substance, etc.

e. Equipment problems not related to a particular patient/resident/client.

E. Objectives For Reporting – The report is a factual account of the details of an occurrence and provides a method for ensuring identification and for initiating an investigation of causes. The specific objectives are:

1. To improve the management of patient/resident/client care and treatment by assuring that appropriate and immediate intervention is done on the patient/resident/client's behalf and to prevent the possibility of a reoccurrence.

2. To provide a factual record of the occurrence so that the care being given can be evaluated and adequate care standards developed.

3. To further staff education through case review and discussion.

4. To provide trend analysis for Department Heads with the goal of reducing the number of occurrences and improving patient/resident/client safety.

5. To provide a factual record of the occurrence as a basis for immediate notification to the Risk Management Department so that the occurrence can be evaluated for potential liability exposure.

An effective reporting process can impact favorably on the quality of patient/resident/client care through needed operational modification, intensification of inservice education and orientation programs and strengthening of the proactive function of Risk Management.

F. Procedure For Reporting

1. Any employee or physician who discovers, witnesses or to whom an occurrence is reported is responsible for documenting the occurrence immediately via the Occurrence Report. Any employee who requires assistance should contact his/her supervisor. Supervisors must review all reports.

2. A Occurrence Report must be completed for all unusual occurrences.

3. An occurrence that results in an injury or potential injury to a patient/resident/client requires that a patient/resident/client's attending physician be immediately notified. If the attending physician is not in-house at the time of the occurrence, a member of the house staff or covering physician must also be notified.

4. The Medical/Client Record must reflect the objective facts relating to the patient/resident/client occurrence. No references to a completed Occurrence Report should be made in the Medical/Client Record.

5. All sections of the Occurrence Report must be completed. Security personnel will complete the Security Incident/Occurrence Report.

6. Once completed, the Occurrence Report should go directly to the Department Manager who will forward it to the Risk Management Department within 48 hours. The Security Officer/Director will send a copy of the Security Incident/Occurrence Report to the Risk Management Department.

7. Occurrences occurring in ancillary departments must follow the protocol outlined above.

8. Occurrences resulting in serious injury to a patient/resident/client or visitor must be reported to the Risk Management Department immediately by telephone and followed-up with an Occurrence Report. At the same time Risk Management is notified of a serious incident, the appropriate Administrator on-call must be notified. Also see Policy on Sentinel/Serious Occurrence Reporting.

9. Occurrence Reports are not to be used for punitive reasons or as a means of documenting alleged misconduct on the part of employees of other staff.

10. Occurrence Reports should never become a part of the patient/resident/client's chart and may not be copied or reproduced.

SENTINEL EVENT POLICY

(Use your own Organization's Policy here – or use this sample as a template for policy development)

POLICY:

It is the policy of the _____ to conduct a full investigation of all occurrences
Organization Name
which seriously compromise the quality of patient/resident/client care as well as patient/resident/client safety.

DEFINITION:

A **Sentinel Occurrence** is defined as an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of serious adverse outcome.

At least two of the following criteria should be met in order for the occurrence to be defined as a Sentinel Occurrence:

1. The occurrence has resulted in an unanticipated death or major permanent loss of function.

2. The occurrence is associated with significant deviation from the usual processes for providing health care services or managing the organization.

3. The occurrence has undermined, or has significant potential for undermining, the public's confidence in

_____.
Organization Name

A **Serious Occurrence** is one, which could seriously compromise quality assurance or patient/resident/client safety – i.e.:

Level 5: An event occurred that resulted in permanent patient/resident/client harm or a near death occurrence, such as anaphylaxis; or

Level 6: An event occurred that resulted in patient/resident/client death.

DETERMINATION OF SENTINEL AND/OR SERIOUS OCCURRENCES: The determination of whether an adverse occurrence is to be classified as a Sentinel and/or Serious Occurrence shall be made by the **Risk Manager (or individual designated by your organization).** If it is determined that the occurrence rises to the level of "Sentinel" or "Serious", the following persons shall be convened: CEO, Administration, VP of Nursing Service, Director of Performance Improvement, Director of Risk Management, President of the Medical Staff, appropriate Clinical Chairman **(list your facility's designed representatives).** Other key individuals may be called upon as appropriate to the nature of

the occurrence. This group shall also determine who in the hospital/organization will be assigned to the investigation if the occurrence is classified as sentinel and/or serious.
It is recognized that when an occurrence results in an unfavorable outcome, consideration of known complications, and/or patient/resident/client information regarding the risk/complication through informed consent, will be utilized in determining if a Sentinel Occurrence has occurred.

SENTINEL OCCURRENCES: Include, but are not limited to the following examples:

- Infant discharged to the wrong family
- Inpatient/resident/client suicide
- Rape (by another Patient/resident/client or staff)
- Hemolytic transfusion reaction
- Surgery on the wrong Patient/resident/client or wrong body part

See the Canadian Council of Health Services Accreditation Website listing for Sentinel Events at www.cchsa.ca

PROCEDURE: When a Sentinel Occurrence has been determined to have occurred, a Root Cause Analysis (RCA) shall be completed within 45 days of the occurrence and will be performed as follows:

- The Director of Risk Management **(or designated individual in your facility)** will notify the physicians involved, including those who are to be part of the RCA Team, and will follow up with the physicians involved accordingly.

- The RCA Team assigned to assess the Sentinel Occurrence and chaired by the Director of Risk Management **(Director of Performance Improvement or individual assigned in your facility)** will include staff at all levels closest to the issues, **(CEO, Administrator, Vice President of Nursing, Director of Performance Improvement, President of Medical Staff, etc.)**

- The Team will confer as frequently as necessary.

- The Director of Risk Management or his/her designee will document the findings and recommendations of the group. No other written documentation will be made or maintained except for peer review purposes. Oral progress reports will be made to senior management by the Director of Risk Management **(or individual designated in your facility).**

- The RCA Team will be responsible for determining the common causes of the occurrence that lie in the larger organizational systems supporting the health care providers. These systems include but are not limited to: credentialing and privileging for physicians and other licensed independent practitioners; hiring and competency review for others; continuing education of staff; management of information, including facilitation of communication, accessibility of knowledge-based information, and linkage of information sources; work process design; and measurement of performance with respect to both processes and outcomes.

- The RCA Team will focus attention on systems that can be redesigned for improvement, rather than on processes and people who cannot control causes outside themselves and who have only limited control over their own ability to avoid human error.

- The RCA Team will use multiple techniques including brainstorming and flow charts. The question "Why" will form the basic structure of the inquiry and will be re-addressed until all causes have been determined.

- The RCA Team may have access to Personnel Files and Peer Review Files if necessary to complete the investigation.

- Recommendations for change in the health-care-delivery process will be communicated on an ongoing basis and at the end of the investigation.

All minutes, reports, recommendations, communications and actions made or taken pursuant to this policy are deemed to be covered by the provisions of any federal or provincial legislation providing protection to peer review for related activities. Furthermore, the department directors, committees and/or panels charged with making reports, findings, recommendations or investigations pursuant to this policy shall be considered to be acting on behalf of the hospital/organization and Board of Directors when engaged in such quality review activities and thus shall be deemed to be protected under Section 8.1 of the Evidence Act of Newfoundland & Labrador.

Policy on Just/Fair Reporting

(Use your own Organization's Policy here – or use this sample as a template for policy development. Consider involving Human Resources in development of this policy.)

POLICY:

It is the policy of _____ to support the Culture of Safety through a non-punitive approach to occurrence reporting.

PURPOSE:

- To encourage open and honest reporting of injuries or hazards to patients/residents, visitors and staff.
- To limit disciplinary action to only those that involved willful or malicious misconduct or those in which the employee did not report or follow remediation recommendations.
- To facilitate education and problem resolution through forthright disclosure of process failure and/or human error.

PROCEDURE:

1. All occurrences or unusual occurrences, as defined in the Policy on Occurrence Reporting, shall be reported immediately via the Occurrence Report form and processed in accordance with that policy.
2. Reports will be completed by the employee who is involved in, witnesses, or discovers an occurrence or unusual occurrence, particularly those which pose a safety hazard.
3. Employees are not subject to disciplinary action EXCEPT as follows:
   a. The occurrence involves sabotage, malicious behavior, chemical impairment or criminal activity.
   b. False information is provided on the Occurrence Report or in follow-up investigation.
   c. An employee fails to respond to educational efforts and/or fails to participate in the education or other preventive plan.
4. Employees who meet any of the "Exceptions" listed in #3 will be subject to progressive review/disciplinary action in accordance with Human Resources policy and procedure and/or work rules.

EDUCATION

EMPLOYEE ORIENTATION

PATIENT/RESIDENT/CLIENT SAFETY

(To Be Adapted For Your Own Organization)

How Did We Get Here?

According to the Canadian Adverse Events Study, 2000/01:

- **Adverse Events occurred in 7.5% of the hospital admissions studied**
- **If this rate was applied to the almost 2.5 million annual hospital admissions in Canada similar to the type studies – it would mean**
  - **185,000 of hospital admissions are associated with an adverse event**
  - **70,000 of those are potentially preventable.**
- **Adverse Events may cause between 9,250 – 23,750 deaths per year.**
- **More people die from adverse events than from breast cancer, HIV or MVAs combined.**
- **The two most common types of events were:**
  - **34% were related to surgical procedures**
  - **24% were related to drug or fluid related events.**

**** From the CIHI Document "Health Care in Canada" 2004***

According to the British National Health Service Report, *An Organization with a Memory(2000):*

- **Adverse events in which harm is caused, occur in approximately 10% of patient admissions (or about 850,000 times a year!)**

According to the *Quality in Australian Health Care Study* (Wilson et al, 1995):

- **16.6% of admissions were associated with an adverse event.**
- **Of those – 51% were considered highly preventable**

According to another Canadian study (Wanzel, Jamieson, et al, 2000):

On a general surgery service:

- **75 patients (39%) of 192 inpatients suffered a total of 144 complications. Of these:**
  - **29% were considered trivial**
  - **63% were considered of moderate severity**
  - **7% were considered life threatening**
  - **1% were fatal**
  - **18% were considered potentially attributable to error.**

Medical Error By The Numbers

- **Leape (1991) – medical errors caused 1 out of every 5 injuries or deaths**
- **Brennan (1991) – one out of every 25 hospitalized patients is injured by medical errors.**
- **Iatrogenic injuries occur in 3.7% of hospitalizations; 70% are preventable.**
  (Harvard Medical Practice Study, 1991)
- **How much is 1%? – In the airline industry, it would be 3 jumbo jet crashes every 2 days.**
- **Canadian Adverse Events Study – 1 in 13 hospital patients in Canada experience an adverse event as a result of their care.**

Why Isn't It Fixed Yet?

- **Provider barriers to progress**
- **Resistance to change.**
- **Fear of looking incompetent.**
- **Fear of discipline or retaliation.**
- **Failure to appreciate the complexity.**
- **No national strategies/consistencies to date– as discussed in " Building a Safer System" (2002) – however since then the issue has been targeted by new groups such as:**
    - **Provincial Safety Committees have been established ie The Provincial Adverse Event/Patient Safety Committee co chaired by Loretta Chard of the DOHCS & Jeannie House of the NLHBA**
    - **A National Body – the Canadian Patient Safety Institute was established in December 2003.**

Factors That Contribute To Error

- **Cognitive lapses:**
  - **Mental "slips"**
  - **tendency to over generalize**
  - **confirmation bias**
  - **overconfidence**
  - **reversion under stress**

Moving Beyond Blame

- **Errors do occur and will always occur.**
- **Employee accountabilities relating to occurrences include:**
    - **Duty to prevent occurrence/error when possible**
    - **Duty to report occurrence**
    - **Duty to remedy resultant injuries**

Goals of Patient/ Resident/Client Safety Program

- **Promote a culture of safety**
- **Promote "moving away from blame" reporting environment**
- **Reinforce communication amongst the healthcare team and with patients/residents/clients and families**
- **Engage patients/residents/clients in the safety of their care**

GOAL 1 – Promote A Culture Of Safety

- **Educate all staff about Culture of Safety Policy**
- **Incorporate "Patient/resident/client Safety" tenets in employee orientation and employee competencies**
- **Regular analysis of internal reporting to identify systems that could potentially cause harm**
- **Positive recognition for those reporting safety issues internally**

GOAL 2 – Promote Reporting Environment That De-emphasizes Blame

- **Develop Human Resource Policy to create a system of occurrence reporting that moves away from blame**

- **Regular reporting of trends and patient/resident/client safety issues in non identifiable aggregate format to the (Medical Executive Committee and Board – *use your organizations reporting mechanisms)***

GOAL 3 – Reinforce Communication Amongst The Healthcare Team And With Patients/Residents/Clients And Families

- **Identify for patients/residents/clients who is responsible for guiding their care.**
- **Ongoing education of physicians and employees on communication skills.**

GOAL 4 – Engage Patients/Residents/Clients In The Safety Of Their Care

- **Patients/residents/clients and families must be treated as partners in their care.**
- **Involve patients/residents/clients in all care decisions.**
- **Distribute brochures to encourage patients/residents/clients to be involved in their care.**
- **Involve patients/residents/clients in improving our processes.**
- **Making patients/residents/clients accountable for their care – e.g. if they do not understand about a medication, they need to ask.**

Culture of Safety Policy

- **Purpose:**
  - **It is the purpose of this policy to define the responsibilities of all employees in relation to the culture of safety.**
- **Policy:**
  - **Promotion of safety and prevention of injury must be the first consideration in all actions, and is the responsibility of each employee. Promoting safety is a condition of employment.**

Individual Employee Responsibility

- **Know and follow policies and procedures applicable to assigned duties.**
- **Use sound judgment and awareness of potential hazards before taking action.**
- **Promptly report occurrences or situations of actual or potential harm.**

Management Responsibility

- **Educate staff on:**
  - **Occurrence reporting**
  - **Continuous safety improvement**
  - **Identifying system flaws and potential corrective action required**
- **Focus on the "how" *not* the "who" of an occurrence while underscoring individual accountability and responsibility.**
- **Ensure safe practice by all individuals by appropriate evaluative processes.**

Administrative and Medical Staff Responsibilities

- **Promote / implement improvements in safety.**
- **Encourage reporting.**
- **Enlist assistance in identifying real or potential hazards.**
- **Provide continual education of physicians and employees regarding safety issues and practices.**
- **Promptly report occurrences/errors or situations of actual or potential harm.**

Governing Body Responsibilities

- **Receive and monitor on-going safety reports.**
- **Allocate adequate resources to support a comprehensive patient/resident/client safety program**

Policy On Adverse Occurrences

Purpose

- **Disclose to patients/residents / clients/ families**
- **Mechanism to identify, report, investigate and resolve adverse occurrences**
- **Educate providers and patients/residents / clients/ families on patient/resident/client safety**
- **Improve patient/resident/client care process**

Severity of Occurrence

MINOR:

- **Level 1: An event occurred but the Patient/resident/client was not harmed; or**

- **Level 2: An event occurred that resulted in the need for increased patient/resident/client assessments and there is no resultant patient/resident/client harm and no treatment/intervention is required.**

MODERATE:

- **Level 3: An occurrence occurred that resulted in the need for treatment and/or intervention and caused temporary patient/resident/client harm.**

- **Level 4: An occurrence occurred that resulted in initial or prolonged hospitalization, and caused temporary patient/resident/client harm.**

SEVERE:

- **Level 5: An occurrence occurred that resulted in permanent patient/resident/client harm or near death occurrence, such as anaphylaxis.**

- **Level 6: An occurrence occurred that resulted in patient/resident/client death.**

Handling the Occurrence

The first priority upon discovering an adverse occurrence is to have the patient/resident/client evaluated, have the adverse occurrence remedied, if possible, insure that others are not at risk and obtain and sequester all relevant information, equipment, products, etc. for future analysis.

Reporting

- **Internal reporting to track and trend – as per policy #**

- **Outside agency reports. For Example:**
    - **insurers,**
    - **legal advisors,**
    - **adverse drug reactions,**
    - **hazardous equipment, etc.**

What Occurrences Should Be Disclosed?

Severity levels 3-6, for example, unexpected admission to ICU, return to OR, unexpected death. Levels 1 and 2 occurrences need not be disclosed, unless there was a variance in the expected outcome.

To Whom Should Disclosure Be Made?

To the affected patient/resident/client and, when appropriate, patient/resident/client's family or designated decision maker.

When Should Disclosure Take Place?

As soon as practical when patient/resident/client is stable and able to comprehend. Disclosure to family may occur sooner depending on severity of occurrence and need to know this information.

Who Should Disclose?

Usually the attending physician/most responsible party.
Sometimes investigation will be needed to determine which individual(s) should be involved.
Also, nursing, social workers, pastoral care, or staff known to the family may be asked to participate.

If the attending physician/most responsible party is unwilling or unable to disclose the occurrence, of if investigation determines that this could exacerbate the problem, Senior Administration will identify an appropriate individual.

How To Disclose An Occurrence

- **Straight-forward and non-judgmental.**
- **Expression of sorrow is often appropriate and not an admission of guilt.**
- **Avoid speculation and focus only on what is known at the time.**
- **Answer questions and offer assurance that unanswered questions will be investigated further.**
- **Describe what, if anything, can be done to correct the consequences of error.**
- **Offer a second opinion, involvement of outside assistance, or transfer of case to another person.**

Physician Education

Reasons to Disclose

- **Golden rule**
- **Supports patient/resident/client autonomy / ability to provide informed consent**
- **May relieve patient/resident/client distress**
- **Could facilitate compensation process and mitigate loss**
- **Can increase trust**
- **"It's the right thing to do"**

Deciding Whether to Disclose

- **In general, obligation to disclose a clear mistake that causes significant harm that is able to be remedied, mitigated or compensated.**
- **In controversial cases, get a second opinion from risk management.**
- **Consider notification of insurer, in a timely manner.**

What to Say

- **Convene all affected parties who would benefit by the disclosure (patient/resident/client, family, significant others)**
- **Treat it as an instance of "breaking bad news"**
- **Begin by stating that you regret this has occurred.**
- **Describe the decisions that were made, including those in which the patient/resident/client participated.**
- **Describe the course of occurrences, using non-technical language.**
- **State the nature of the mistake, consequences and corrective action, including what is being done to prevent future occurrences.**
- **Elicit questions or concerns and address them.**
- **Express personal regret, again.**

Conclusion

- **Human beings will always make mistakes**
- **How will we handle them?**
- **Patient/resident/client safety and physician welfare will be well served if we can be more honest about our mistakes to our patients/residents/clients, our colleagues and ourselves.**

Documentation of Disclosure

- **Relevant information and the medical record should be on hand.**
- **Summary of disclosure and attendees documented in medical record.**

POLICY ON OCCURRENCE REPORTING

Occurrence Reports are used to:

- **Enhance quality of patient/resident/client care**
- **Assist in providing safe (risk-reduced) environment**
- **Allow prompt response to potential liability exposure**
- **Achieve consistency in reporting**
- **Serve as information base for devising corrective measures**
- **Target problem areas through trend analysis**
- **Promote open channels of communication**

Occurrences may involve patient/resident/client care or operation of department / organization.

Patient/resident/client Care Occurrences reported via Occurrence Reports

1. **Adverse Occurrence/Event (AO/AE)** –
   An unexpected and undesired incident/occurrence directly associated with the care or services provided to the patient/resident/client; or
   An incident/occurrence that occurs during the process of providing health care and results in patient/resident/client injury or death; or
   An adverse outcome for a patient/resident/client, including an injury or complication.
   Based on the "Canadian Patient Safety Dictionary" Oct. 2003

2. **Error** –The failure to complete a planned action as it was intended, or when an incorrect plan is used in an attempt to achieve a given aim. *"Canadian Patient Safety Dictionary" Oct. 2003*

3. **Critical Incident/Occurrence (Sentinel Event)** – An occurrence resulting in serious harm (loss of life, limb, or vital organ) to the patient/resident/client or the significant risk thereof. Occurrences are considered critical when there is evident need for immediate investigation and response. *Based on the "Canadian Patient Safety Dictionary" Oct. 2003*

   From the Joint Commission of Accreditation for Health Care Organizations (JCAHO)-USA: serious psychological injury would also be considered. Moreover, they state that the phrase "or risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

   From the Canadian Council of Health Services Accreditation – they add that the occurrence is unexpected, and related to system or process deficiencies – leading to death or major and enduring loss of function

4. **Hazardous Condition – Any set of circumstances (exclusive of the disease or condition in which the patient/resident/client is being treated), which significantly increases the likelihood of a serious adverse outcome.**

5. **Near Miss – Used to describe any process variation which did not affect the outcome, but for which a recurrence carries a chance of an adverse outcome.**

Department/Facility /Organization– Reported via Occurrence Reports

1. **Damage or loss of property owned by either the organization or patient/resident/client/visitor.**

2. **Visitor behavior problem.**

3. **Failure to follow organization policies (non-patient/resident/client care related).**

4. **Unsafe environment.**

Employee injuries are reported on a (*Workers' Compensation Incident Report)*
insert the name of your organizations form

Examples of Reportable Occurrences:

Patient/resident/client Care

- **Inpatient/outpatient/resident/client injury on hospital/organization premises**
- **Violation of Rights – patient/resident/client does not give consent; patient/resident/client information is released**
- **Blood wastage or infection control issues.**
- **Unexplained or unexpected medical/surgical outcome or mishap**
- **Equipment problems related to a particular patient/resident/client**

Department/Organization

- **Visitor injury or fall**
- **Theft or assault**
- **Confiscated weapon, illegal substance, etc.**
- **Equipment problems not related to a particular patient/resident/client**

Procedure: (*adapt to your organization's policy*)

1. **Any employee or physician who discovers, witnesses or to whom an occurrence is reported is responsible for documenting the occurrence immediately via the Occurrence Report. Any employee who requires assistance should contact his/her supervisor. Supervisors must review all reports.**

2. **An Occurrence Report must be completed for all unusual occurrences.**

3. **An occurrence that results in an injury or potential injury to a patient/resident/client requires that a patient/resident/client's attending physician be immediately notified. If the attending physician is not in-house at the time of the occurrence, a member of the house staff or covering physician must also be notified.**

4. **The Medical/Client Record must reflect the objective facts relating to the patient/resident/client incident. No references to a completed occurrence report should be made in the Medical/Client Record.**

5. **All sections of the occurrence report must be completed. Security personnel will complete the Security Incident/Occurrence Report.**

6. **Once completed, the occurrence report should go directly to the Department Manager who will forward it to the Risk Management Department within 48 hours.**

7. **A copy of the Security Incident/Occurrence Report will be sent to the Risk Management Department by the Security Officer/Director.**

8. **Occurrences occurring in ancillary departments must follow the protocol outlined above.**

9. **Occurrences resulting in serious injury to a patient/resident/client or visitor must be reported to the Risk Management Department immediately by telephone and followed-up with a Occurrence Report. A member of the Risk Management Department is available 24 hours per day, seven days per week, via beeper. At the same time Risk Management is notified of a serious incident, the appropriate Administrator on-call must be notified.**

10. **Occurrence reports are not to be used for punitive reasons or as a means of documenting alleged misconduct on the part of employees or other staff.**

11. **Occurrence reports should never become a part of the patient/resident/client's chart and may not be copied or reproduced.**

NLAHRM PATIENT/RESIDENT/CLIENT SAFETY MANUAL

POLICY ON SENTINEL / SERIOUS OCCURRENCES

Sentinel Occurrence Definition:

A Sentinel Occurrence is defined as an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of serious adverse outcome.

At least two of the following criteria should be met in order for the occurrence to be defined as a Sentinel Occurrence:

1. **The occurrence has resulted in an unanticipated death or major permanent loss of function.**

2. **The occurrence is associated with significant deviation from the usual processes for providing health care services or managing the organization.**

3. **The occurrence has undermined, or has significant potential for undermining, the public's confidence in the Hospital/Organization.**

Sentinel Occurrences (in addition to major permanent injury or unanticipated death)

- **Infant abduction**
- **Infant discharged to wrong family**
- **Inpatient/resident/client suicide**
- **Rape (by another patient/resident/client or staff)**
- **Hemolytic transfusion reaction**
- **Surgery on wrong patient/resident/client or wrong body part**

Requires Root Cause Analysis

Serious Occurrence Definition:

A Serious Occurrence is one, which could seriously compromise quality assurance or patient/resident/client safety.

Serious Occurrence Examples:

- **Deaths due to injuries, suicide or unusual circumstances**
- **Deaths due to malnutrition, dehydration or sepsis**
- **Deaths or serious injuries due to a medication error**
- **Elopements**
- **Transfers to another hospital/organization as a result of injuries or accidents**
- **Complaints of patient/resident/client abuse, whether or not confirmed by the facility/organization**
- **Rape**
- **Surgery performed on the wrong patient/resident/client or on the wrong body part**
- **Hemolytic transfusion reaction**
- **Infant abduction or infant discharged to the wrong family**
- **Significant disruption of services due to disaster such as fire, storm, flood or other occurrence**
- **Notification of termination of any services vital to the continued safe operation of the facility/organization or the health and safety of its patients/residents/clients and personnel, including, but not limited to, the anticipated or actual termination of electric, gas, steam heat, water, sewer and local exchange telephone service.**
- **Unlicensed practice of a regulated profession**

The individual responsible for Risk Management in your organization determines if an adverse occurrence rises to the level of sentinel and/or serious occurrence.
If so, a Root Cause Analysis will be conducted

NLAHRM PATIENT/RESIDENT/CLIENT SAFETY MANUAL

Guidelines To Prevent Falls In The Hospital

1. Always follow your physician's orders and the nurses' instructions regarding whether you must stay in bed or if you require assistance to go to the bathroom.

2. When you need assistance, use your call light or bell by your bed or in the bathroom and wait for the nurse/assistant to arrive to help you.

3. Ask the nurse for help if you feel dizzy or weak getting out of bed. Remember you are more likely to faint or feel dizzy after sitting or lying for a long time. If you must get up without waiting for help, sit in bed awhile before standing. Then rise carefully and slowly begin to walk.

4. Wear non-skid slipper socks whenever you walk in the hospital. If you don't have any, ask your nurse.

5. Remain lying or seated while waiting for assistance. Please be patient someone will answer your call as promptly as possible.

6. Do not tamper with side rails that may be in use. Side rails are reminders to stay in bed and are designed to ensure your safety.

7. Walk slowly and carefully when out of bed. Do not lean or support yourself on rolling objects such as IV poles or your bedside table.

8. Do not use furniture to assist youself.

How Can I Prevent Problems?

If you were injured, wish to report an adverse occurrence, want to discuss concerns you have with the quality of care you received, or an unanticipated outcome, or even wish to offer suggestions for Patient/resident/client safety, please contact:

_____

insert name & phone number of contact person in your facility

"Your well-being is our primary concern"

List Facilities :

_____

Hospital Name or Logo

A Culture of Safety

Our first priority is promotion of safety and prevention of injury.

Despite constant and committed efforts, it happens from time to time, that patients/residents are harmed rather than helped by healthcare. While these outcomes are often unavoidable, at other times, they result from preventable mistakes or errors in the provision of care.

To assist you in managing your care, we are providing information on medical errors, falls and reporting safety issues.

What Are Medical Errors?

Medical errors happen when something that was planned as a part of medical care doesn't work out, or when the wrong plan was used in the first place. Medical errors can occur anywhere in the health care system:

What Can You Do?

1. The single most important way you can help to prevent errors is to be an active member of your health care team.

2. Make sure that all of your doctors know about everything your are taking. This includes prescription and over-the-counter medicines, and dietary supplements such as vitamins and herbs.

3. Make sure your doctor knows about any allergies and adverse reactions you have had to medicines.

4. When your doctor writes you a prescription, make sure you can read it.

5. Ask for information about your medicines in terms you can understand both when your medicines are prescribed and when you receive them.

6. When you pick up your medicine from the pharmacy, ask: Is this the medicine that my doctor prescribed?

7. If you have any questions about the directions on your medicine labels, ask.

hospital, clinics, outPatient/resident/client surgery centers, doctors' offices, nursing homes, pharmacies, patients/residents' homes. Errors can involve: medicines, surgery, diagnosis, equipment, lab reports. They can happen during even the most routine tasks, such as when a hospital Patient/resident/client on a salt-free diet is given a high-salt meal.

8. Ask your pharmacist for the best device to measure your liquid medicine. Also, ask questions if you're not sure how to use it.

9. Ask for written information about the side effects your medicine could cause.

10. If you have a choice, choose a hospital at which many patients/residents have the procedure or surgery you need.

11. If you are in a hospital, consider asking all health care workers who have direct contact with you whether they have washed their hands.

12. When you are being discharged from the hospital, ask your doctor to explain the treatment plan you will use at home.

13. If you are having surgery, make sure that you, your doctor, and your surgeon all agree and are clear on exactly what will be done.

14. Speak up if you have questions or concerns.

15. Make sure that someone, such as your personal doctor, is in charge of your care.

16. Make sure that all health professionals involved in your care have important health information about you.

17. Ask a family member or friend to be there with you and to be your advocate (someone who can help get things done and speak up for you if you can't).

18. Know that "more" is not always better.

19. If you have a test, don't assume that no news is good news.

20. Learn about your condition and treatments by asking your doctor and nurse and by using other reliable sources.

Falls - - Are You At Risk?

Certain conditions make us more prone to falls and other accidental injuries. Here are just a few:

- **Multiple medications**
  The more medications you take, the more likely you are to experience dizziness or other risky side effects. Tell all of your health care providers about all of the drugs you take. Ask them about any side effects that might place you at risk for falls.

- **Walking difficulties**
  Shuffling, weakness, stooped over posture, inability to walk a straight line, numbness or tingling of toes can make falls more likely. Ask your doctor about assistive devices such as a cane or walker and learn how to use them correctly.

- **Chronic conditions that interfere with thinking, such as Alzheimer's Disease**

- **Impaired vision or hearing**

- **Two or more falls in the past 6 months**

  If you are falling frequently, see your doctor. It's important to find out why.

- **Fear of Falling**
  Do not cut back on your normal activities. Inactivity can actually lead to more falls because of lost muscle strength. Your doctor can also recommend an exercise program to increase muscle strength and coordination, which can help to reduce the risk of falling. If you feel unsteady on your feet, talk to your doctor. You may benefit from a cane or walker.

FORMS

_____
Hospital Name

PATIENT/RESIDENT/CLIENT SAFETY TRACKING TOOL

(Use Additional Sheet If Necessary) **Addressograph**

Occurrence Date _____ Time _____
Day of Week _____ Shift _____
Unit/Location of Occurrence _____

REPLACE WITH YOUR ORGANIZATION'S OCCURRENCE REPORT FORM

NLAHRM PATIENT/RESIDENT/CLIENT SAFETY MANUAL

REPLACE WITH YOUR ORGANIZATION'S CRITICAL/SENTINEL OCCURRENCE REPORT FORM

_____
Hospital Name

SAFETY ASSURANCE PEER REVIEW PROCESS

OCCURRENCE REPORT FOLLOW-UP REPORT FORM PROTECTED BY PA PEER REVIEW PROTECTION ACT

Patient/resident/client Name _____ Date of Follow-Up Report _____

Date of Occurrence/Potential Occurrence _____ Unit _____

FALL
Was foreign substance on floor? _____
Was patient medicated? _____
What medication? _____
Other environmental hazards? _____
Was pt. identified as high risk for falls? _____
Were restraints being used? _____
Patient's Footwear? _____

EQUIPMENT/DEVICE INFORMATION:
Name of Equipment _____
Manufacturer _____
Model No. _____
Serial No. _____
Lot No. _____
Equipment Sent To _____

1. List contributing factors, cause or reason for occurrence if known:
   _____

2. In your opinion, was the standard of care/practice upheld in this situation?
   ☐ Yes ☐ No ☐ Not Sure

3. What was the immediate treatment and/or corrective action taken: _____
   _____

4. What are results of x-ray or other diagnostic tests, if appropriate to occurrence: _____
   _____
   If results positive, were they reported to attending physician? _____
   What is Patient/resident/client's status/condition after occurrence and/or treatment:
   ☐ Unchanged
   ☐ Other: Specify _____

5. Evaluation:
   ☐ Isolated or single occurrence; no-trend noted. ☐ Recurring occurrence; trend/pattern noted. Systems Issue Identified
   Specify: _____

6. Follow-up: Check all that apply:
   ☐ A thorough investigation has been initiated/completed. Indicate by whom and outcome.
   _____
   ☐ A staff development plan will be initiated to address identified issues, e.g. educational session/inservice.
   ☐ Referred to _____
   ☐ Reviewed at staff meeting as a teaching opportunity.
   ☐ Other action

Note Occurrence Severity Index _____. (Level 3-6 must be discussed with Patient/resident/client by physician)

Signatures:
Employee/Staff Member _____ Date: _____
Department Head: _____ Date: _____
Administration: _____ Date: _____

Directions: This form is to be filled out completely. It is used exclusively for evaluation of the quality and efficiency of services provided by professional healthcare workers. This applies to all occurrences that are unusual occurrences, accidents or any situation where there is an actual or potential adverse (undesirable) outcome for a Patient/resident/client, visitor, staff member or volunteer. Please do not duplicate the completed form.

NLAHRM PATIENT/RESIDENT/CLIENT SAFETY MANUAL

AGGREGATE DATA COLLECTION PER 1000 PATIENT/RESIDENT/CLIENT DAYS

(Divide # of Patient/resident/client days for the month into the # of occurrences & multiple by 1000)

Aspect of Care & Indicators	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Medication Related												
Blood/Blood Products Related												
Treatment /Test												
Falls Related												
Theft												
Property Damage												
Equipment Related												
Smoking Related												
Missing Acute Care Client/Elopement												
Missing LTC Client/Elopement												
Discharged Against Medical Advice												
Unplanned Return to OR												
Unplanned return to ER												
Breach of Confidentiality												
Restraints Related												
Consent Related												
Suicide Attempt												
Assault/Abuse/ Harassment												
Anaesthesia Related												
OB Related												
Complaint												

Severity Codes:	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Level 1													
Level 2													
Level 3													
Level 4													
Level 5													
Level 6													

Level 1 □ An occurrence occurred but the Patient/resident/client was not harmed
Level 2 □ An occurrence occurred that resulted in the need for increased Patient/resident/client assessments but no change in vital signs and no Patient/resident/client harm
Level 3 □ An occurrence occurred that resulted in the need for treatment and/or intervention and caused temporary Patient/resident/client harm
Level 4 □ An occurrence occurred that resulted in initial or prolonged hospitalization, and caused temporary Patient/resident/client harm
Level 5 □ An occurrence occurred that resulted in permanent Patient/resident/client harm or near death occurrence, such as anaphylaxis
Level 6 □ An occurrence occurred that resulted in Patient/resident/client death

NLAHRM PATIENT/RESIDENT/CLIENT SAFETY MANUAL

AGGREGATE DATA COLLECTION PER 1000 PATIENT/RESIDENT/CLIENT DAYS
(WHOLE NUMBER)

Aspect of Care & Indicators	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Medication Related													
Blood/Blood Products Related													
Treatment /Test													
Falls Related													
Theft													
Property Damage													
Equipment Related													
Smoking Related													
Missing Acute Care Client/Elopement													
Missing LTC Client/Elopement													
Discharged Against Medical Advice													
Unplanned Return to OR													
Unplanned return to ER													
Breach of Confidentiality													
Restraints Related													
Consent Related													
Suicide Attempt													
Assault/Abuse/ Harassment													
Anaesthesia Related													
OB Related													
Complaint													
TOTALS													

Severity Codes:	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Level 1													
Level 2													
Level 3													
Level 4													
Level 5													
Level 6													

Level 1 ☐ An occurrence occurred but the Patient/resident/client was not harmed
Level 2 ☐ An occurrence occurred that resulted in the need for increased Patient/resident/client assessments but no change in vital signs and no Patient/resident/client harm
Level 3 ☐ An occurrence occurred that resulted in the need for treatment and/or intervention and caused temporary Patient/resident/client harm
Level 4 ☐ An occurrence occurred that resulted in initial or prolonged hospitalization, and caused temporary Patient/resident/client harm
Level 5 ☐ An occurrence occurred that resulted in permanent Patient/resident/client harm or near death occurrence, such as anaphylaxis
Level 6 ☐ An occurrence occurred that resulted in Patient/resident/client death

DEFINITIONS for Aggregate Data Collection:

Where applicable, all occurrences should include the "near misses", in other words occurrences that were caught before the error could be made.

Medication related – preventable events in the medication use process. Any occurrence involving the medications, this includes ordering, transcription, administration, reactions etc.

Examples include, but are not limited to occurrences involving:

- Incorrect date/time
- Failure to instruct patient/family
- Incorrect dosage
- Incorrect route/site
- Omitted dose(s)
- Unordered medication given
- Improper medication regime ordered
- Improper preparation of medication
- Wrong medication administered
- Outdated drug or solution
- Wrong patient
- Improper IV rate
- Significant Extravasations
- Order expired
- Adverse Drug Reactions – previously known or newly detected side effects of drugs that may occur in the course of error free medication use. This includes Contrast Media reactions.

Blood Product Related – any occurrence, other than consent, related to the process of blood or blood product administration. This includes, but is not limited to ordering, delivering, reactions, monitoring. Examples include:

- Delay in administration
- Failure to insure contamination free
- Infiltration
- Transfusion problem
- Wrong additive
- Wrong flow rate
- Wrong patient
- Wrong solution
- Wrong type of blood or product
- Needle stick injury

Test/ Treatment Related: This refers to any diagnostic or treatment procedure or test performed anywhere in the health care organization– including inpatient, outpatient and community services. Laboratory and diagnostic imaging and operating room procedures are included in this category. Examples include but are not limited to:

- complications
- delayed or omitted treatment procedures
- delays, omitted or incorrect results or reports
- failure/delay in referral/consultation
- improper or omitted monitoring
- improper performance of treatment/procedure
- improper treatment/course
- omitted history/physical

- incorrect client
- equipment failure
- defective medical device
- specimens (lost, mislabeled, transport, etc)
- Retained foreign body
- Improper sponge and needle count

Falls Related-

A witnessed or unwitnessed event that results in a person coming to rest on the ground or floor or other lower level. (RNAO) All repeat falls should be reported on occurrence reports.

Theft/Suspected Theft: Missing patient/resident/client articles of any value that are suspected of being stolen, whether or not the occurrence is reported to the police.

Property Damage: Any occurrence resulting in damage to the patient/resident/client's personal property. This includes but is not limited to examples such as:

- Motor vehicle damage in parking lot
- Water damage
- Aggressive behavior leading to property damage.
- Break and enter.

Equipment/Product Related: refers to any occurrence that involves equipment related to client use. Examples include, but are not limited to:

- Equipment malfunction/failure
- Improper maintenance/inspection or testing
- Lack of adequate equipment
- Product adverse outcome.
- User error
- Not following manufacturer instructions
- Loaning and returning equipment issues
- Product/Equipment recall or warning issued.

Smoking Related: Any occurrence involving the use of smoking materials in non-smoking designated areas.

Missing Client/Elopement: Any occurrence where the client is not accounted for; specifically the client has an unassisted, unsupervised, unscheduled or unauthorized departure from the unit, facility, organization or place of residence.

Self Discharge (Against Medical Advice): the client leaves the health care facility against advice from health care professionals.

Unplanned Return to Operating Room (OR) – an unplanned return to the operating room within 48 hours of the initial surgery.

Unplanned Return to Emergency Department (ER) – an unplanned return to the emergency department within 24 hrs for a similar or related complaint.

Breach of Confidentiality – Confidentiality refers to a third party's obligation to ensure that personal information is only accessible to those authorized to have access. Examples include but are not limited to:

- Discussion of confidential client information in public areas, such as elevators, lobbies, cafeterias or off premises;
- Discussion of confidential client information in the presence of persons not entitled to such information
- Inappropriate access to and/or distribution of e-mails
- Inappropriate access to and/or distribution /communication of information related to co-workers, relatives, or neighbors

Restraint Related:
Refers to any occurrence involving restraints. A restraint refers to any physical, chemical or environmental means of restricting, limiting and/or inhibiting an individual's freedom of movement.
For Example a physical restraint is: any device, material or equipment that restricts freedom of movement or access to his/her (the resident's) body. This may include, but is not limited to, vest restraints, lap belts (in front or behind closures), pelvic restraints, mittens, chairs with lap trays and anklets/wristlets. These items are not restraints if used for customized seating purposes as prescribed by an Occupational Therapist, and/or can be easily removed by the resident, or if, without the device, the resident could not voluntarily move the part of the body over which the device is attached. (Ref SJNHB Least Restraint policy). " Bed rails are not included in this definition."

Consent Related Occurrence:
Any occurrence resulting from the inadequate disclosure and/or documentation of information by the health care provider which thereby prevents the patient/resident/client from making an informed health care decision. This includes, but is not limited to, the following examples:

- Failure to obtain informed consent/waiver as per organizational policies and procedures
- Failure to obtain informed consent under current legislative requirements (i.e. legal/mental capacity)
- Failure to properly instruct the patient/resident/client or family.
- Issues relating to the application of the advanced health care directives act.

Suicide Attempt – any occurrence where a patient/resident/client attempts to end his or her own life.

Assault/ Abuse/Harassment: Any occurrence resulting from intimidation, domination or violent assault which threatens the person's health, safety and well-being. The abuse may be physical, emotional, sexual or financial. This includes but is not limited to the following examples:

- Mistreatment or neglect of a child
- Action or inaction which results in harm to or jeopardizes the health, well being and safety of an adult
- Threats of violence or endangerment
- Unwelcome comments or physical advances which are intimidating, humiliating, malicious or sexually explicit
- Improper or illegal use of a person's funds, assets, property or resources for another person's profit or gain.

Anaesthesia Related: Any occurrence involving anaesthesia. Examples include, but are not limited to:

- Improper pt assessment
- Failure to monitor
- Improper airway maintenance
- Improper anaesthesia administration
- Improper choice of anaesthesia
- Improper positioning

OB Related- any occurrence involving the perinatal period, including but not limited to:

- Delay/failure to monitor/treat fetal status
- Delayed delivery (induction/C Section)
- Choice of delivery methods
- Injury to mother or baby
- Retained foreign body

Significant Complaint:
A complaint that has resulted in or has the potential for an adverse occurrence; or has implications for legal action, and which requires follow-up and/or investigation.
(Note: A minor complaint is a complaint which can be resolved satisfactorily at the staff or department level and where the perceived risk is minimal – these will not be included with the aggregate data collection tool.)

Complaint Category Definitions:

Access - Concerns that relate to a person's access to treatment or diagnostic services being offered by ……(organization's name). This includes concerns re wait times and inability to contact appropriate staff. For our purposes this has been broken down into Access to Diagnostic Services and Access to Treatment by health care providers.

Administrative - This includes issues that relate to matters arising from ……..(organization's name) policies or procedures.

Attitude/Communication - Attitude includes a person's response to a situation. Communication includes breakdowns of communication, lack of information. For our purposes this has been broken down into three categories i.e. Nursing, Medical, and Other (Disciplines).

Confidentiality - Issues with relate to the Freedom of Information and Protection of Privacy Act. These may relate to patients/residents/clients or family members requesting information or access to personal data being kept or stored by the …….(Organization's Name).

Environment - those issues, which relate to the level of noise, availability of parking or level of heat, etc.

Financial - issues related to additional room fees or other fees.

Hospital Services - concerns that relate to the cleanliness of rooms, meals, access to amenities etc

Inadequate Information - issues which relate to the patient/resident/client not being given enough information that he/she feels should have been shared with him/her concerning his/her treatment.

Lost Articles - concerns raised relating to lost or misplaced personal items during patient/resident/client's stay in hospital/clinics/departments.

Patient/Resident/Client Safety - occurrences due to lack of physical or procedural safety measures (eg patient falls), also includes concerns re other patients/residents/clients.

Quality of Care - those issues which relate to deficiencies in actual care provided by health care professionals, usually nursing or medical (also includes concerns of misdiagnosis). Again this has been broken down into three categories (Nursing, Medical & Other).

Other - e.g. wanting information on health related issues and/or how to contact ……(*organizations name*) etc.

NLAHRM PATIENT/RESIDENT/CLIENT SAFETY MANUAL

SAMPLE FAILURE MODE, AND EFFECT ANALYSIS FORM

High Risk Process: _____

Severity

_____

☐ 3 - An occurrence occurred that resulted in the need for treatment and/or intervention and caused temporary patient/resident/client harm

☐ 4 - An occurrence occurred that resulted in initial or prolonged hospitalization, and caused temporary patient/resident/client harm.

☐ 5 - An occurrence occurred that resulted in permanent patient/resident/client harm or near death occurrence, such as anaphylaxis

☐ 6 - An occurrence occurred that resulted in patient/resident/client death.

Selected Through:

☐ JCAHO Sentinel Occurrence Alert on _____ (attach alert)

☐ Patient/resident/client Safety Tracking Tool (OCCURRENCE REPORT)-Occurrence:

☐ Multiple OCCURRENCE REPORTs - # of occurrences _____ within _____ months

☐ Other (specify): _____

Review conducted by: _____ Date: _____ Participants: _____

Complexity (Steps in process from initial activity to identification of error)

	Would failure at this step adversely affect patient/resident/ client?	If yes, rank possibility: 1 = remote 5 = already documented elsewhere 10= documented & almost certain to occur	If yes, rank severity of overall failure: 1 = no harm to patient/resident/client 5 = may affect patient/resident/client adversely 10 = injury or death will occur	If yes, likelihood of detection BEFORE accident takes place: 1 = will always be detected 5 = might be detected 10 = detection not possible	Criticality Index: (mean of possibility, severity, detection – divide by 3): 1 = no action needed 5 = action must be considered 10 – action a must
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					

9.					
10.					

Is Root Cause Analysis (RCA) indicated (anything above 5 in Severity or in Criticality Index)? If yes, attach RCA Summary & complete information on reverse side of this form

ERROR REDUCTION ACTION(s)

Remove Alternatives

- ☐ Eliminate dangerous items/procedures
- ☐ Limit use or access
- ☐ Certification or privileging
- ☐ Avoid potential confirmation bias (look-alike containers, names, abbreviations)
- ☐ Minimize consequence of error
- ☐ Other (specify): _____

Improve Detection

- ☐ Orientation, education, additional training
- ☐ Protocols & procedures
- ☐ Hazard warnings & signs
- ☐ Technology
- ☐ Improved inspection process
- ☐ Other (specify): _____

Prevent Completion of Action

- ☐ Fail safe (automatic shut-off, locking device, etc)
- ☐ Forcing function (non-compatible connectors, etc)
- ☐ Technology (automatic med dispensing system, etc.)
- ☐ Other (specify): _____

Minimize Consequence of Error

- ☐ Reduce supply (volume, concentration, number, etc)
- ☐ Modify defaults
- ☐ Other (specify): _____

FOLLOW-UP FOR EFFECTIVENESS OF ERROR REDUCTION ACTION(s)

Date of First Review: _____ Reviewer: _____
(individual or committee)

☐ Action(s) resolved problem

☐ Action(s) reduced problem.
Needs modification as follows:
_____
_____
_____
Date action will commence: _____

☐ Action did not resolve problem,
New action to be implemented:
_____
_____
_____
Date action will commence: _____

If not completely resolved, review on: _____
(date)

Date of Second Review: _____ Reviewer: _____
(individual or committee)

☐ Action(s) resolved problem

☐ Action(s) reduced problem.
Needs modification as follows:
_____
_____
_____
Date action will commence: _____

☐ Action did not resolve problem,
New action to be implemented:
_____
_____
_____
Date action will commence: _____

INSERT ASHRM'S FMEA WHITE PAPER

Insert JCAHO Documents on Root Cause Analysis

NLAHRM PATIENT/RESIDENT/CLIENT SAFETY MANUAL

Insert the three ASHRM Monographs on Disclosure

Submitted by

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Eastern Health

Eastern Health

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The Task Force on Adverse Health Events
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May 27, 2008

Thank you for the opportunity to make a submission to the Task Force on Adverse Health Events.

My submission is intended to highlight the place of clinical ethics in improving the approach to disclosure of adverse events.

Clinical ethics services typically have three main functions: policy review and development, education, and case consultations. The challenge in health care ethics is to get a right balance between doing the right thing and doing the thing right. Health care organizations in our province, like elsewhere in Canada and around the world, have no shortage of policies, procedures, laws, standards, and guidelines that direct how to do things right. There is often lack of attention and response to the examination of doing the right thing. An active ethics service provides a resource to health care professionals, administrators and the public. Such a service is proactive in the articulation of the ethical issues pertaining to matters of policy, it is a resource for development and coordination of ethics education, and providing consultation on specific cases and issues.

Alberta has established the Provincial Health Ethics Network (PHEN). Nova Scotia has recently started the recruitment process for a health ethics network. In Newfoundland and Labrador we have grown a somewhat informal network out of the services provided from Eastern Health, but the demand has gone beyond the resources available and the obvious next steps cannot be taken without dedicated resources and a provincial mandate.

My brief submission is to underscore what you likely already know: that clinical ethics has an essential place in the approach to disclosure of adverse events. I also take the opportunity to recommend that resources be dedicated to the development of a provincial clinical ethics network to support policy development, ethics education, and case consultations.

I would be pleased to further discuss these ideas with you if they are of interest.

Yours truly,

Rick Singleton, D. Min
Director

Submitted by

Provincial Advisory Council on the
Status of Women Newfoundland and Labrador

PROVINCIAL ADVISORY COUNCIL ON THE STATUS OF WOMEN NEWFOUNDLAND & LABRADOR

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June 12, 2008

Mr. Robert Thompson, Chair
The Task Force on Adverse Health Events
P.O. Box 8700
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St. John's, NL A1B 4J6

Dear Mr. Thompson:

Re: Submission to the Task Force on Adverse Health Events

The Provincial Advisory Council on the Status of Women is concerned with all issues which impact women in Newfoundland and Labrador. The Commission of Inquiry into Hormone Receptor Testing has revealed many shortcomings in our province's health-care system and raises serious concerns about the service women are receiving.

Our submission to the Task Force on Adverse Health Events addresses two areas:

1. The need for a transparent and accountable disclosure policy.
2. The need for patient involvement in development of policy and practice.

Requirement for Full Disclosure

There is no doubt health-care providers have both an ethical obligation and legal duty to disclose health information fully, honestly and in a timely manner to their patients. Whether the rationale is patient autonomy or for the purpose of therapeutic decision-making, truth telling is required. Full disclosure is essential, whether the information relates to general health concerns or an adverse event which causes death.

Research has shown patients want as much information as possible about their health condition. They want to be involved in all decision making affecting their health. This is not possible if information is withheld. In her testimony before the Commission of Inquiry on Hormone Receptor Testing on March 24, 2008, Rosalind Jardine expressed what is required:

> *"The ultimate would be a top-notch, efficient, effective, transparent system whereby everybody affected with a disease such as cancer would be privy and would be a part of that communication system openly, because that's so important. That gives the patient, like just speaking from me, that gives us a power that we still have input and somewhat, though very limited, control on this disease process that's happening, and when you're not informed and it's happening kind of outside of you, you feel so insignificant. You feel that our life doesn't count at all. You don't feel that you're a team."*

Historically, health care has not been based in a philosophy which includes notions of "patient autonomy" and "patient safety." From today's vantage point, it is surprising non-disclosure was the accepted practice until the recent past. *"A 1961 survey of 219 physicians in the USA found that 90% would not disclose a diagnosis of cancer to a patient."* In the 1990's, the Ontario court, *"failed to find fault with a neurologist and a family physician who, for more than 7 years, did not tell a patient that she likely had multiple sclerosis."* (Symaniw v. Zajac and Birnbaum, 1996). (Extracts from a paper, Disclosure: Ethical and Policy Considerations, pp 4-5, prepared by Philip C. Hebert for the Commission of Inquiry on Hormone Receptor Testing, Newfoundland and Labrador 2007-2008).

Surprising or not, we fear this outdated attitude of paternalism continues to influence health care providers both individually and systemically. We hear many stories of patronizing attitudes and information being withheld from patients and their families.

We also worry that stereotypical notions about women increase the likelihood of non-disclosure "for her own good." Ethnicity, class, race, age and disability may exacerbate the perception that the truth will cause worry and stress and, therefore, will be withheld.

Gerry Rogers provided a very clear example of medical paternalism, including its effects on patients, during her testimony to the Commission of Inquiry into Hormone Receptor Testing on March 25, 2008:

> *"...and then I asked her...why did Eastern Health never call me back and why didn't Eastern Health speak directly to the women who were involved, because there was so much confusion. There was so much fear, and I think mistrust grew out of that as well, and she said "well, we don't want to frighten women," and I said again...it makes no sense...we're adults who take part in our health care, and that, in fact what they did was exactly the opposite. They caused fear. They caused confusion. They caused mistrust. They caused unnecessary anxiety..."*

Patient Involvement in Decision Making

One way to address this shortcoming is by the involvement of patients and their advocacy groups in the development of appropriate disclosure guidelines. It is not acceptable for these to be developed and sanctioned exclusively by health-care providers. Community agencies and advocates represent patients' rights and interests; they know what is needed and are well placed to provide this advice.

In addition, the patient's voice must be directly represented on the proposed health quality council in Newfoundland and Labrador.

It is possible our health-care systems will make the shift to a blame-free environment, one which encourages and supports the reporting of errors, including adverse health events. It is our understanding this culture shift would require accountability for errors and systemic problems in health care delivery. It would also create an avenue to improve patient safety, which must become paramount. As part of this culture shift, it will be essential for the public to be made fully aware of the intent, scope and impact of the new environment.

Recommendations

The provincial health-care system must:

1. Commit to full disclosure in regard to response and communication of adverse events within the health system.

2. Presume complete information sharing is required unless the patient has indicated otherwise or is legally incompetent.

3. Consider age, geography, socio-economic status, gender, race, disability and ethnicity and cultural norms in the manner of communication but these factors must not influence whether information is shared.

4. Provide mandatory training in gender sensitivity and communication skills for all health-care providers.

5. Educate all health-care providers about disclosure policy and procedure. It is vital this education is provided at both the entry level and to those presently working in the system.

6. Include community members with knowledge of equality issues in the development and monitoring of health-care disclosure policy.

7. Include patient representation on the proposed health quality council in Newfoundland and Labrador.

8. Inform and educate the general public about the scope and impact of a blame-free health care environment.

We hope the Task Force is successful in paving the way for a more accountable and responsible health-care system which maintains patient safety and full disclosure as primary values.

Sincerely,

Leslie MacLeod
President/CEO

Submitted by

Schizophrenia Society of
Newfoundland and Labrador

Schizophrenia Society of Newfoundland & Labrador
A Reason to Hope. The Means to Cope

The Task Force on Adverse Health Events
Suite 1100
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A1B 4J6

On behalf of the Schizophrenia Society of Newfoundland and Labrador I would like to say thank-you for the opportunity to participate in the Provincial Forum on Adverse Health Events held on May 26th of 2008 in St. John's. It is wonderful to see government bring stakeholders together in this way, to obtain input and ideas regarding the communication and evaluation of adverse health events.

Before we can fully understand how to address and deal with an adverse health event the concept itself needs to be specifically defined. Given that deaths occur every year because of an adverse health event, it is important to define exactly what this would include so it may be identified as such, and guidelines can be established for dealing with it immediately. Any definition of an adverse health event, we believe, should be concise, easy to understand and should address gaps in services as well as the services themselves.

The Schizophrenia Society of NL believes that disclosure of an adverse health event should take place immediately. It is important that individuals in any organization feel safe to disclose to supervisors without the fear of being reprimanded. Open door policies need to be created whereby individuals at all levels of an organization can feel free to disclose important information to their supervisors, in an attempt for all to work equally together in addressing the problem. Disclosure to families should also be done as quickly as possible; Professionals need to collaborate and communicate more openly with families and individuals at the onset of the problem, by clarifying what went wrong and why or how such an event could have occurred. Regular communication and explanation of the honest facts will help create a culture of trust between the professional and individual/family that may help them move forward. Individuals have a right to information around the adverse health event at the time it happens, so they can be active participants in decreasing its' impact if this is possible. Families may also be able to provide insight as to where to go from here.

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At the point that an adverse event happens, combining resources as quickly as possible to do what is in the best interest of the patient is extremely valuable. When treating an individual, service providers need to take into account that they are part of a larger picture. More collaboration between professionals and community groups need to take place. There is a wealth of knowledge that exists in within each patient's environment that could provide insight into a potential or developed situation if it were utilized. In addition to this issues need to be addressed around educating professionals about community resources. Often there are resources that exist in the community that can help the people who are adversely affected. These resources need to be drawn upon by individuals needing them, through the guidance of the professional.

Finally, when elements align at the right place and time to create an adverse health event, the individual closest to the event tends to be blamed by the affected parties. It is of critical importance that responsibility for an apology, reside with all involved and not be limited to the front line worker or the supervisor. Accountability is important if we are to change routine practices and behaviors that contribute to the problem. When accountability is not upheld then there is little incentive for change. Steps need to be taken to assess all possible causes or alignment of causes so that these may be addressed accordingly and changed where possible. Through, complete and accurate knowledge of the truth, professionals, individuals, families and community groups can work together to help decrease critical incidents and more properly address the needs of an individual who has been affected by one.

The Schizophrenia Society of NL would like to thank you for allowing us the opportunity to put forward our ideas for consideration.

Sincerely,

Christina McGrath
Executive Director, SSNL

Florence Budden
President, SSNL

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Task Force on Adverse Health Events

Background Documents
Volume I: Public Submissions

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