Newfoundland Labrador

Task Force on Adverse Health Events

Background Documents
Volume II: Additional Reports

December 2, 2008

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Case Summary Report

Prepared for the Task Force on Adverse Health Events

Government of Newfoundland and Labrador

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Background

In Ireland, the health care system is public and is governed by the 2004 Health Act. The Act established a single national entity, the Health Services Executive (HSE), responsible for managing the delivery of the entire health service and social services to all those living in the Republic of Ireland. The annual budget of the HSE is €15 billion.[1] The Minister for Health and Children has responsibility for setting overall policy with regard to health service is in Ireland.

Prior to the establishment of the HSE, health services were delivered through ten regional health boards, the Eastern Regional Health Authority and many different agencies and organizations. [2] The HSE has four administrative areas (HSE Dublin Mid-Leinster, HSE Dublin North-East, HSE South and HSE West).[3] Acute hospital services, ambulance and emergency response are managed by the National Hospitals Office (NHO).[4] Acute hospital services are delivered through ten hospital networks in Ireland. Each network is managed by a Network Manager who reports to the National Director of the NHO.[5]

Portlaoise is a town located in southeastern central Ireland in the county of Laois between Dublin and Cork.[6] The Midland Regional Hospital at Portlaoise (MRHP) is part of the Midland Hospital Network which consists of three hospitals.[7] The network has a staff of 5,000 and provides health care and social services to approximately 225,000 people who live in Mid-Leinster (Laois, Longford, Offaly and Westmeath).[8] This case summary will review the management of an adverse event with respect to breast radiology services at MRHP.

Warning Signs

In 2002, five years prior to the identification of a potential adverse health event, a surgeon from MRHP wrote the then Minister for Health about inadequacies in breast cancer services provided in Portlaoise.[9] A subsequent letter written three years later in July 2005 by the same surgeon to the present Minister for Health further outlined concerns with breast services at the hospital and specifically stated that breast radiology services were being provided by people without expertise in the area.[10]

The following year, in December 2006, a letter from the radiology department to hospital management at MRHP advised that a new digital mammography imaging system was needed to replace the existing film system. The rationale for seeking the newer technology was attributed to poor image quality and unnecessary repeat X-Rays that were being performed, thereby exposing patients to higher than normal levels of radiation. The letter also cautioned that poor image quality was resulting in missed or delayed diagnoses of breast cancer or in false positive diagnoses with unnecessary surgical consequences.[11]

Identification

In late June 2007, a Clinical Nurse Specialist (CNS) for oncology/ breast care, expressed concern to the Director of Nursing at the hospital about long wait times and possible over diagnoses by mammography by a radiologist at MRHP. Her concern was based on complaints she had received from patients and from her own observation of patients having to undergo multiple diagnostic investigations at up to three different hospitals.

The CNS believed the multiple diagnostic investigations were leading to a four to eight month delay in diagnosis. She also informed the Director of Nursing about differences in reporting between original radiology services performed at MRHP and subsequent reports issued from other hospitals.[12] Upon hearing her concerns, the Director of Nursing requested that she complete Incident/ Near Miss Report Forms. From July 26 to August 13, 2007, the CNS reported eight instances where diagnoses at MRHP differed from that of St. Vincent's University Hospital. [13]

Assessment

On August 15, 2007, the Director of Nursing in a letter formally summarized the incidents to the Network Manager of the Midland Hospital Network. Two weeks later, on August 28, 2007, a meeting was held to discuss the matter. The meeting was attended by the Network Manager; General Manager (Acute Hospital Services); Manager (Strategic Planning and Performance Management); Hospital Manager (MRHP); Risk Manager; Director of Nursing; and the Clinical Nurse Specialist. Based on the information attained from the meeting, the Network Manager made the decision to initiate a clinical review of breast radiology services (mammograms and ultrasound films) provided at MRHP. The following day, Dr. Ann O'Doherty, a radiologist with St. Vincent's Health Care Group and Clinical Director of Breast Check in Dublin, was asked by the Assistant Director of Quality, Risk and Customer Care for the NHO to conduct a clinical review of mammograms taken from November 2003 to August 2007 and to review ultrasounds performed from August 2005 to August 2007.

The clinical review of mammograms was carried out by seven radiologists associated with BreastCheck, Ireland's national breast screening program. Each mammogram was reviewed, reported and assigned a code by one radiologist. Patients "with technically inadequate mammograms were identified as requiring further evaluation by repeat mammography."[14] Because it was not possible to review hard copies of the ultrasounds, it was decided that a chart review by a surgeon would be required, and repeat ultrasounds performed if deemed necessary.

The review process took eight weeks to complete, four weeks longer than previously anticipated. A total of 3,037 mammograms (2,150 patients) and 648 ultrasounds (607 patients) performed at MRHP were reviewed. The review of mammograms revealed that poor image quality was most likely caused by processing, rather than the mammography machine.[15] Consequently, twenty-nine women had to undergo repeat mammograms to allow for a diagnosis, and 101 patients were identified as needing further assessment.[16] A

total of nine false negatives out of the 3,037 mammograms reviewed were discovered. In other words, there were nine cases of "underdiagnosis," rather than "overdiagnosis," as previously thought by the CNS. The false negative rate fell within published norms of similar reviews. The time between the reviewed mammogram and the definitive diagnosis of the false negative patients ranged between four and a half months to two years and nine months.[17] Of the 648 ultrasounds reviewed, a total of 130 women were called back for surgical review. No missed or delayed diagnoses were found in the review of ultrasounds.[18]

Although the total false negative rate fell within norms, several key deficiencies with radiology services at MRHP were noted in the Report:

- A lack of expertise in mammography by the main radiologist involved in screening.
- An absence of triple assessment (clinical assessment; ultrasound and/or mammogram and biopsy) in diagnosis.
- A lack of clarity and conclusions to direct clinical management in mammography and ultrasound reports.
- A suboptimal image quality associated with a mammography machine that had been in use for 15 years, despite having only an 11-year life.
- No evidence that image-guided biopsies were performed at MRHP. This may have led to unnecessary surgical procedures.
- An absence of diagnostic multidisciplinary meetings which are essential for ensuring that patients receive the highest standard of care.
- A significant and avoidable delay in the diagnosis of breast cancer was caused by suboptimal breast imaging practices.[19]

Initial Action

Based on the information attained from the August 28, 2007 meeting with senior management of the HSE and the MRHP, the Network Manager made the following decisions:

- Initiate a clinical review of breast radiology services (mammograms and ultrasound films) provided at MRHP.
- Suspend breast radiology services at MRHP (despite reservations expressed by three high-level HSE managers). [20]
- Place the radiologist who performed the majority of breast radiology services at the hospital at the MRHP on administrative leave.[21]

The following day, on August 29, 2007, Dr. Ann O'Doherty was asked by the Assistant Director of Quality, Risk and Customer Care for the NHO to conduct a clinical review of mammograms and ultrasounds. On August 30, 2007, a briefing note was sent from the Midlands Hospital Network Office to the Department of Health summarizing the decisions from the meeting and stating that St. Vincent's Hospital would conduct, most likely finish, the review within one month.[22] A formal request in writing from the Network Director, HSE Dublin Mid-Leinster, was received on August 31, 2007. Shortly thereafter, a Review Facilitation Group was established by the HSE.

The first meeting of the Review Facilitation Group was held on September 13, 2007. Members of the Group included the Network Manager; Assistant Director of Quality, Risk and Customer Care (HSE); General Manager (Acute Hospital Services); Manager (Strategic Planning and Performance Management); Director of Nursing (MRHP); and a Consultant Surgeon (MRHP). During the course of the review the RVC met on only three occasions with not all members in attendance.

Disclosure

Towards the end of August 2007, disclosure of the clinical review of mammograms was announced by the HSE through the media and not directly to the patients themselves. Patient Focus, an Irish patients' rights organization, was disturbed that many patients were not first informed directly by the HSE.[23] It was generally thought that best practice would have been to write to the patients whose cases were being reviewed at the start of the process.[24] In many instances, patients who had received breast radiology services at MRHP during the period of the review were first informed of a recall for further testing in November 2007 through the media. The "waiting game" led to further anxiety for those affected by the review. To help minimize worry, all patients who were recalled for further mammogram assessment had the results of their imaging reported to them during the visit to the clinic.[25]

The HSE was negatively perceived for opting to contact the 364 women who were given the all-clear on their ultrasounds prior to contacting those who needed a recheck. Local newspapers reported that some women who required a recheck were left messages on their answering machine. Such disclosure practices contributed to high anxiety and violated the patients' right to privacy. Upon calling the Helpline, many of the women were forced to leave a phone message and wait for a nurse to return their call.

The following excerpts from local newspapers clearly show how the public perceived the disclosure processes of the HSE:

> *"I have had a breast scare in the last two years and now I'm worried sick. If this can happen in Cork and Portlaoise, then who is to say it hasn't happened in the clinic I attended. The unfortunate thing about this scare is now a lot of patients will be ringing up in a panic. These clinics are under pressure as it is, and now thanks to these blunders they are going to be under extreme pressure. It really is time to do something about the health system in our country. How many more scares will it take for the government to do something they need to stop looking for a scapegoat and get something done?"* [26]
>
> *"The fact that the HSE could not even operate an effective information phone line for worried women speaks volumes about the whole affair."* [27]
>
> *"I am in despair about this latest fiasco in the health service of this country. I have no confidence in the HSE or the Department of Health to run the*

service properly, let alone tell the truth about what has been going on. My daughter had a mammogram about three months ago in a Dublin hospital and was given the all-clear, now she is beside herself with worry and trying desperately to get another appointment." [28]

Subsequent Actions

In mid-November 2007, following the release of results through the media, the Minister for Health commissioned three reports relating to the breast cancer issue at MRHP. The first was completed by the Acting Head of the National Hospitals Office of the HSE, Dr. Ann O'Doherty. It provided background information into the decision by HSE to suspend services. The circumstances that led to this decision have been summarized on the preceding page. The second report, commissioned by the HSE Board, was completed by John Fitzgerald. His report examined the governance, management and communications of the HSE after it suspended services and began the clinical review. [29] [30] [31] [32] *A summary of Mr. Fitzgerald's findings appears under the Communication, Coordination and Leadership section of this case study.* The third report, completed by Dr. Ann O'Doherty, summarized the results of the clinical review of mammography services at MRHP and provided recommendations for future breast services. An additional chart review of breast ultrasounds at the Portlaoise hospital was completed by an MRHP surgeon. The review of mammograms involved a four-year period (2003-2007), while the review of ultrasounds involved two years (2005-2007).

In response to weaknesses identified in the three reports, the Minister for Health announced measures on March 5, 2008, that will be taken to strengthen the governance and management of future serious incidents by the HSE. In particular, she called for "clearer reporting relationships and lines of accountability; appointing permanent managers to top posts and fostering a strong sense of corporate identity."[33] She also stated that, in future, the Chief Medical Office will have a central role in managing incidents relating to patient safety. The appointment of one person within HSE at a national level to ensure that future reviews are conducted in accordance with the procedure [34]

The Minister instructed that the following revisions be made to the HSE serious-incident policy:

- *The interests of the patients shall always be paramount over all other considerations and all matters affecting, or potentially affecting, a patient will be communicated to that patient first before any such information is made available to other organisations, the Oireachtas or the media.*
- *The lead person for each review will inform all those within the HSE, and others involved in the review, of their respective roles, and all communications will be cleared by them. One point of contact between organisations involved such as the Department will be established at this stage and will apply throughout the process. Numbers of cases under review and associated information will not normally be made*

public until the patients' interests in the review process have been addressed.

- *Immediate consideration will be given to whether a service needs to cease operating in order to prospectively protect patients (pending the outcome of any review), in which circumstances an appropriate contingency must be made to allow patients to access an alternative service.*
- *There will be a thorough check of whether a health professional over whom sufficient concerns arise worked elsewhere and for what time periods, and a decision made as to whether other locations need to be notified so that a determination can be made on the need for reviewing care in these other locations.*
- *The Department of Health & Children, HIQA, the Medical Council and/or any other regulatory body, as appropriate, will be advised of the incident and the status of any HSE review.*
- *An investigation will be undertaken to examine what happened so that "learnings" (including clinical, managerial and governance) can be identified and applied to all similar care settings. A standard template will be developed that would provide the necessary preparedness for management of serious incidents. It will cover issues such as establishment, terms of reference, procurement of legal advice, communications with patients, professionals and the media and other aspects that would benefit from standardisation.*
- *Offers of early counselling for patients will be made where appropriate.*
- *All patients identified who need follow- up care, will have it arranged as quickly as possible, outside of regular clinics if necessary. There will be no delay incurred by waiting until there is a cohort of patients.*
- *First contact with the patient will where possible, offer an actual (early) appointment date for the next stage of care.*
- *Any patient where a fault has been found (e.g. an incorrect test) through a review will be informed of this event (open disclosure) even if it is clinically determined that there has been no impact on their care.*
- *All reviews will be completed as thoroughly and quickly as possible.*

The HSE announced on March 5, 2008, that health care professionals should follow the National Quality Assurance Standards for Breast Disease (published in 2006) and should transfer cancer services to one of the eight centres of excellence. [35]

Communication, Coordination and Leadership

On September 3, 2007, the HSE also reported that the review of mammograms would be completed within a month, and that "any patient affected will be contacted directly by the HSE."[36] This information later proved to be inaccurate: two different time periods were reviewed and the Review took eight weeks to complete. The Review report sanctioned by the Minister was not made available until March 5, 2008.[37]

On November 7, 2007, the Minister for Health issued a press release outlining the sequence of events that had transpired since the identification of the adverse events attributed to breast radiology services at MRHP, as well as and the lessons learned. The press release did not provide any reference to a review of breast ultrasounds, and at this point the patients were unaware that such a review was being conducted. On this date the media learned that a consultant surgeon at Portlaoise had written to the Minister of Health in December 2006 and informed her that breast radiological services were being provided at MRHP by people with no expertise.[38]

On November 22, 2007, the HSE announced that 97 women who had breast ultrasounds would have to be called back for surgical review after they had already been given the all-clear, and that an additional 177 ultrasounds remained to be reviewed (the final number for recall was 130). At this point, the public believed the review was only of mammograms. In fact, the ultrasound announcement was made to the public by an HSE official before the women themselves, the Minister for Health or the CEO of the HSE were notified of the need for the surgical review.[39] This new information created adverse media attention. The following excerpt from a local newspaper clearly shows the negative press.

> *"The disclosure that ninety-seven patients who attended at Portlaoise for ultrasound scans were being recalled for a surgical review was bad enough, but the fact these women heard about this development over the airwaves is scandalous. And then we learn today that these women have not yet even been contacted by the HSE, never mind being offered the counselling that they will now need."* [40]

The two review processes involved, for the most part, two different cohorts of patients.[41] It was also stated on this date that the review of mammograms and ultrasounds had two different look-back time frames. The justification provided by HSE for the different time frames was that "similar reviews in other countries indicated that it is not necessary to look back further in such cases."[42] In the interview with the media it was also stated that the "97 women who are being recalled were to be contacted by phone today."[43]

Local newspapers and transcripts from the parliamentary debates of the Dáil show that there were fundamental problems, particularly relating to communication by the MRHP and within the HSE to patients, the government and the public. On November 27, 2008, the following was transcribed during the Dáil parliamentary debate: *"It is now three months since the Health Service Executive and the Department of Health and Children first became aware of the problem in Portlaoise, and neither the Taoiseach nor the Minister for Health and Children appear to be in a position to give the House or the public any coherent explanation as to what exactly happened in Portlaoise. All we seem to find out is that the problem is getting worse with each passing week."* [44] It was this debate and the subsequent public reaction that prompted the Minister for Health to commission the three reports relating to the breast cancer issue at MRHP.[45]

On March 5, 2008, the Minister for Health issued a press release to announce the publication of two reports relating to breast cancer services at MRHP. Both reports were made available to the public through the government's website. The press release

apologized for the delay in diagnosis for the nine patients and acknowledged that there were serious weaknesses in the governance, management and communication in the handling of the situation at MRHP, which had resulted in unnecessary anxiety. The press release contained a summary of actions that would be taken to avoid future occurrences of similar events and to help alleviate anxiety. On this day, a dedicated HSE toll-free telephone line was launched for those with concerns relating to breast care services.[46]

All efforts were made to keep the women informed during the review. However, the longer than anticipated review process, and the inaccurate and unanticipated release of information to the public in a "drip-feed" manner, stimulated a media frenzy and created significant anxiety for both those affected and the general public.

The report prepared by John Fitzgerald, an external independent consultant, assessed the management, governance and communication issues associated with the Review.[47] He identified several examples of critical weaknesses:

- Too many people from different levels and areas within the HSE were involved in the Review process, and as a result there was an absence of authoritative coordination and clear management roles. Those involved in the Review did not have an understanding of their roles and responsibilities. Confusion existed with regard to who had the most up-to-date information, who had responsibility for providing definitive information, who was making decisions and why the decisions were being made.[48]

- The Review Facilitation Group did not work effectively and had met on only three occasions. Attendance at the meetings varied, and members did not control the integrity of the communications process with patients, the Department of Health or internally. The Group never signed off on the terms of reference for the review and never exerted any control over the communications process with the patients, with the Department of Health or internally. The Review Group only included members from the HSE; there was no independent, external expertise. As a result of the poor management and governance, communication was inconsistent, and, in many cases, lacking. The review of mammograms and ultrasounds was initially supposed to come together under one Review. However, with time, the Review became separated into two distinct processes. The mammography review dominated briefings and discussions until mid-November 2007.

- The press releases were inconsistent, lacked clarity and there was an ongoing release of contradictory numbers with respect to how many patients were affected. The "drip feed" of numbers could only have heightened the anxiety and uncertainty of those patients potentially affected. In Fitzgerald's opinion, the numbers should not have been released until the review process was completed.[49]

- The Review process took longer than anticipated. This was largely because those involved were also fulfilling their normal job obligations. It seems then that there was a need for a dedicated resource to exclusively manage the critical

incident. The HelpLine put in place by the HSE to provide information to concerned patients was inadequately staffed, and many women were not able to speak directly to a person about the review when they.

- Communication between the HSE and the Department of Health was poor. The multiplicity of communication channels created confusion and contributed to the lack of clarity. As an example, both the CEO of the HSE and the Minister for Health were unaware of the ultrasound review. When the HSE released information pertaining to the review of ultrasounds, both the government and the CEO were not ready to respond in an effective manner. The process could have been handled more effectively if key people had been assigned the responsibility of providing status reports within the HSE and to the Department of Health.

While there are several incidences where poor management resulted in poor communication, it would be remiss to not commend the HSE for its efforts in quickly contacting the patients who were recalled as a result of the ultrasound review. Of the 97 patients who were recalled on Thursday, November 22, 2007, by that Saturday, just two days later, 80 of these patients had been at a clinic. Those who required further clinical treatment were seen again on Sunday morning. The remaining people, who were not able to contacted, were seen on Monday, November 26, 2007. The HSE should be commended for their efforts in ensuring that all women were contacted, seen and reviewed promptly.[50]

Evaluation

The HSE will be writing all women who were affected by the Review process to provide them with the opportunity to express their feedback.[51] A report should be written that summarizes the patients' views:

Between 2005 and 2007, both the Department and HSE, did not fully understand the warning signals that inadequacies existed with breast radiology services at the hospital. Consideration should be given to performing an evaluation of the government's actions in relation to the Review, and explanation provided as to why the letter written to the Minister in 2005 by the surgeon at MRHP was not acted upon.

Case 2 - Sterilization of Gynecological Instruments - Labrador City

Background

The Captain William Jackman Memorial Hospital is located in Labrador City and was formerly part of the Health Labrador Corporation (HLC). On April 1, 2005, the HLC and Grenfell Regional Health Services merged to form the Labrador-Grenfell Regional Health Authority. This case summary will review a multi-patient adverse event that occurred in the gynecology clinic at the hospital.

Identification

In March of 2003, it was discovered that the sterilization of reuseable medical instruments at the gynecology clinic of the Captain William Jackman Hospital was not being conducted in accordance with hospital standards. Since January 1999 it had been hospital policy to send the instruments to the Central Supply Room for steam sterilization. A former staff member who returned to work at the clinic noticed the sterilization policy was no longer being followed and that staff were soaking and scrubbing the instruments with Aseptizyme (an antiseptic agent). She reported her observation to the nurse manager who then reported it to the Chief Operating Officer and the Risk Manager of the former Health Labrador Corporation (HLC).

Assessment

It was quickly determined that the concerns were legitimate and that a breach in sterilization policy had occurred at the hospital. Hospital documentation revealed that over an 18-month period (between October 2001 and March 2003) medical instruments used at the gynecology clinic were not properly sterilized.

Disclosure

Although the problem was identified and corrected in March 2003, the hospital did not notify patients of the potential for infection until eight months later. A press release was issued by the HLC on November 10, 2003, and on the same day the HLC sent registered letters to the patients advising them of its failure to properly sterilize the instruments, the minimal risk of contracting an infection, and the need for medical testing to determine hepatitis B, hepatitis C, HIV, chlamydia, and/or gonorrhea status. Unfortunately, some of the letters sent via registered mail did not reach the intended recipients until after the media release, which resulted in high anxiety for those who had been tested during the specified time period. Some patients believed the media should never have been informed of the adverse event.

Another source of anxiety was caused by the disclosure method (registered mail) and by the hours of operation of the testing clinic. Affected patients could be easily identified by those in the small community. This lack of confidentiality caused considerable embarrassment and anxiety for many. In retrospect, many patients would have preferred to have learned of the adverse event directly from their physician.

A dedicated helpline was launched at the hospital for those with concerns. Hospital staff was available by phone, or in person to answer questions from concerned patients. A standard script was used as a basis for these conversations. The HLC was able to establish contact with 311 of the 333 at-risk patients. A clinic operated during extended hours to collect the blood and urine specimens required for testing.

A class action lawsuit against HLC was filed on behalf of 327 women on November 25, 2003, in the Supreme Court of Newfoundland and Labrador. The suit was filed on behalf of residents of the Labrador City area who were injured by the failure of the hospital to: follow proper sterilization procedures at gynecology clinics; disclose in a timely manner, which denied patients the opportunity to seek early medical treatment and to avoid spreading the diseases to others; and to maintain the patients' right to privacy. Patients felt they should have been first informed of the problem through their physician so they could manage the issues within the confidentiality of the physician-patient relationship.

Action

Based on the assessment that a breach in sterilization policy had occurred, senior management immediately made the following decisions:

- Immediately re-establish the correct sterilization process.
- Initiate a review to determine how long the correct policy was not practiced.
- Conduct a review to ascertain the number of people who may have been treated with the improperly sterilized equipment.
- Perform a Risk Assessment to assess the level of risk posed to patients.
- Review infection control protocols at the hospital.

The re-establishment of the correct sterilization procedures was immediately instituted in March 2003. Hospital documentation revealed that over an 18-month period (between October 2001 and March 2003) medical instruments used at the gynecology clinic were not properly sterilized. Experts from Health Canada, the Medical Officer of Health and the Risk Manager for HLC spent six weeks reviewing data on 537 patients who had attended gynecology clinics during the specified time frame. HLC had a high level of confidence in the data collected by these people.

A risk assessment was conducted by Health Canada to assess the level of risk posed to the patients. It was determined that 333 patients were treated with improperly sterilized instruments and were considered to be at a low risk for contracting chlamydia, gonorrhea, hepatitis B virus, hepatitis C virus and/or HIV. Although the likelihood of infection was determined to be extremely low (estimated at 1:10 million to 1:1 million), Health Canada recommended that all of the 333 at-risk patients be tested for the diseases. Dr. Jim Hutchinson, Infection Control, former Health Care Corporation of St. John's, and other disease specialists agreed with Health Canada's recommendation. By January 2004, most of the patients had been tested by the St. John's Public Health Laboratories. According to HLC the test results were as expected and within normal limits.

In November 2003, an infection control expert from the former Health Care Corporation of St. John's visited the hospital. An independent review of infection control protocols

practiced at the hospital was conducted. It was found that the cleaning and disinfection/sterilization of the gynecology instruments were in accordance with Health Canada's recommendations.

Since the class action lawsuit was filed, the Captain William Jackman Memorial Hospital implemented several measures to prevent a similar situation in the future:

- An independent review was conducted by the Director of Infection Control at the former Health Care Corporation of St. John's. All recommendations were implemented.
- Sterilization policies and procedures were revised. Equipment used at the clinic would be cleaned initially and then sent for heat sterilization at the Central Supply Room.
- A licensed practical nurse was hired to manage the gynecological clinic.
- A Medical Service Aid was given primary responsibility to ensure the proper sterilization of the gynecological equipment.
- The increased use of disposable products/equipment to reduce sterilization requirements.
- The introduction of an improved orientation program for all staff involved in sterilization practices at the hospital.

As per the August 1, 2007 settlement agreement, the health authority:

- Published a notice with an outline of the changes to policy and procedures that had been implemented since the event, as well as an apology to those affected. A copy of this notice was placed on the Board's corporate website.
- The Chief Executive Officer for the Board was available to the media to discuss and publicize the implemented changes in sterilization procedures.
- The Board will appoint a community representative to the Physical Environmental Continuous Quality Improvement Team (responsible for developing infection control processes).
- The insurer will conduct an educational seminar on the topic of infection control.
- Affected women and their spouses will receive $450 and $100 respectively.

A *Telegram* article reported that some women believed the settlement to be fair. It was noted that the class action suit against the former HLC was not about laying blame or about monetary gain. It was about making changes to policies to improve future health care in the region.

Communication, Coordination and Leadership

The key issue with this multi-patient adverse event related to the method and timing of disclosure to patients. Prior to the disclosure, there was considerable discussion about how to disclose to the patients and how to invite them for further testing. The three key players in this discussion were the CEO, MOH and the Quality/Risk Officer. Experts were also consulted from across the country, and much assistance was provided by Dr. Jim Hutchinson. The Medical Officer of Health for the region was extensively involved, and provided continuous leadership and knowledge of infectious diseases. The MOH was also the key spokesperson for the RHA.

This group met a number of times over several months to assess the level of risk posed to the patients. The decision to disclose once the Chart Review and Risk Assessment had been completed was made very shortly after the identification of the adverse event. The board was advised about the issue before disclosure occurred. The MOH was the designated spokesperson for the RHA. Legal counsel and insurers were consulted and involved at several junctures throughout the process. A press release was issued by the HLC on November 10, 2003. It advised the public that instruments in the gynecology clinics at the hospital were not properly sterilized between October 2001 and March 2003, and that letters had been mailed to patients asking them to undergo further medical testing.

Evaluation

The class action lawsuit in itself acted as a form of evaluation in terms of how the adverse event was managed. Follow-up evaluation was not specified in the settlement agreement or in the announcement made by the Board. Routine surveillance of the sterilization procedures should occur to avoid a future recurrence of the event.

Case 3 - Inadequate Sterilization - Vegreville, Alberta

Background

Vegreville is a town located in central Alberta approximately 100 kilometres east of Edmonton. Within Vegreville is St. Joseph's General Hospital (SJGH), a 25 acute-care facility.[52] In March 2007, due to continued outbreaks of MRSA (methicillin resistant staphylococcus aureus) and improperly sterilized surgical equipment [53] a Public Health Order was issued that stopped all new admissions to the hospital, closed the central sterilization room (CSR) and cancelled all surgeries.

Staphylococcus aureus is a bacterium that commonly lives on the skin or in the noses of healthy people. It can become highly resistant to certain classes of antibiotics. MRSA is extremely difficult to eradicate once it has been introduced into a hospital setting. It is easily transmitted through direct person-to-person contact; the hands of health care workers are considered to be the most significant source of transmission. This case summary will review the events that resulted in the Public Health Order and will review the management of issues relating to sterilization practices at SJGH.

Identification

MRSA

In April 2003, the boundaries for the regional health authorities changed in Alberta. Vegreville was transferred from the Lakeland Health Authority to East Central Health Region (ECH). A review of surveillance data completed in August 2003 showed a higher than normal number of MRSA cases at SJGH than in the rest of the regional health authority. Several measures were developed to reduce the incidence of MRSA at the hospital. However, despite these initiatives, outbreaks continued to occur in the following years. [54]

Nearly four years later, at a meeting on March 15, 2007, the issue of repeated MRSA outbreaks was discussed with senior management and the Boards of SJGH and ECH. The following day the IPC Coordinator and Medical Officer of Health (MOH) for ECH visited the hospital to determine if infection control directives had been undertaken. It was quickly determined that housecleaning solutions had not been changed as previously requested, and that contact precautions were not being applied to new and previously positive MRSA patients.[55] It was believed that seven recent MRSA cases were acquired during a hospital stay at SJGH.[56]

Inadequate Sterilization of Hospital Equipment

The first indication of a problem with sterilization occurred in November 2003. It was identified by ECH that SJGH did not have a scope washer-sterilizer and that the sterilization of scopes was not being conducted as per ECH policy. A report presented to ECH senior management in March 2004 requested that endoscopic sterilization practices

be compliant with the *ECH Central Sterilization Manual*. However, the sterilization practices at SJGH did not change as per ECH policy.

An audit of CSRs in ECH commenced in August 2006 and was completed January 22, 2007. Several key deficiencies were found relating to the sterilization of scopes at SJGH. Three days later, on January 25, 2007, scope procedures were cancelled for the next scheduled date of February 19, and an infectious disease specialist was consulted. Following a meeting on February 13, 2007, it was determined that the CSR should be closed and that surgical instruments should be sent elsewhere for sterilization.[57] Over a month later, March 15, 2007, it was reported by ECH nursing administration that the surgical instruments were not being sent to outside hospitals for sterilization. On the following day, on March 16, it was determined that the CSR had not been closed as per the directive issued over the month before.[58]

Initial Action

On March 16, 2007, the MOH for ECH inspected the CSR, determined there was a risk to patient safety and issued the a Public Health Order citing concerns about continued outbreaks of MRSA and inadequate sterilization of hospital equipment at SJGH.[59] Under the Order, the hospital was closed to new admissions, the CSR was closed and all surgeries were cancelled.[60] An ECH nursing manager was appointed to be on site at the hospital to ensure that appropriate cleaning procedures and quality control measures were immediately implemented.

Hospital staff immediately took measures to align infection control practices with ECH policy. On April 16, 2007, the hospital began a phased-in approach to admitting acute-care patients.[61] Regular monitoring and inspection will ensure that proper infection prevention control measures continue at SJGH.[62] The CSR remained closed and surgical instruments continued to be sent to other hospitals for sterilization.[63]

A four-year "look-back" of patient records dating back to April 1, 2003, was initiated on March 27, 2007. The purpose of the look back was to identify patients who were at risk for contracting a blood-borne disease through the inadequately sterilized equipment.[64] The first groups of patients to be offered testing were those who had tonsillectomies and/or internal biopsy scoping procedures. [65] [66] As of November 27, 2007, 98 per cent of the 2,872 patients had been contacted, and 1,850 patients had chosen to undergo testing.[67] As of June 2008, test outcomes have not been reported to the media or on the ECH corporate website. The risk for contracting a blood-borne disease as a result of a surgical procedure at SJGH is considered to be low.[68]

Assessment

In March 2007, the Minister of Health and Wellness appointed an interim Board of Management to oversee the operation and administration of SJGH and engaged the Health Quality Council of Alberta (HQCA) to conduct a review of the underlying causes and contributing factors that led to the Public Health Order.[69] The HQCA is legislated under Section 13 of the *Health Quality Council of Alberta Regulation* to conduct inquiries into the safety and quality of patient services in the province.[70] All

Investigative Team and Expert Advisory Panel activities were performed under the "auspices of the Quality Assurance Committee of the HQCA and were protected by the Alberta Evidence Act."[71]

On July 25, 2007, the HQCA released its findings and recommendations to the public, which allowed the general public and patients to have a full explanation of the events that triggered the Public Order. The report included over 100 findings and recommendations for the health system in Alberta. Key finding were as follows:

- The legislation and agreements that governed ECH and SJGH were unclear. There was a lack of agreement as to which entity had final authority in making operational decisions for SJGH.[72]
- The working relationship between SJGH and ECH was strained. There was a lack of understanding as to who had authority, accountability and responsibility for quality and safety. The Service Agreement needed to be better defined.[73]
- The organizational structure was not arranged adequately to support patient safety at ECH. As a result, key safety issues were not quickly identified to allow prompt action by senior administration and at the board levels in both ECH and SJGH.[74]
- The "look-back" audit process was not handled expeditiously and with the required level of urgency.
- The audit of CSRs in 11 other acute -care sites in ECH revealed deviations from the standards of the Canadian Standards Association.[75]

Disclosure

A March 20, 2007 news release from ECH stated that patients who were exposed to inadequately sterilized equipment would be contacted and be recommended for HIV and Hepatitis B and C testing. On March 27, 2007, a press release from ECH confirmed that former patients of SJGH who may have been exposed to blood-borne diseases during surgical procedures performed at the hospital since April 1, 2003, were in the process of being contacted. A toll-free line was launched to help those with questions. ECH had started the process of contacting former patients by phone or registered mail. Patients who underwent testing had their results reported to them by a health professional. The first patients contacted consisted of those who had tonsillectomies. These were followed by those who had undergone internal scope biopsy procedures.[76]

Communication, Coordination and Leadership

On March 15, 2007, the regional MOH was requested by ECH to visit SJGH and confirm if the previously requested infection prevention control measures had been undertaken. It was confirmed that inadequately sterilized equipment was continuing to be used at SJGH. The following day the MOH issued a Public Health Order that resulted in the hospital being closed to new admissions, the shutting down of the CSR and the cancellation of all surgeries. Under the Public Health Act regional MOHs have the legislative authority to make such decisions.

There was a four-day delay in disclosure to the public about the Public Health Order. Initial disclosure occurred through a news release by the MOH for ECH on March 20, 2007. No explanation was provided in the news release for the delay.[77] It was not until

November 27, 2007, that ECH released an Information Bulletin that stated that 98 per cent of the former patients had been contacted and that 65% had chosen to be tested. The Bulletin did not provide data pertaining to the number of those tested who had positive results. It did, however, state that the test results were within normal limits. In an interview with media, the MOH for ECH stressed that it was not known whether the positive test results were linked to improper sterilization. The MOH said "The numbers we have found so far are much lower than what you would expect in the general population."[78] It appears that no further updates relating to this have been published by ECH since November 2007.

Subsequent Actions

On June 12, 2007, the provincial government of Alberta introduced Bill 41: *Health Professions Statutes Amendment Act*, in the legislative session. If passed, the Bill would "require health professions to immediately report to the Medical Officer of Health nuisances or threats that may be dangerous or cause injury to the public."[79] The Bill "contains provisions to allow government to ensure that health professions include standards of practice in their bylaws and codes of conduct."[80]

Following the release of the HQCA recommendations on July 25, 2007, the provincial government stated that the relationship between ECH and SJGH was proven to be unworkable, and that the Board will be replaced with two official administrators to oversee ECH operations. The provincial government announced that it will:

- *Develop provincial standards and measures for infection prevention and control, and monitor and enforce compliance.*
- *Direct that all sterilization processes for East Central Health be carried out by Capital Health and the David Thompson Health Region until further notice.*
- *Implement provincial guidelines for managing and preventing Methicillin-Resistant Staphylococcus aureus (MRSA) outbreaks in health care facilities.*
- *Bring forward legislative and regulatory changes to ensure clarity of roles and responsibilities, to confirm that regional health authorities are responsible for health services in their regions.*
- *Ensure that voluntary operators work with, and be accountable to, health regions for services they provide, and that all practices are consistent with provincial policy and standards.*
- *Work with health regions, voluntary health boards, faith-based voluntary organizations and other stakeholders to review the master agreement and service agreements, to improve governance arrangements and clarify roles and responsibilities for quality and patient safety.*
- *Clarify the authority of regional medical officers of health with respect to infection prevention and control and establish direct linkages to the province's Chief Medical Officer of Health.*
- *Ensure that professional bylaws, standards of practice and employee codes of conduct make clear that anyone who becomes aware of a real or potential risk to patient safety is duty bound to take appropriate and timely action.*
- *Review the role, function and capacity of the Health Facilities Review Committee in the quality assurance process.*[81]

An announcement by ECH on April 13, 2007, stated the arrival of a new washer/disinfector and scope sterilizer for the hospital and announced renovations to the CSR. The CSR remained closed and it was announced on January 8, 2008, that the hospital will no longer operate a CSR.[82 83]

Evaluation

The provincial government news release of July 25, 2007, announced significant measures to be undertaken as a result of the sterilization issues at the Vegreville hospital. However, it did not provide a time frame as to when all the recommendations will be implemented. On May 15, 2008, the nine regional health authority boards in Alberta were replaced by a single provincial health services board. Some of the recommendations announced by government, and in the HQC Report, will need to be modified for the new single board setting.

Case 4 - Nova Scotia: Creutzfeldt-Jakob Disease and Infection Control

Background

In Nova Scotia, during April and May of 2004, two patients were investigated for suspected Creutzfeldt-Jakob disease (CJD). CJD is a rare, degenerative brain disorder that affects the nervous system and results in rapidly progressive dementia, loss of motor control, paralysis and death.[84] There is no treatment for the disease. In most cases, CJD is fatal within one year from the onset of symptoms. A protein in CJD is resistant to sterilization. The disease is rarely contracted through contaminated surgical equipment. However, the incubation period for developing the disease is very long, and can take up to 30 years.[85]

The disease is not easy to diagnose. There is currently no diagnostic test that uses easily accessible biological tissue. Physicians rely on the patient's symptoms combined with the results of electroencephalography and brain biopsy. Other diseases that cause similar symptoms can be ruled out through other diagnostic testing techniques, such as lumbar puncture or imaging. Most definitive diagnoses are not made until after a post-mortem neuropathological examination. [86] This case summary will review the management of events in relation to the possible exposure of multiple patients to CJD at two hospitals in Nova Scotia.

Identification

In April 2004, a patient was admitted to the Queen Elizabeth II Health Sciences Centre (QEII) in Halifax for the investigation of neurological symptoms. The QEII is the largest academic health centre in Atlantic Canada and is part of Nova Scotia's Capital Health District Authority (CHDA). A tissue specimen was taken from the patient and tested at the hospital's pathology laboratory. The tissue had characteristics associated with CJD, but, a definitive diagnosis was not given. The specimen slide was sent to a specialized neuropathology laboratory in Toronto for diagnostics. The Toronto lab reported that a CJD diagnosis was a remote possibility and alerted the Health Canada Surveillance System. Health Canada reviewed the findings, upgraded the likelihood of CJD to a probable diagnosis and identified that there was a potential risk to patients who may have been exposed to possibly contaminated medical equipment.

All parties involved in reviewing the slide determined the patient's case to be extraordinarily complex and that a third opinion was necessary. The slide was sent to a specialist in Geneva where CJD was definitively ruled out. The entire diagnostic process took approximately six weeks (three days for initial opinion; 10 days for national opinion; and 27 days for last opinion).[87]

A few days later, a second case of CJD was suspected. The patient was initially admitted to Yarmouth Regional Hospital (YRH), part of the Southwest Health District Authority. The patient underwent a clinical investigation where the possibility of CJD was not

considered. The patient was later admitted to the QEII for further investigation, and whereupon CJD was considered probable by the attending physician. YRH was not notified of the possible diagnosis. The media coverage caused the family of the patient from Yarmouth to contact YRH and identify their family member as possibly having CJD. A pathologist from the YRH and officials at Health Canada and the Department of Health reviewed a tissue sample from the second patient who had come in contact with a medical device that was used on the patient. Three days after the public was notified of the second suspected case, it was determined that no patients who had undergone procedures with the same medical device as used on the potentially infected patient were at risk of exposure to CJD.[88]

Assessment

A trace-back process was performed by QEII and YRH to determine what instruments may have been contaminated from possible exposure to CJD and to identify the patients who had procedures performed with the potentially infected equipment. A total of 59 patients were identified as being potentially exposed to the disease (26 through the first patient and 33 through the second). The risk of infection differed between patient groups. The first patient had undergone a procedure in which medical devices were used on high-risk tissue, whereas the second patient had a procedure deemed by Health Canada to be low risk.[89]

April 29, 2004, the Minister of Health ordered a joint review of the actions taken by the involved organizations on. The review was undertaken by the provincial Department of Health, Health Canada and Capital Health.[90] The report was submitted to the Minister of Health on August 5, 2004.

Disclosure

An ethics review was conducted by Capital Health to determine appropriate disclosure measures. Despite the extremely low risk of possible exposure to CJD, it was suggested in the review that health officials should have first notify all patients who were at risk before informing the media. The ethical decision-making framework was based on the premise that individuals have the right to full information about their own health status and safety risks.[91]

Approximately two weeks after the first patient had been admitted to QEII with symptoms related to CJD and it was determined by Health Canada to be a probable diagnosis, physicians began notifying the 26 at-risk patients. Media releases were also issued at this time by both the Department of Health and the Capital Health District Authority (CHDA). To assist in patient inquiries, a public information line was set up by CHDA. Within 24 hours of the determination that the second patient was suspect for having CJD, health officials at YRH began the process of notifying the 33 at-risk patients. Communication with patients was accomplished in three days.[92]

Not all patients reacted well to the news of the possibility of being exposed to CJD. A patient was quoted as saying, “They said we might have infected you with this gadget, but don’t worry about it until we find out for sure.”[93] This same patient was then told

that he would not know with certainty if he had been infected with the slow moving disease until symptoms presented, which could take up to 30 years.[94]

In retrospect, perhaps more consideration should have been given to the clinical urgency of contacting patients before it was known whether or not they were in fact at risk of being exposed to the fatal disease. It may have been prudent to factor in the long incubation period for the development of the disease in the decision of whether or not to disclose the information prior to definitive diagnoses of the two index cases. Without doubt, the at-risk patients, as well as members of the general public, experienced unnecessary anxiety. When the risk of contamination with CJD was ruled out, all at-risk patients were notified and contacted about the negative diagnostic test outcomes.

Actions

Both Capital Health and Southwest Health conducted a trace-back process to determine what instruments may have been contaminated, and to identify the patients who were at risk for exposure to CJD. As a safety measure, medical equipment used on the two patients suspected of having CJD were quarantined at both hospitals. However, the timing of isolation differed. In the first case, the isolation occurred ten days after the Toronto laboratory considered CJD as a remote possibility. At YHD, the equipment was removed more promptly (less than 24 hours after it was determined by family members that the patient was suspect for CJD).[95]

On April 29, 2004, in response to the management of events that transpired in relation to the two suspected cases of CJD, the Minister of Health ordered a joint review of the actions taken by the involved organizations. The joint review was undertaken by the provincial Department of Health, Health Canada and Capital Health.[96] The report was submitted to the Minister of Health on August 5, 2004. It contained 16 recommendations relating to communication, disclosure and infection control. The recommendations resulting from the joint review are verbatim as follows:[97]

1. *A system-wide policy should be implemented which specifies the circumstances and requirements under which DOH expects health care agencies to notify the Department regarding major patient- safety events.*
2. *The process for accessing administrative staff of each health care agency and the DOH after regular working hours should be outlined and shared across the health system.*
3. *A process should be developed for collaborative communication planning when informing the public about actual or theoretical exposure to risk within the health care system.*
4. *Mechanisms for safeguarding confidential patient information in public communications should be clearly outlined in communication protocols for all organizations.*
5. *Current provincial policy development on disclosure (underway) should incorporate the use of a consistent ethical framework for decision making.*

6. *Collaboration between Public Health, the medical examiner and neuropathology should be encouraged to obtain timely autopsy information in order to provide definitive information regarding risk to contacts who may have been exposed.*
7. *Processes for mandatory reporting of CJD to the provincial Department of Health should be clearly outlined and communicated to the health system.*
8. *Thresholds for reporting of CJD should be clearly stated (i.e. at what level of diagnostic certainty – confirmed, probable, possible) to the following:*
    - *the Department of Health*
    - *the CJD surveillance system (Health Canada)*
    - *Infection Control practitioners within a facility or district*
    - *Infection Control practitioners or other clinicians in other jurisdictions*
    - *the Canadian Blood Services*
9. *Health Canada CJD terminology should be used consistently across the province when referring to cases of CJD as confirmed, probable or possible.*
10. *Operational infection control procedures related to CJD developed by Capital Health should be reviewed for relevance and applicability to other hospitals in Nova Scotia.*
11. *A provincial checklist should be developed for use when multi-stakeholder teams are mobilized in order to assign responsibilities for requisite notifications and procedures as outlined in guidelines and regulations.*
12. *Guidelines outlining the type of information to be provided when patients with suspected or confirmed CJD are transferring between Nova Scotia facilities should be developed.*
13. *The feasibility of developing a uniform tracking system for high-risk instruments should be explored for use throughout the province.*
14. *The process for all Nova Scotia hospitals to access infectious disease expertise at the two provincial health care centres (IWK and QEII) should be outlined and shared across the health system.*
15. *The review of Department of Health capacity to provide a provincial resource as well as a coordinating role in infection control across the system should continue to be supported with a view to further development.*
16. *Mechanisms should be sought to share lessons learned from the Nova Scotia experience with all health care agencies as well as other jurisdictions across Canada.*[98]

Communication, Coordination and Leadership

Media reports and debates within the Nova Scotia Legislature point to dissatisfaction with the timeliness of public communication.[99] Disclosure of information to the public created much negative publicity. Examples of newspaper headlines are as follows:

> "N.S. Hospital Warns Patients of Fatal Brain Disease Contamination" - *National Post* - April 28, 2004
>
> "QEII used instruments on 26 before learning of probable Creutzfeldt-Jakob case - *Chronicle Herald*," April 29, 2004.

> "QEII faces probe over handling of instruments - review to examine how patients may have been exposed to CJD"-*Chronicle Herald*, April 29, 2004.[100]

Several communication challenges were faced by the involved organizations, particularly during the first 48 hours following the first suspected case of CJD. The multi-patient/ multi-jurisdictional events required collaboration within the health organization, between health district authorities, with the Department of Health and with Health Canada. Several barriers prevented effective communication:

- There was an absence of protocols for communication. Central Health did not immediately contact Southwest Health to inform them that one of their former patients was suspect for CJD.
- Reporting relationships and requirements within and external to the HDAs were not known.
- There was a lack of a system policy for notifying the Department of Health of potential safety concerns.
- No threshold existed for the reporting of CJD to the Department of Health, Health Canada, the Infection Control practitioners within a facility, Health District or other jurisdictions, the Canadian Blood Services, those at risk, or the general public.
- A joint communication strategy was not developed by the organizations and the Department of Health.

Despite the communication challenges, a number of positive communication steps did occur. In an effort for consistency in messaging, QEII and YRH shared their patient notification protocols and scripts. The Provincial Medical Officer of Health and the Department of Health were accessible and helpful in coordinating information among organizations. On August 5, 2004, the government released the Report of the joint review to the public, which allowed the public and patients to gain an understanding of the actions taken by the organizations involved in the two recent cases of CJD and to be informed of the recommendations to improve procedures with the management of such events.

Evaluation

In March 2005, the Nova Scotia Department of Health released the *Disclosure of Adverse Events Policy*. This document provides information to facilitate organizations in developing their own policies, structures and terminology, while considering legal, regulatory and administrative issues. The document outlines requirements (mandatory) and considerations (discretionary) associated with the disclosure of adverse events.[101] In October 2005, the "Reporting of Notifiable Diseases and Conditions Regulations" were updated by Nova Scotia.[102]

Case 5 - Pediatric Cardiac Surgery -Manitoba[103]

Background

Pediatric cardiac surgery is a highly complex, low-error-tolerant field with patients often requiring complex corrections at a very early age.[104] During 1993, the Pediatric Cardiac Surgery (PCS) program at the Winnipeg Health Sciences Centre (WHSC) underwent many changes, with the resignation of its program director, its surgeon and all but one of it cardiologists. A new pediatric cardiac surgeon, Dr. Jonah Odim, was recruited and began performing surgeries at the Children's Hospital on February 28, 1994. During that year, 12 children died while undergoing, or shortly after having, cardiac surgery at the WHSC. This case summary will review events that triggered an inquiry and will provide a synopsis of key findings.

Identification

In February 1994, Dr. Odim began his duties as Chief of Service, PCS program at WHSC. Dr. Odim had recently completed his medical residency. The surgeries he performed at WHSC were the first he had performed without the supervision of a senior specialist. Within a few months of Dr. Odim commencing work, five children died after having cardiac surgery. In May 1994, nurses from the surgical and intensive care teams, as well as anesthesiologists, expressed concerns about the deaths to those in authority at the hospital. On May 17, 1994, the Section of Pediatric Cardiac Anaesthesia withdrew services and refused to participate in any further open-heart pediatric surgeries until a review was conducted.

A review committee was appointed. There was an immediate slowdown in the PCS program, with only low-risk surgeries being performed during the review period. More complex cases that required immediate attention were transferred to pediatric cardiac surgical facilities in other provinces. At the end of July the PCS program was expanded to include medium-risk cases and two more children died after having cardiac surgery.

In September 1994, the review committee recommended that the program return to full service. From that point until mid-December 1994, five more children died. In total 12 children died after receiving heart surgery at WHSC. The Head of the Children's Hospital requested that no further pediatric cardiac patients be referred for surgery to the PCS program until a review was conducted by an external review team. In February 1995, the review team presented its findings and the PCS program was suspended indefinitely.

Assessment

Shortly after the withdrawal of anesthesiology services an internal review committee was established by the WHSC departmental leadership. During the summer months the committee reviewed individual patient cases and discussed issues relating to morbidity and mortality, length of bypass and cannulation and problems with team work. Although the meetings occurred on a weekly basis, there were no official minutes. By the end of

July, the committee had been in place for over two months and had not produced a statistical review or achieved a consensus as to whether or not the PCS program should return to full operation. That committee suffered from a number of deficiencies from the outset. It lacked a mandate broad enough to address the issues that were being raised privately by anesthetic and nursing staff. The committee did not appear to have developed a systematic approach to reviewing cases, nor did it develop an action plan to address the issues that had been identified, such as case selection, communication and monitoring. Despite these weaknesses, the Committee recommended the PCS program return to full service in September 1994.

The program continued to suffer from high morbidity and mortality rates, which led the Head of the Children's Hospital to fully suspend the program and order an external review. Two external consultants, Dr. Bill Williams, head of cardiovascular surgery at the Toronto Hospital for Sick Children, and Dr. Larry Roy, a cardiac anaesthetist from the same hospital, were contracted to complete the review in a very short time frame. A notice for written submissions was sent to all physicians involved in the PCS program. The nurses were not asked to prepare written submissions. The nurses later learned about the review from a colleague and prepared a submission that overviewed problems with the program.

The review was completed in early February and reported on a number of issues where the CPS program required improvement. While Williams and Roy stated that Dr. Odim's technical competence was questionable, they did acknowledge that he had to adopt WHSC's methods during surgery rather than stay with his own preferences. The report stated that there was a lack of protocols for effectively resolving disagreements concerning patient care, and questioned whether there was an adequate population for a pediatric cardiac surgeon to maintain his clinical expertise in Manitoba.

On February 14, 1995, the WHSC announced that the PCS program would undergo an extensive six-month review, and that patients requiring pediatric cardiac surgery would continue to be transferred until completion of the review. The announcement prompted many parents of the deceased to demand a public inquiry into the deaths of their children. In response to their request, the Chief Medical Examiner for the province ordered an inquest. The inquest led by Justice Sinclair, began its hearings in December 1995. Over 80 witnesses were heard over a course of 285 days. In November 2000, Justice Sinclair released his report.

Disclosure

The shutdown of the PCS program was first announced through the media and not directly to the parents of the deceased. Many of the families had not received long-promised autopsy reports. The news of the closure created high anxiety. At this point, one of the families was informed that an autopsy had not been performed on their son, as previously thought. It was not until the families started contacting the hospital that the WHSC realized a response was necessary. Coordinators of the Patient Representative Office contacted families and offered them the opportunity to meet with WHSC staff.

Parents should have been informed of the decision to suspend the program in February 1995, prior to the decision being made public.

At the meetings, physicians reviewed the medical issues with families and provided the opportunity to ask questions. From the evidence presented to the Sinclair Inquiry it is evident the families were not satisfied with the outcomes of the meetings. Some felt as if they were getting a "runaround," while others were frustrated that no one at the meeting was able to explain the reason why the program had been shut down. The history of the PCS program and the summer shutdown were not properly explained to the families, and they were they not advised about the Williams and Roy report.

Parents were not fully informed in advance of their child's surgery about the surgeon's lack of experience in performing a particular procedure. In some cases, it was the first time the surgeon had executed such a procedure. In many instances, the indication for risk presented to parents was reflective of profession-wide risk, and not that associated with having the procedure performed at the WHSC. Parents whose children had surgeries after May 17, 1994, were not informed about the anesthetists withdrawal of service, or the decision to perform low-risk procedures only.

Actions

WHSC took precautionary measures in May 1994 by first initiating an internal review and limiting surgery to low-risk patients. In July, the PCS program was extended to include medium-risk patients, and in September the program was granted authority to resume full service. However, no recommendations were developed to deal with issues relating to case selection, communication or monitoring. In December 1994, following the death of the 12th child, the Head of the Children's Hospital requested that no further pediatric cardiac patients be referred for surgery until an external review was conducted. Despite these actions by WHSC, the inquiry found that systemic problems were not addressed in an appropriate and timely manner, and that parents were not provided with full information to allow for informed consent to surgery.

Communication, Coordination and Leadership

Several barriers prevented effective communication, coordination and leadership:

- The responsibility for the PCS program was jointly held by the Head of the Department of Surgery and the Head of the Department of Pediatrics. There was much confusion about who was responsible for the monitoring of the performance of the surgeon, and who had responsibility for taking action when problems were identified.
- The decision to conduct the initial review was made by WHSC departmental heads (Pediatrics, Surgery and Anesthesia) and did not include hospital administrators.
- There was not a consensus by all committee members to return to full service in September 1994. Some members felt that there were still issues with reinstituting the PCS program.
- There was no tracking of common indicators, such as cardiopulmonary bypass times, duration of circulatory arrest times and the volume of blood loss.

- There was also no comparison of the PCS Program with other programs in Canada.
- Complications associated with surgery were not often recorded, charted or reported. Only one incident report was filed out of the 12 deaths that occurred. Complications during surgery were often not charted, recorded or reported to the Standards Committee.
- Nurses made sustained efforts to express their concerns about the surgeon's competency. Their concerns were not taken seriously at WHSC. The external reviewers never formerly asked the nurses to provide a submission.
- The Office of the Chief Medical Examiner did not maintain an up-to-datedata base of hospital deaths. As a result, the problems with the PCS program were not identified in a timely manner.

Evaluation

Justice Sinclair found that during 1994, the PCS program did not provide the standard of care that it was mandated to provide and that parents expected their children to receive. The recruitment of the pediatric cardiac surgeon was flawed. The assessment of the surgeon's skill should have included a discussion with his previous supervisor and an observation of him performing surgery. It was determined that at least five deaths were preventable. Surgeries continuously were being performed that were beyond the skill level of the surgical team. The Sinclair report made many recommendations regarding improvements to the organizational structure of the surgery programs, specifically relating to the assigning of responsibility for decision making. Sinclair recommended several changes to team building, communication, risk management and quality assurance practices.

In response to the report of the Inquiry, the Minister of Health established a Review and Implementation Committee in June 2001 to review the recommendations from the Inquest. One year later, a progress report was published that determined:

- *what actions had already been taken to address the recommendations,*
- *what future actions should be taken, and*
- *the implications of the recommendations for the broader health system.*[105]

Through the collaborative work of many health system stakeholders, eight provincial policies were developed in response to the Inquiry.

1. *Critical Occurrence and Critical Clinical Occurrence Reporting - To ensure that health authorities develop timely, comprehensive and factual reporting and investigating processes for critical incidents and other significant occurrences.*
2. *Internal Disclosure of Staff Concerns - To ensure that health authorities have a process, whereby staff may disclose concerns, and that these disclosures are routed to appropriate people and addressed in a suitable and timely manner.*

3. *Integrated Risk Management Strategy - To ensure that a comprehensive approach is taken to risk management within health care organizations, encompassing all elements that directly or indirectly affect the safety and well-being of clients, staff, medical staff and visitors.*
4. *Quality Audits - To ensure that health authorities use the quality audit process to provide systematic, critical analysis of clinical care and services.*
5. *Health Authority's Guide to Health Services - To ensure that health authorities provide the public with contact points for questions and complaints.*
6. *Notification to Manitoba Health of Critical Occurrences and Critical Clinical Occurrences - To provide a consistent process for health authorities to notify Manitoba Health of critical occurrences and critical incidents.*
7. *Board Governance and Board/Chief Executive Officer/Chief Operating Officer Accountability - To ensure that health authorities develop good governance practices and strategies for continuously improving programs and services.*
8. *Reporting of Significant Changes to the Office of the Chief Medical Examiner - To ensure that all significant changes in health care programs and reviews that are conducted as a result of program-related deaths are reported to the Office of the Chief Medical Examiner by health authorities.*[106]

Case 1 - Ireland Breast Radiology	**Case 2 - NL** Sterilization of Gynecological Equipment	**Case 3 - Alberta** Inadequate Sterilization	**Case 4 - Nova Scotia** Suspected CJD & Infection Control	**Case 5 - Manitoba** Pediatric Cardiac Surgery
Identification Nurse noticed differences in reporting between original radiology services performed at Portlaoise hospital and subsequent reports issued from other hospitals.	**Identification** A former staff member who returned to work at the clinic noticed the sterilization procedures had changed.	**Identification** - Four years of repeated MRSA outbreaks. IPC Coordinator and MOH determined that infection control directives (issued three years previous) had not been undertaken. - A report to RHA Senior Management in 2004 requested endoscopic sterilization practices be compliant with the *RHA Central Sterilization Manual*. This did not occur.	**Identification** Two suspected CJD cases from two different RHAs. First case - Health Canada reviewed the findings, upgraded the likelihood of CJD to a probable diagnosis and identified that there was a potential risk to patients who may have been exposed to possibly contaminated medical equipment. Second case - Initially treated at one hospital and not suspected as having CJD. The patient was later admitted to the QEII in which CJD was considered probable by the attending physician. The first hospital was not notified of the patient's possible diagnosis. The media coverage caused the family of the patient from Yarmouth to contact YRH and identify their family member as being suspect for having CJD.	**Identification** - In February 2004, a new residency graduate, Dr. Jonah Odim, commenced work as the only pediatric cardiac surgeon at the Winnipeg Health Sciences Centre (WHSC). - Within a few months, five children died after having cardiac surgery. - In May 1994, nurses and anesthesiologists expressed concerns about the deaths to those in authority at the hospital. - On May 17, 1994, the Section of Pediatric Cardiac Anaesthesia withdrew services and refused to participate in any further open-heart pediatric surgeries until a review was conducted. - From that point until mid-December 1994, five more children died. In total 12children died after receiving heart surgery at WHSC.

Case 1 - Ireland Breast Radiology	**Case 2 - NL** Sterilization of Gynecological Equipment	**Case 3 - Alberta** Inadequate Sterilization	**Case 4 - Nova Scotia** Suspected CJD & Infection Control	**Case 5 - Manitoba** Pediatric Cardiac Surgery
Assessment 1. Clinical review of breast radiology services. * The Review findings showed false negative rate fell within published norms.	**Assessment** 1. Hospital documentation revealed that over an 18-month period (between October 2001 and March 2003) medical instruments used at the gynecology clinic were not properly sterilized	**Assessment** 1. The Minister of Health and Wellness appointed an interim Board of Management to oversee the operation and administration of SJGH and engaged the Health Quality Council of Alberta (HQCA) to conduct a review of the underlying causes and contributing factors that led to the Public Health Order.[107]	**Assessment** 1. An assessment of the risk of infectivity was conducted. 2. A trace-back was performed to determine what instruments may have been contaminated, and to determine the patients who had procedures performed with the potentially infected equipment.	**Assessment** 1. Shortly after the withdrawal of anesthesiology services, an internal review committee was established. The Committee recommended the PCS program return to full service in September 1994. 2. The program continued to suffer from high morbidity and mortality rates, which led the Head of the Children's Hospital to fully suspend the program and order an external review. The review commenced in January 1995 and was completed in early February. It reported on a number of items where CPS program required improvement. 3. On February 14, 1995, the WHSC announced that the PCS program would undergo an extensive six-month review 4. The Chief Medical Examiner for the province ordered an inquest. The inquest, led by Justice Sinclair, began its hearings in December 1995. Over 80 witnesses were heard over a course of 285 days. In November 2000, Justice Sinclair released his report.

Case 1 - Ireland Breast Radiology	**Case 2 - NL** Sterilization of Gynecological Equipment	**Case 3 - Alberta** Inadequate Sterilization	**Case 4 - Nova Scotia** Suspected CJD & Infection Control	**Case 5 - Manitoba** Pediatric Cardiac Surgery
Disclosure - Clinical review of mammograms was announced by the HSE through the media and not directly to the patients. - The delay in review results, inaccurate and unanticipated release of information to the public in a "drip-feed" manner stimulated a media frenzy and created significant anxiety for those affected and the general public.	**Disclosure** - Patients were not notified of the potential for infection until eight months after identification. - A press release was issued, and on same day letters were sent via registered mail to the patients. - Some of the letters sent via registered mail did not reach the recipient until after the media release. This resulted in high anxiety for those who received testing. - Anxiety was caused by the disclosure method (registered mail) and the hours of operation of the testing clinic, which allowed individuals to be easily identified.	**Disclosure** - There was a four-day delay in disclosure to the public about the Public Health Order. - Initial disclosure to the public occurred through a news release by RHA. No explanation was provided in the news release for the delay. - RHA contacted former patients by phone or by registered mail.	**Disclosure** - An ethics review to determine appropriate disclosure measures. - Public not satisfied with timeliness of disclosure (Two weeks after the first patient and 24 hours after second patient were suspected of having CJD). - Media releases were issued by the Department of Health and the HDA. - Not all patients reacted well to the news of the possibility of being exposed to CJD. - In retrospect, more consideration should have been given to the clinical urgency of contacting patients. It may have been prudent to factor in the long incubation period in the decision to disclose the information prior to definitive diagnoses.	**Disclosure** - The shutdown of the PCS program was announced first through the media and not directly to the parents of the deceased. - Many of the families had not received long-promised autopsy reports. - At this point, one of the families was informed that an autopsy had not been performed on their son, as previously thought. It was not until the families started contacting the hospital that the WHSC realized that a response was necessary. Coordinators of the Patient Representative Office contacted families and offered them the opportunity to meet with WHSC staff. Parents should have been informed of the decision to suspend the program in February 1995 prior to the decision being made public. - The history of the PCS program and the summer shutdown were not properly explained to the families, and they were not advised about the External Review report. - Parents were not fully informed in advance of their child's surgery about the surgeon's lack of experience in performing a particular procedure.

Summary Table

Case 1 - Ireland Breast Radiology	**Case 2 - NL** Sterilization of Gynecological Equipment	**Case 3 - Alberta** Inadequate Sterilization	**Case 4 - Nova Scotia** Suspected CJD & Infection Control	**Case 5 - Manitoba** Pediatric Cardiac Surgery
Preliminary Actions 1. Initiated a clinical review. 2. Suspended breast radiology services 3. Placed the radiologist who performed the majority of breast radiology services on administrative leave. **Subsequent Actions** The Minister for Health commissioned three reports: 1) Review of governance, management and communications relating to the event. 2) Review of decision to suspend services. 3) Summary of results of clinical review.	**Actions** 1. Review to determine how long the correct policy was not practised. 2. Review to ascertain how many people may have been treated with the improperly sterilized equipment. 3. Risk assessment to assess the level of risk posed to patients. 4. Review infection control protocols at the hospital. .	**Initial Actions** 1. A Public Health Order was issued by MOH for RHA. Hospital was closed to new admissions, the CSR was closed and all surgeries were cancelled. **Subsequent Actions** 1. The provincial government of Alberta introduced Bill 41, *Health Professions Statutes Amendment Act,* in the legislative session. If passed, the Bill would "require health professions to immediately report to the Medical Officer of Health nuisances or threats that may be dangerous or cause injury to the public. 2. The provincial government announced several measures it would take to prevent future problems of similar nature.	**Actions** 1. Both Capital Health and Southwest Health conducted a trace-back process to determine what instruments may have been contaminated and to determine the patients who were at risk for exposure to CJD. 2. Both HDAs took safety measures by removing medical equipment used on the two suspected CJD patients. 3. The Minister of Health ordered a joint review of the actions taken by the involved organizations. The joint review was undertaken by the provincial Department of Health, Health Canada and Capital Health.	**Actions** **1.** WHSC took precautionary measures in May 2004 by first initiating an internal review and limiting surgery to low-risk patients. 2. In July, the PCS program was extended to include medium-risk patients, and in September the program was granted authority to resume full service. 3. In December 2004, following the death of the 12th child, the Head of the Children's Hospital requested that no further pediatric cardiac patients be referred for surgery until an external review was conducted.

Case 1 - Ireland Breast Radiology	**Case 2 - NL** Sterilization of Gynecological Equipment	**Case 3 - Alberta** Inadequate Sterilization	**Case 4 - Nova Scotia** Suspected CJD & Infection Control	**Case 5 - Manitoba** Pediatric Cardiac Surgery
Communication, Coordination & Leadership - Too many people from different levels and areas within the HSE were involved in the Review process. - Absence of authoritative coordination and management roles. - Limited understanding of roles and responsibilities. -Confusion existed with regard to who had the most up-to-date information, who had responsibility for providing definitive information, who was making decisions and why the decisions were being made. - Press releases were inconsistent, lacked clarity and there was an ongoing release of incomplete numbers with respect to how many patients were affected.	**Communication, Coordination & Leadership** - The key issue with this multi-patient adverse event related to the method and timing of disclosure to patients. - Prior to the disclosure, there was considerable discussion about how to disclose to the patients and how to invite them for further testing. - The three key players in this discussion were the CEO, MOH and the Quality/Risk Officer.	**Communication, Coordination & Leadership** - The regional MOH was requested by ECH to visit SJGH and confirm if the previously requested infection prevention control measures had been undertaken. - The following day the MOH issued a Public Health Order. - There was a four-day delay in disclosure to the public about the Public Health Order. - It was not until November 2007 that ECH released an Information Bulletin that stated that 98 per cent of the former patients were contacted and that 65% had chosen to be tested. It did, however, state that the test results were within normal limits.	**Communication, Coordination & Leadership** Several barriers prevented effective communication: - Absence of communication protocols. - Reporting relationships and requirements within and external to the HDAs were not known. - There was a lack of a system policy for notifying the Department of Health of potential safety concerns. - No threshold for the reporting of CJD to the Department of Health, Health Canada and Infection Control practitioners within a facility, Health District or other jurisdictions, the Canadian Blood Services, those at-risk, or the general public. - A joint communication strategy was not developed by the organizations and the Department of Health.	**Communication, Coordination & Leadership** - The responsibility for the PCS program was jointly held by the Head of the Department of Surgery and the Head of the Department of Pediatrics. There was much confusion about who was responsible for the monitoring of the performance of the surgeon and who had responsibility for taking action when problems were identified. - The decision to conduct the initial review was made by WHSC departmental heads (Pediatrics, Surgery and Anesthesia) and did not include hospital administrators. - There was not a consensus by all committee members with the decision to return to full service in September 1994. Some members felt that there were still issues with reinstituting the PCS program. - There was no tracking of common indicators, such as cardiopulmonary bypass times, duration of circulatory arrest times and the volume of blood loss. - There was also no comparison of the PCS Program with other programs in Canada. - Complications associated with surgery were often not recorded, charted or

				reported. Only one incident report was filed out of the 12 deaths that occurred. – Complications during surgery were often not charted, recorded or reported to the Standards Committee. - Nurses made sustained efforts to express their concerns about the surgeon's competency. Their concerns were not taken seriously at WHSC. The external reviewers never formerly asked the nurses to provide a submission. - The Office of the Chief Medical Examiner did not maintain an up-to-date database of hospital deaths. As a result, the problems with the PCS program were not identified in a timely manner.

Case 1 - Ireland Breast Radiology	**Case 2 - NL** Sterilization of Gynecological Equipment	**Case 3 - Alberta** Inadequate Sterilization	**Case 4 - Nova Scotia** Suspected CJD & Infection Control	**Case 5 - Manitoba** Pediatric Cardiac Surgery
Evaluation - The HSE asked all affected patients for their feedback about the process, - The Minister for Health announced measures to strengthen the governance and management of future serious incidents (e.g., clearer reporting relationships and lines of accountability; the Chief Medical Office will have a central role in managing incidents relating to patient safety.	**Evaluation** - Routine surveillance of sterilization procedures to avoid a future recurrence of the event.	**Evaluation** - The Provincial government introduced Bill 41. The Bill requires "health professions to immediately report to the MOH nuisances or threats that may be dangerous or cause injury to the public." - Government announced several measures that it will take to manage future MRSA outbreaks (e.g., the implement of provincial guidelines and legislative and regulatory changes to ensure clarity of roles and responsibilities). - No time frame as to when the recommendations will be implemented was provided.	**Evaluation** -In March 2005, the Nova Scotia Department of Health released the *Disclosure of Adverse Events Policy*. This document provides information to facilitate organizations in developing their own policies, structures and terminology, while considering legal, regulatory and administrative issues. The document outlines requirements (mandatory) and considerations (discretionary) associated with the disclosure of adverse events. -In October 2005, the *Reporting of Notifiable Diseases and Conditions Regulations* were published.	**Evaluation** -Justice Sinclair found that the PCS program did not provide the standard of care that it was mandated to provide and which parents expected their children to receive. The recruitment of the pediatric cardiac surgeon was flawed. - The assessment of the surgeon's skill should have included a discussion with his previous supervisor and an observation of him performing surgery. - It was determined that at least five deaths were preventable. Surgeries continuously were being performed that were beyond the skill level of the surgical team. - Sinclair recommended several changes to team building, communication, risk management and quality assurance practices. - The Minister of Health established a Review and Implementation Committee in June 2001 to review the recommendations from the Inquest. One year later, a progress report was published.

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Health Professionals: Codes of Ethics

A Background Document Prepared for the Task Force on Adverse Health Events

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Table of Contents

Introduction – Policies, Codes of Ethics and Standards of Practice of Select Health Care Professionals

The following paper is a review and update, where necessary, of codes of ethics, standards of practice, and relevant policies of select groups of health professionals as they relate to the management of adverse events in general and, more specifically, to the disclosure of such events.

Two comprehensive background papers on Canadian health care professionals' duty to disclose adverse events were published in 2006[1] and 2007[2]. In March 2008, a third review of the existing literature on the disclosure of adverse events within the Canadian health care system was completed by Dr. Sherry Espin for the Newfoundland and Labrador Commission of Inquiry on Hormone Receptor Testing.[3] A general overview of the relevant codes of ethics, standards of practice, and policies of select groups of health professionals follows. Greater detail is presented in the attached appendices.

Registered Nurses

Nurses' ethical practice is based on the Canadian Nurses Association's (CNA) *Code of Ethics for Registered Nurses*. It provides direction for ethical relationships, responsibilities, behaviours and decision making. The *Code* is intended to be used in combination with the professional standards, laws and regulations that guide practice.

Points eight and nine under the value of "Safe, Competent and Ethical Care" in the Code state:

> 8. *Nurses must admit mistakes and take all necessary actions to prevent or minimize harm arising from an adverse event.*
>
> *9. Nurses must strive to prevent and minimize adverse events in collaboration with colleagues on the health care team. When adverse events occur, nurses should utilize opportunities to improve the system and prevent harm.*

These sections of the *Code* do not explicitly state to whom disclosure or admission of a mistake should be made. The terms "mistakes," "harm" and "adverse event" are not defined in the 2002 version of the *Code of Ethics*.

Most of the provincial and territorial nurses' associations, including Association of Registered Nurses of Newfoundland and Labrador, adopted the 2002 *Code of Ethics* and integrated it into their standards of practice including the (See Appendix A). In the jurisdictions where the **Code** was not adopted, other provisions relating to taking responsibility for errors or the relationship of trust between a nurse and a patient suggested a similar duty to admit mistakes.

In 2003, CNA issued a *Position Statement on Patient Safety*.[4] The CNA's position on disclosure provided that

> *Patients have a right to know when an adverse event has occurred in their care and to have appropriate treatment to address the problem as far as possible. When such an event results in injury or even death, there must be open and honest communication with the patient or the family as soon as possible. The implementation of clear agency policies on the reporting of adverse events and near misses, and on disclosure of adverse events to the patient and family, are necessary to support good clinical practice and to the overall improvement of patient safety in the system.*

Noteworthy is the fact that nurses have taken the following position:

> *Whistleblowing legislation should be enacted in all jurisdictions so that, after all avenues of addressing the problem have been tried, nurses who speak out publicly in good faith can be protected from reprisals.*

The *Code of Ethics* undergoes periodic revisions. The latest version was released in June 2008 after a three-year revision process. It provides a definition of adverse events, although the terms "harm" and "mistakes" remain undefined. Adverse events are defined as "unexpected, undesirable incidents resulting in injury or death that are directly associated with the process of providing health care or health services to a person receiving care."[5]

Point five under the value of "Providing Safe, Compassionate, Competent and Ethical Care" in the revised Canadian Nurses Association's (CNA) *Code of Ethics for Registered Nurses* states:

> *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 harm.*

*The *Code of Ethics* encourages nurses to be aware of the provincial and territorial legislation and nursing practice standards that may include direction regarding disclosure and reporting, and that provide further clarity on whether there is a clear risk of harm.

The *Code of Ethics* provides guidance for nurses in the event a nurse encounters a situation where harm is underway or there is a clear risk of imminent harm. The *Code* suggests that immediate steps should be taken to protect the safety and dignity of the persons receiving care. Examples of appropriate immediate steps in cases of actual or imminent harm include, but are not limited to, speaking up if a potential error in drug calculation is detected, questioning an unclear order, intervening to prevent unsafe restraint practices, protecting patients when a colleague's performance appears to be impaired for any reason, or interfering with a serious breach of confidentiality involving people with sexually transmitted infections.

In the event nurses encounter situations where harm is not imminent but there is potential for harm, they are encouraged to work to resolve the problem as directly as possible in ways that are consistent with the good of all parties. Nurses are encouraged to review relevant statements in the *Code of Ethics for Registered Nurses* and other relevant standards, legislation, ethical guidelines, policies and procedures for reporting incidents or suspected incompetent or unethical care, including any legally reportable offence.

In February 2008, the Association of Registered Nurses of Newfoundland and Labrador released a *Position Statement on Registered Nurses' Professional Duty to Address Unsafe and Unethical Situations*.[6]

> The duty to identify and address unsafe and unethical situations is a professional, ethical, and legal responsibility arising out of the RN's obligation to protect clients from harm and to uphold the integrity of the nursing profession.

All registered nurses are responsible to provide leadership in the identification and resolution of unsafe and unethical situations that adversely affect or could affect the quality of client care.[7] The position statement provides examples of potential unsafe and unethical situations grouped in two categories. The first are concerns regarding the practice or behaviour of another health professional or individual in the workplace. The second are concerns regarding the workplace. A framework that reflects the process registered nurses need to follow when addressing such situations is presented and discussed. The framework consists of the following steps:

1. Verify the concern
2. Take appropriate action
3. Make a report
4. Document the concern
5. Follow-up if the concern (s) is unresolved.[8]

Canadian Nurses Protective Society (CNPS)

Health care organizations in Canada and their employed health care providers generally have liability insurance coverage provided through provincial or regional insurance reciprocals or commercial insurers. The Canadian Nurses Protective Society (CNPS) is a non-profit society owned and operated by nurses for nurses. It offers legal liability protection related to nursing practice. In 2005, CNPS issued an information sheet stating that disclosure to patients is appropriate based on the patient's right to know their own health information.[9]

The fear of professional disciplinary proceedings is a potential obstacle to disclosure of adverse events. However, as more ethics codes mandate disclosure, health care professionals may be subjected to disciplinary proceedings for the failure to disclose.

Licensed Practical Nurses

The Canadian Council for Practical Nurse Regulators does not have a code of ethics.[10] Each provincial college/association has its own code, only one of which refers specifically to admitting mistakes and taking action to prevent or minimize harm arising from an adverse event. However, in several jurisdictions acts to prevent or minimize adverse events are addressed in the Standards of Practice documents (See Appendix B).

The College of Licensed Practical Nurses of Newfoundland and Labrador (CLPNL), in accordance with the Licensed Practical Nurses' *Act*, has the legislative responsibility for regulating the practice of Licensed Practical Nurses (LPNs) in the province. Similar to the Saskatchewan Association of Licensed Practical Nurses *Code of Ethics* and *Standards of Practice*, CLPNL's *Code of Ethics* and the *Standards of Practice* do not specifically address adverse health events, harm or mistakes. In contrast, the *Code of Ethics* of the College of Licensed Practical Nurses of British Columbia provides that Licensed Practical Nurses "Admit mistakes and take action to prevent or minimize harm arising from an adverse event." Although the *Code of Ethics* of the College of Licensed Practical Nurses of Alberta does not specifically address adverse events, *Standard 3: Patient Safety* of the *Standards of Practice* (2008) provide that

> *The Licensed Practical Nurse takes responsibility for their own safe nursing practice and patient safety. The LPN acts to prevent or minimize adverse events through identification and reporting of situations that are unsafe or potentially unsafe for clients or health providers, and reports unsafe practice, abusive behavior or unprofessional conduct to the appropriate authority.*

In Nova Scotia, the College of Licensed Practical Nurses, College of Occupational Therapists, College of Physicians and Surgeons, College of Registered Nurses, College of Pharmacists, and the College of Physiotherapists released a Joint Position Statement on Patient Safety.

> *In their quest to assist individuals to achieve an optimum level of health, health care professionals also take action to prevent or minimize harm…Health care professionals in all practice settings are responsible to identify and report actual or potential unsafe situations, including near misses, errors, and adverse events…[and are] expected to support organizational efforts to fully investigate near misses and adverse events: to identify the root causes of unsafe situations, with the goal of improving the system.*

Physicians

Section 14 of the Canadian Medical Association's *Code of Ethic*s states:

14. Take all reasonable steps to prevent harm to patients; should harm occur, disclose it to the patient.

This provision has been adopted in most of the provincial colleges' codes of ethics. The colleges in some provinces have instituted a specific policy addressing disclosure of harm, including the College of Physicians and Surgeons of Newfoundland and Labrador.

In all cases, some obligation is placed on physicians to inform the patient of an adverse event, although the triggering situation differs. A breach of the Code of Ethics in Newfoundland and Labrador constitutes conduct deserving of sanction, and in New Brunswick constitutes professional misconduct (See Appendix C). In 2000, Alberta enacted legislation to provide that a breach of a code of ethics or standards of practice constitutes unprofessional conduct.[11]

Canadian Medical Protective Association (CMPA)

The Canadian Medical Protective Association (CMPA)[12] is a not-for-profit mutual defense organization that provides medico-legal assistance for physicians who practice in Canada. This assistance includes legal defense and indemnification. The CMPA is independent of the liability insurers of institutions/hospitals and other health professionals.

The CMPA encourages physicians to disclose to patients the occurrence and nature of adverse outcomes, including those caused by adverse events, as soon as it is reasonable to do so after their occurrence. In 2008, the CMPA published a booklet titled *Communicating with Your Patient about Harm: Disclosure of Adverse Events.*[13] This educational tool offers suggestions to help physicians "meet their patients clinical, information and emotional needs after an adverse event."

The disclosure road map consists of the following:

1. First things first: Attend to clinical care
    a. Address clinical needs
    b. Deal with emergencies
    c. Consider the next steps in clinical care
    d. Provide emotional support
    e. Document your care
2. Planning the initial disclosure
    a. What are the facts?
    b. Think about what you will say
    c. Who will be present? Who will lead?
    d. When will the initial meeting occur?

   e. Decide where to meet
3. The initial disclosure meeting
   a. Provide facts as known
   b. Express regret as appropriate
   c. Avoid blame and speculation
   d. Confirm plan for future clinical care
   e. Outline expectations for further information
   f. Arrange follow-up, identify contact process
   g. Document the disclosure discussions in the medical record
4. Analysis
5. Post-analysis disclosure
   a. Provide further facts and information on any actions taken
   b. Express regret again, consider apology only if appropriate
   c. Document the discussions. [14]

Pharmacists

The Canadian Pharmacists Association does not have a code of ethics. Each provincial association has its own code, only two of which refer specifically to disclosure of adverse events (See Appendix D).

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Appendix A: Policies, Standards and Codes of Ethics for Nurses

Jurisdiction	Is there a duty to disclose an adverse event?	What circumstances or conditions prompt the duty to disclose?	What must be disclosed?
Alberta	There is a duty to admit mistakes and take the necessary action to prevent or minimize harm arising from an adverse event. The CNA's *Code of Ethics for Registered Nurses* (2002) is integrated into the College and Association of Registered Nurses of Alberta's *Nursing Practice Standards (2003)* under "Standard #3, Ethical Practice," which states that: "The registered nurse complies with the Canadian Nurses Association (CNA) *Code of Ethics for Registered Nurses (2002).*"	The terms "mistakes," "harm" and "adverse event" are not defined.	Not addressed
British Columbia	There is a duty to admit mistakes and take the necessary action to prevent or minimize harm arising from an adverse event. The CNA's *Code of Ethics for Registered Nurses* (2002) is adopted in "Standard 4: Code of Ethics" in the College of Registered Nurses of British Columbia's *Professional Standards for Registered Nurses and Nurse Practitioners* (2008).	The terms "mistakes," "harm" and "adverse event" are not defined.	Not addressed
Manitoba	There is a duty to admit mistakes and take the necessary action to prevent or minimize harm arising from an adverse event. "Standard I: Professional Responsibility and Accountability" and "Standard V: Ethical Practice" of the College of Registered Nurses of Manitoba's *Standards of Practice for Registered Nurses* (2004) provide that nurses should practice in a manner consistent with the CNA's *Code of Ethics for Registered Nurses* (2002).	The terms "mistakes," "harm" and "adverse event" are not defined.	Not addressed
National Canadian Nurses Association	The revised Canadian Nurses Association's *Code of Ethics for Registered Nurses* (2008) provides that nurses must admit mistakes * and take all necessary actions to prevent or minimize harm	The terms "mistakes" and "harm" are not defined. The term "adverse events"is defined as "unexpected, undesirable incidents resulting in injury or death that are directly	Nurses should be aware of the provincial and territorial legislation and nursing practice standards that may

Jurisdiction	Is there a duty to disclose an adverse event?	What circumstances or conditions prompt the duty to disclose?	What must be disclosed?
(CNA) **2008**	arising from an adverse event. *Provincial and territorial legislation and nursing practice standards may include further direction regarding requirements for disclosure and reporting.	associated with the process of providing health care or health services to a person receiving care" (Hebert, Hoffman & Davies, 2003). If a nurse encounters a situation where harm is underway or there is a clear risk of imminent harm, he or she should take immediate steps to protect the safety and dignity of the persons receiving care. Some examples of appropriate immediate steps in cases of actual or imminent harm could include, but are not limited to, speaking up if a potential error in drug calculations is detected, questioning an unclear order, intervening to prevent unsafe restraint practices, protecting patients when a colleague's performance appears to be impaired for any reason (see CRNNS, 2006b) or interfering with a serious breach of confidentiality involving people with sexually transmitted infections. When nurses encounter situations where harm is not imminent but there is potential for harm, they work to resolve the problem as directly as possible in ways that are consistent with the good of all parties. As they work through these situations, nurses review relevant statements in the *Code of Ethics for Registered Nurses* and other relevant standards, legislation, ethical guidelines, policies and procedures for reporting incidents or suspected incompetent or unethical care, including any legally	include direction regarding disclosure and reporting and provide further clarity on whether there is a clear risk of harm.

Jurisdiction	Is there a duty to disclose an adverse event?	What circumstances or conditions prompt the duty to disclose?	What must be disclosed?
		reportable offence.	
National: Canadian Nurses Association (CNA) **2002**	The Canadian Nurses Association's *Code of Ethics for Registered Nurses* (2002) provides that nurses must admit mistakes. Although it does not specify that they must admit them to the patient, this can be inferred from the context. They must also take all necessary actions to prevent or minimize harm arising from an adverse event. The Value of "Safe, Competent and Ethical Care" provides that: 8. Nurses must admit mistakes and take all necessary actions to prevent or minimize harm arising from an adverse event. 9. Nurses must strive to prevent and minimize adverse events in collaboration with colleagues on the health care team. When adverse events occur, nurses should utilize opportunities to improve the system and prevent harm.	The terms "mistakes," "harm" and "adverse event" are not defined.	Not addressed
New Brunswick	There is a duty to admit mistakes and take the necessary action to prevent or minimize harm arising from an adverse event. The CNA's *Code of Ethics for Registered Nurses* (2002) has been adopted by the Nurses Association of New Brunswick. Their *Standards of Practice for Registered Nurses* (2005) provides under "Standard 4: Ethical Practice" that nurses must practice in accordance with the *Code of Ethics*.	Not addressed	Not addressed
Newfoundland/ Labrador	There is a duty to admit mistakes and take the necessary action to prevent or minimize harm arising from an adverse event. The CNA's revised *Code of Ethics for Registered Nurses* (2008) has been adopted by the Association of Registered Nurses of Newfoundland and Labrador. Their	The terms "mistakes," "harm" and "adverse event" are not defined.	Not addressed

Jurisdiction	Is there a duty to disclose an adverse event?	What circumstances or conditions prompt the duty to disclose?	What must be disclosed?
	Standards for Nursing Practice in Newfoundland and Labrador (2007) provides under "Standard 1: Self-regulation and Professional Accountability" that each registered nurse understands, promotes, and complies with the values and beliefs in the *Code of Ethics for Registered Nurses*. In "Standard 4: Professional Interactions and Advocacy" each registered nurse acts as an advocate to protect clients from harm due to unsafe and/or incompetent or unethical care.		
Northwest Territories and Nunavut	There is a duty to admit mistakes and take the necessary action to prevent or minimize harm arising from an adverse event. The Registered Nurses Association of Northwest Territories and Nunavut has adopted the CNA's *Code of Ethics for Registered Nurses* (2002). *The Standards of Practice for Registered Nurses NWTRNA* (2002) provides that a nurse must practice in accordance with the CNA's *Code of Ethics*.	The terms "mistakes," "harm" and "adverse event" are not defined.	Not addressed
Nova Scotia	The CNA's *Code of Ethics for Registered Nurses* (2002) has been adopted by the College of Registered Nurses of Nova Scotia in their *Standards of Nursing Practice* (2004), which details under "Standard 1: Accountability" that nurses must practice in accordance with the CNA's *Code of Ethics for Registered Nurses* (2002). Indicator 1.3 of this standard states that each registered nurse recognizes and reports errors and takes all necessary action to prevent or minimize harm arising from an adverse event.	The terms "mistakes," "harm" and "adverse event" are not defined.	Not addressed
Ontario	The College of Nurses of Ontario published its professional standards in 2002. The *Professional Standards* (2002) provides, under the heading of "Accountability," that a nurse demonstrates the standard by taking responsibility for errors when	The term "errors," which is not defined.	Not addressed

Jurisdiction	Is there a duty to disclose an adverse event?	What circumstances or conditions prompt the duty to disclose?	What must be disclosed?
	they occur and taking appropriate action to maintain client safety. Further, under the heading of "Ethics" nurses are directed to follow the College's *Ethics Practice Standard* (2002) which does not specifically deal with disclosure, although the obligation to disclose might be inferred from the section on "Maintaining Commitments to Quality Practice Settings – Truthfulness." Truthfulness means speaking or acting without intending to deceive. Truthfulness also refers to providing enough information to ensure the client is informed. Omissions are as untruthful as false information. As health care has changed, so have the restrictions on disclosure in dealing with clients. Many health professionals formerly believed that clients could be harmed by knowing the details of their illnesses. Health professionals now believe that clients have the right to, and will benefit from, full disclosure. Honesty builds trust, which is essential to the therapeutic relationship between nurses and clients. Clients from other cultures, however, may view truthfulness differently from the health care team. Situations may arise in which full disclosure is difficult, and conflicts may develop among team members. Conflicts may also occur among the team, the family and the client, as each group or person brings a particular set of values to the situation.		
Prince Edward Island	There is a duty to admit mistakes and take the necessary action to prevent or minimize harm arising from an adverse event. The CNA's *Code*	The terms "mistakes," "harm" and "adverse event" are not defined.	Not addressed

Jurisdiction	Is there a duty to disclose an adverse event?	What circumstances or conditions prompt the duty to disclose?	What must be disclosed?
	of Ethics for Registered Nurses (1997) has been adopted by the Association of Nurses of Prince Edward Island. The *Standards for Nursing Practice* (1999) provide under "Standard I - Code of Ethics" that nurses must practice in accordance with the CNA's *Code of Ethics for Registered Nurses* (2002).		
Quebec	In the 2003 version of the *Code of Ethics of Nurses*, duty to disclose may be inferred from ss. 11 and 28, which emphasize the relationship of trust between a nurse and patient: 11. A nurse shall not abuse the trust of her or his client. 28. A nurse shall seek to establish and maintain a relationship of trust with her or his client. 10. A nurse shall fulfill her or his professional duties with integrity. O.C. 1513-2002, s. 10. 11. A nurse shall not abuse the trust of her or his client. O.C. 1513-2002, s. 11. 12. A nurse shall report any incident or accident that results from her or his intervention or omission. The nurse shall not attempt to conceal such an incident or accident. When such an incident or accident has, or could have ,consequences for the client's health, the nurse shall promptly take the necessary measures to remedy, minimize or offset the consequences of the incident or accident. However, there is no express duty to disclose in the latest version of the *Code of Ethics of Nurses* (2008). Section 3.02.01 of the *Code* (2008) emphasizes the integrity of the nurse:	Not addressed	Not addressed

Jurisdiction	Is there a duty to disclose an adverse event?	What circumstances or conditions prompt the duty to disclose?	What must be disclosed?
	A nursing professional must discharge his professional duties with integrity and shall not abuse his client's good faith.		
Saskatchewan	There is a duty to admit mistakes and take necessary action to prevent or minimize harm arising from an adverse event. The Saskatchewan Registered Nurses' Association's *Standards and Foundation Competencies for the Practice of Registered Nurses* (2007) provides, under Assumptions #13: "All registered nurses practice in a manner consistent with the common law, provincial and federal legislation and the current Canadian Nurses Association code of ethics for registered nurses." **Standard I – Professional Responsibility and Accountability:** 17. **[**The nurse**]** Reports unsafe practice or the professional misconduct of a health care worker to appropriate authorities. 18. Recognizes, reports and takes action in a timely manner, in unsafe situations when client/staff safety and/or well-being is potentially or actually compromised. 19. Challenges and takes action as necessary, on questionable orders, decisions or actions made by other health team members, to safeguard the client. 20. In accordance with agency policy and legislation, and in a timely manner, recognizes, and reports near misses, adverse events and critical incidents, takes action to minimize harm,	The terms "mistakes," "harm" and "adverse event" are not defined.	In accordance with agency policy and legislation, and in a timely manner, recognizes, and reports near misses, adverse events and critical incidents, takes action to minimize harm, and participates in root cause analysis. Reports critical incidents through appropriate channels.

Jurisdiction	Is there a duty to disclose an adverse event?	What circumstances or conditions prompt the duty to disclose?	What must be disclosed?
	and participates in root cause analysis. 21. Utilizes a systems approach to patient safety, participates with others in the prevention of errors, near misses and adverse events. 22. Integrates quality improvement principles and activities into nursing practice in an ongoing manner. **Standard III – Ethical practice** 66. [The nurse] Practices in accordance with the values of the current CNA code of ethics for registered nurses and the accompanying responsibility statements, as amended from time to time. **Standard IV – Self-regulation** 98. **[**The nurse**]**Takes the needed action to protect the client from unsafe nursing care. 99. Reports critical incidents through appropriate channels. 100. Understands and participates in the development and utilization of a framework that addresses quality improvement.		
Yukon	There is a duty to admit mistakes and take the necessary action to prevent or minimize harm arising from an adverse event. The CNA's *Code of Ethics for Registered Nurses* (2002) has been appended to the *Standards for Registered Nursing Practice in the Yukon* (2005), whose "Code of Ethics" (standard 4), provides that nurses must uphold the values contained in the CNA's *Code of Ethics* (2002).	The terms "mistakes," "harm" and "adverse event" are not defined.	Not addressed

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Appendix B: Policies, Standards and Codes of Ethics for Licensed Practical Nurses

Jurisdiction	Is there a duty to disclose an adverse event?	What circumstances or conditions prompt the duty to disclose?	What must be disclosed?
Alberta	The College of Licensed Practical Nurses of Alberta's *Code of Ethics* (2008) does not address adverse events. However, "Standard 3: Patient Safety" of the *Standards of Practice* (2008) provides that "The Licensed Practical Nurse takes responsibility for own safe nursing practice and patient safety. The LPN acts to prevent or minimize adverse events through identification and reporting of situations that are unsafe or potentially unsafe for clients or health providers.	The term "adverse events" is not defined.	Not addressed
British Columbia	There is a duty to admit mistakes and take action to prevent or minimize harm arising from an adverse event. This is addressed in the Value Statement on Safe, Competent and Ethical Care in the document *Code of Ethics for LPNs: Companion Guide* (2004).	The terms "mistakes," "harm" and "adverse event" are not defined.	Not addressed
Manitoba	The College of Licensed Practical Nurses of Manitoba (2004) "Standard IV –Ethical Practice" provides that the LPN identifies, responds to and reports situations of unsafe practice or professional misconduct to appropriate authorities.	Not addressed	Not addressed
New Brunswick	The Association of New Brunswick Licensed Practical Nurses *Code of Ethics* (2002) or *Standards of Practice* (2002) do not address adverse events.	Not addressed	Not addressed
Newfoundland/ Labrador	The College of Licensed Practical Nurses of Newfoundland and Labrador's *Code of Ethics* (1995) and *Standards of Practice* (2004) do not address adverse events.	Not addressed	Not addressed
Nova Scotia	The College of Licensed Practical Nurses of Nova Scotia's *Code of Ethics* (2005) and *Standards of Practice* (2005) do not address adverse events. However, the College released a Joint Position Statement on Patient Safety with the Colleges of Occupational Therapists, Physicians and Surgeons, Registered Nurses, Pharmacists, and Physiotherapists. The position states: "*In their quest to assist individuals to achieve an optimum level of health, health care professionals also take action to prevent or minimize harm…Health care professionals in all practice settings are responsible to identify and report actual or potential unsafe situations, including near misses, errors, and adverse events…[they are] expected to support*	"Error" and "harm" are not defined. "Adverse event" is defined as an unexpected event in health care delivery that results in harm and is not attributable to a recognized complication (CPSI, 2007). "Near miss" is defined as an event that did not reach a patient because of	Not addressed

	organizational efforts to fully investigate near misses and adverse events: to identify the root causes of unsafe situations, with the goal of improving the system."	timely intervention or good fortune (CPSI, 2007).	
Saskatchewan	The Saskatchewan Association of Licensed Practical Nurses *Code of Ethics* (2004) and *Standards of Practice* (2004) do not address adverse events.	Not addressed	Not addressed

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Appendix C: Policies, Standards and Codes of Ethics for Physicians

Jurisdiction	Is there a duty to disclose an adverse event?	What circumstances or conditions prompt the duty to disclose?	What must be disclosed?
Alberta	There is a duty to disclose harm, as provided in Section 14 of the CMA *Code of Ethics* (2004), as adopted by the College of Physicians and Surgeons of Alberta.	Harm, which is not a defined term.	Not addressed
British Columbia	There is a duty to disclose harm, as provided in Section 14 of the CMA *Code of Ethics* (2004), as adopted by the College of Physicians & Surgeons of British Columbia in its *Physician Resource Manual* (2005).	Harm, which is not a defined term.	Not addressed
Manitoba	There is a duty to inform a patient of a deficiency in care. This is addressed in Section 26.2 of the *Code of Conduct* (2005) of the College of Physicians and Surgeons of Manitoba (Schedule G of By-law #1): 26.2. When you learn that a deficiency of care has occurred, you should inform the patient and make the responsible physician aware. The College of Physicians and Surgeons of Manitoba Statement No. 169 on *Physician Disclosure of Harm in the Course of Patient Care* (2002) requires that: 1. A physician must promptly inform his or her patient of any harm that has occurred in the course of that patient's medical care. 2. A physician must provide full and frank disclosure to the patient respecting the harm.	"Deficiency of care," which is not a defined term.	In making the disclosure, the following guidelines apply: 1. When harm occurs in the course of a patient's medical care, the physician responsible for that patient (including weekend or vacation coverage) must discuss the event with the patient. The discussion should occur promptly, taking into account the patient's medical condition. 2. In the discussion with the patient, the physician should: A. Advise the patient of the facts in a straightforward and non-judgmental way. The discussion should include advice as to the nature, severity, and cause (if known) of the harm.

Jurisdiction	Is there a duty to disclose an adverse event?	What circumstances or conditions prompt the duty to disclose?	What must be disclosed?
			B. Advise the patient as to what, if anything, can be done to correct the harm sustained. C. Advise of any medical care that the patient requires as a result of the harm that was sustained, and promptly seek appropriate help from other caregivers. D. Disclose only what is known at the time of the discussion. Disclosure is a process. avoid speculation. E. Accept responsibility for one's own actions, but without admitting liability to the patient. The physician must take care not to potentially prejudice the patient's right to indemnity under any insurance or protection plan. However, concern regarding legal liability that might result following truthful disclosure does not affect the physician's responsibility to be honest with the patient. F. Avoid attributing blame to specific individuals. Rarely is an adverse medical event the fault of a single individual. G. Consider whether an apology or an expression of sorrow is appropriate. An apology or an expression of sorrow offered at an early stage in the disclosure

Jurisdiction	Is there a duty to disclose an adverse event?	What circumstances or conditions prompt the duty to disclose?	What must be disclosed?
			process can help prevent bad feelings and legal or professional complaints. 3. Where appropriate, the physician may offer the patient a second opinion, the involvement of outside assistance, or the transfer of care to another physician. 4. The physician must document in the patient's chart the discussion with the patient. 5. A patient has the right to decline disclosure, but must do so of the patient's own initiative. Where a patient declines disclosure, the particulars must be recorded in the patient's chart, and the physician must advise the patient that he or she is willing to discuss the matter if the patient so chooses in the future. 6. Where the harm is particularly serious and/or unexpected, provided the patient consents, a meeting between members of the care team and the patient's family may be held. An open and prompt meeting with all relevant records available can promote understanding of the event, and avoid charges of a "cover-up." As well, advice as to what will be done to prevent a similar occurrence with another patient may offer solace to affected patients/families. The discussions at any such meeting must be carefully documented. 7. Where the harm is particularly serious and/or unexpected and the patient is in a

Jurisdiction	Is there a duty to disclose an adverse event?	What circumstances or conditions prompt the duty to disclose?	What must be disclosed?
			health care facility at the time the harm occurs, the physician should promptly inform the appropriate authority of the harm. 8. Where the patient is in a health care facility at the time an event with potential clinical significance occurs, the physician should consider whether it is necessary to inform the appropriate authority of the event in order to prevent possible harm in the future. 9. Errors committed by others may require reporting and disclosure. If in doubt, an event (such as witnessing a significant error made by another person) must be discussed in a confidential way with the Registrar responsible for Standards. 10. Medical learners fulfil their obligations under this Statement if the disclosure is made to the medical learner's supervisor or Program Director.
National Canadian Medical Association (CMA)	In all provinces except for Quebec, section 14 of the CMA *Code of Ethics* (2004) is embedded, under the heading of "Responsibilities to the Patient," and states as follows: Take all reasonable steps to prevent harm to patients; should harm occur, disclose it to the patient.	Harm, which is not a defined term.	Not addressed
New Brunswick	There is a duty to disclose harm, as provided in Section 14 of the CMA *Code of Ethics* (2004). The Council of the College of Physicians and Surgeons of New Brunswick has adopted the	Harm, which is not a defined term.	It is Council's view that early, candid, and full disclosure of adverse events to patients and their families will be of benefit to all concerned.

Jurisdiction	Is there a duty to disclose an adverse event?	What circumstances or conditions prompt the duty to disclose?	What must be disclosed?
	CMA *Code of Ethics* (2004) and added commentary. Section 32 of Regulation #9 provides that a breach of the Code of Ethics constitutes professional misconduct. In a commentary, dated November 2002, and titled "Reporting of Adverse Events," the Council of the College addressed the reporting of adverse events as follows: The Colleges in several other provinces have mandated, or are considering, specific policies that mandate physicians to disclose adverse events and errors which occur in the course of patient care. Council considered whether such an initiative was necessary here. It was concluded that it was not. This is because it is Council's view that this was already an existing obligation on the part of physicians. In other words, patients remain entitled to have complete information regarding their care, including any adverse events. Council was furthermore of the view that it is improper for such an obligation to be interfered with by other parties.		
Newfoundland and Labrador	Physicians have a duty to disclose adverse outcomes. The College of Physicians and Surgeons of Newfoundland & Labrador's policy, *Disclosure of an Adverse Outcome*, provides as follows: The medical practitioner who was the	The policy provides that "...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	The policy provides that: "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

Jurisdiction	Is there a duty to disclose an adverse event?	What circumstances or conditions prompt the duty to disclose?	What must be disclosed?
	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 that 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. The College has also adopted the CMA *Code of Ethics* (2004). Section 34 (c)(v) of An Act Respecting the Practice of Medicine in the Province (2005) provides that a breach of the code of ethics constitutes "conduct deserving of sanction."	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 recognized risk of the treatment." "Adverse event" also includes 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.	invites 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.... 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. **Note:** The policy provides that, 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.
Nova Scotia	There is a duty to disclose harm, as provided in Section 14 of the CMA *Code of Ethics* (2004), as adopted by the College of Physicians and Surgeons of Nova Scotia by regulation on June 3, 2005.	Harm, which is not a defined term.	Not addressed
Ontario	There is a duty to disclose harm. The College of Physicians and Surgeons of Ontario's *Disclosure of Harm* (2003)	Harm is defined broadly as an unexpected or normally avoidable outcome that negatively affects the	Physicians should take the lead in disclosure rather than waiting for the patient to ask. Disclose as soon as the harm is detected or as

Jurisdiction	Is there a duty to disclose an adverse event?	What circumstances or conditions prompt the duty to disclose?	What must be disclosed?
	policy, provides that: When a physician becomes aware, while treating a patient, that the patient has suffered harm in the course of receiving health care, he or she should consider whether the harm does or can be reasonably expected to negatively affect the patient's health and/or quality of life. If it does, then it is the physician's obligation to inform the patient about the harm sustained.	patient's health and/or quality of life, which occurs (or occurred) in the course of health care treatment and is not due directly to the patient's illness.	soon as reasonably possible when the patient's condition is stable and/or the patient is able to comprehend the information. When communicating with the patient, it is best to avoid speculation and to focus on what is known about the event at the time of the discussion. A short, objective, factual non-technical summary of the event is one method of disclosure. Physicians should avoid attributing blame to specific individuals or providing simple explanations as to "cause" or responsibility. A timely and empathic expression of regret and condolences may be appropriate and should not be construed or taken to be an admission of liability or fault. Discussing a plan of care that addresses the harm is of equal importance.
Prince Edward Island	There is a duty to disclose harm, as provided in Section 14 of the CMA *Code of Ethics* (2004), as adopted by the College of Physicians and Surgeons of Prince Edward Island.	Harm, which is not a defined term.	Not addressed
Quebec	Physicians have a duty to inform a patient of any incident, accident or complication which is likely to have, or which has had, a significant impact on his state of health or personal integrity. Section 56 of the *Code of Ethics of Physicians* (2006), states: A physician must, as soon as possible, inform his patient or the latter's legal representative of any incident, accident	The Act amending the Act Respecting Health Services and Social Services as regards to the Safe Provision of Health and Social Services defines “incident” and “accident” as follows: “Incident” means an action or situation that does not have consequences for the state of health or welfare of a user, a personal member, a professional involved or a third person, but the outcome of which is	Not addressed

Jurisdiction	Is there a duty to disclose an adverse event?	What circumstances or conditions prompt the duty to disclose?	What must be disclosed?
	or complication which is likely to have or which has had a significant impact on his state of health or personal integrity.	unusual and could have had consequences under different circumstances. "Accident" means an action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user, a personal member, a professional involved or a third person.	
Saskatchewan	There is a duty to disclose harm, as provided in Section 14 of the *Code of Ethics for Saskatchewan Physicians* (2005), as adapted from the CMA *Code of Ethics* (2004).	Harm, which is not a defined term.	Not addressed

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Appendix D: Policies, Standards and Codes of Ethics for Pharmacists

Jurisdiction	Is there a duty to disclose an adverse event?	What circumstances or conditions prompt the duty to disclose?	What must be disclosed?
Alberta	In the *Code of Ethics Bylaw* of the Alberta College of Pharmacists (1998) there is no express duty to disclose. Principle I states that a pharmacist holds the health and safety of each client to be the primary consideration. Principle VI states that a pharmacist acts with honesty and integrity.	Not addressed	Not addressed
British Columbia	The *Code of Ethics* of the College of Pharmacists of British Columbia (1998) provides the following, under Value IV: "A pharmacist provides competent care to the patient and actively supports the patient's right to receive competent and ethical health care." It is also stated that: "A pharmacist shall not participate in efforts to deceive or mislead patients about the cause of alleged harm or injury resulting from unethical or incompetent conduct."	Not addressed	Not addressed
Manitoba	The Manitoba Pharmaceutical Association's *Code of Ethics* (2001) and *Standards of Practice* (2006) do not set out an express duty to disclose. However, points one and two of the Code state: 1. Pharmacists shall hold the health and safety of the public to be of first consideration in the practice of the profession of pharmacy, rendering to each patient the full measure of their ability as an essential health care practitioner. 2. Pharmacists shall observe the law, particularly those affecting the practice, and conduct themselves in a manner that entitles them to the respect and confidence of the public.	Not addressed	Not addressed
New Brunswick	There is no express duty to disclose. However, Statements I and VI of the *Code of Ethics* of the New Brunswick Pharmaceutical Society (2003) provide that the health and safety of each patient is of primary consideration and that pharmacists must preserve high professional standards and uphold the dignity and honour of the profession.	Not addressed	Not addressed
Newfoundland/ Labrador	There is no express duty to disclose, but such a duty can be inferred from Statements I and II of the *Code of Ethics* of the Newfoundland Pharmaceutical Association (2001) which declare that the health and safety of each patient is of primary consideration, and that pharmacists must preserve high professional standards and uphold the dignity and honour of the profession.	Not addressed	Not addressed

Jurisdiction	Is there a duty to disclose?	What type of event triggers the duty to disclose?	What must be disclosed?
Nova Scotia	There is no express duty to disclose. Values I and II of the *Code of Ethics* of the Nova Scotia College of Pharmacists (2003) state that the health and safety of each patient is of primary consideration, and that pharmacists must preserve high professional standards and uphold the dignity and honour of the profession.	Not addressed	Not addressed
Ontario	There is no express duty to disclose. Principles one and five of the *Code of Ethics* of the Ontario College of Pharmacists (2006) state that the patient's well-being is at the centre of the member's professional and/or business practice, and that each member acts with honesty and integrity.	Not addressed	Not addressed
Prince Edward Island	There is no express duty to disclose. However, Statements I and II of the *Code of Ethics* of the Prince Edward Island Pharmacy Board (2001) address the primacy of the patient's health and safety, and the importance of a professional relationship with the patient and acting with honesty and integrity.	Not addressed	Not addressed
Quebec	There is an express duty to inform a patient of error in Section 3.02.04 of the *Code of Ethics of Pharmacists* (2008). A pharmacist must inform his patient as soon as possible of any error he has made in rendering a professional service to that patient.	Error. However, a definition of error is not given.	Not addressed
Saskatchewan	There is no express duty to disclose. However, sections 13.1.1 and 13.1.8 of the *Code of Ethics* (2008) of the Saskatchewan College of Pharmacists, state that a pharmacist shall hold the health and safety of the public to be of first consideration in the practice of his profession and shall be governed in advertising practices by highly professional integrity.	Not addressed	Not addressed

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Patient Safety and the Management of Adverse Health Event Education Curriculum

A Background Paper Prepared for the Task Force on Adverse Health Events

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The Task Force on Adverse Health Events would like to acknowledge the following individuals for their submissions of educational curriculum related to patient safety and the management of adverse health events.

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Dr. Sandra LeFort, Director, School of Nursing, Memorial University of Newfoundland

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Introduction

> There is a growing body of literature that demonstrates that when health care professionals understand each others' roles and are able to communicate and work effectively together, patients are more likely to receive safe, quality care.[1]

The potential to educate all health care providers in patient safety and management of adverse health events using an interprofessional approach has been recognized in the United Kingdom[2] , the United States[3] and Australia[4].

Patient Safety Education

> Demands for change in medical education are no longer confined to the medical profession; governments and the community also want change as a result of publicized adverse events…Most medical educators acknowledge that problems are caused by poorly designed systems, but are uncertain what needs to be taught about quality and safety, and how best to teach and assess it. [5]

In 2006, the role of education in improving safety and quality in health care was the subject of an article published in the *Medical Journal of Australia* by Walton and Elliott. Educating doctors about quality and safety and the need to incorporate training and education into the undergraduate and postgraduate medical training are the foci of the article. The authors describe the National Patient Safety Education Framework and suggest "that interdisciplinary and vertically integrated education and training are needed, incorporating innovative methods, to create a safer health care system" (page S63). [6]

In the following sections, a high level overview of the comprehensive patient safety education curriculum developed by the Australian Council for Safety and Quality in Health Care and similar patient safety education curriculum being proposed at the national level in Canada is presented. Finally, patient safety education curriculum currently used by the Schools of Nursing and the Faculty of Medicine in Newfoundland and Labrador are presented.

Patient Safety Education Curriculum - Australia

National Patient Safety Education Framework

In 2005, the Australian Council for Safety and Quality in Health Care published the National Patient Safety Education Framework (NPSF). The framework is

- patient-centred
- identifies the knowledge and performance required by all health care workers in relation to patient safety
- is flexible in design, and
- can be used to develop curriculum, competency-based training programs and other safety and quality initiatives.[7]

The framework targets all health care workers who are defined by 4 categories:

Category 1 – health care workers who provide support services (e.g., personal care workers, volunteers, transport, catering, cleaning and reception staff).
Category 2 – health care workers who provide direct clinical care to patients and who work under supervision (e.g., ambulance officers, nurses, interns, resident medical officers and allied health workers).
Category 3 – health care workers with managerial, team leader, and/or advanced clinical responsibilities (e.g., nurse unit managers, catering managers, department heads, registrars, allied health managers and senior clinicians).
Category 4 – clinical and administrative leaders with organizational responsibilities (e.g., CEOs, board members, directors of services and senior health department staff).[8]

According to the NPSF, health care workers need the following competencies in order to provide safe care:

1. Communicating effectively
   1.1. Involving patients and carers as partners in health care
   1.2. Communicating risk
   1.3. Communicating honestly with patients after an adverse event (open disclosure)
   1.4. Obtaining consent
   1.5. Being culturally respectful and knowledgeable

2. Identifying, preventing and managing adverse events and near misses
   2.1. Recognizing, reporting and managing adverse events and near misses
   2.2. Managing risk
   2.3. Understanding health care errors
   2.4. Managing complaints

3. Using evidence and information

3.1. Employing best available evidence-based practice
3.2. Using information technology to enhance safety

4. Working safely
   4.1. Being a team player and showing leadership
   4.2. Understanding human factors
   4.3. Understanding complex organizations
   4.4. Providing continuity of care
   4.5. Managing fatigue and stress

5. Being ethical
   5.1. Maintaining fitness to work or practice
   5.2. Ethical behaviour and practice

6. Continuing learning
   6.1. Workplace learning
   6.2. Workplace teaching

7. Specific issues
   7.1. Preventing wrong site, wrong procedure and wrong patient treatment
   7.2. Medicating safely

The 22 learning topics are accompanied by learning objectives, knowledge and performance elements. The level of knowledge and performance elements is determined by the health care workers' level of responsibility. Patient narratives highlight topics from the patient's perspective. The term "patient" also applies to consumers and clients.

Patient Safety Education Curriculum - Canada

Recommendations of the Change Foundation and Ontario Hospital Association

Wong & Beglaryan (2004)[9] conducted a review of the research on strategies for hospitals to improve patient safety. Based on the literature available at that time on patient safety and adverse events, several recommendations were made primarily targeting hospitals and, to a lesser extent, professional organizations and governments. The recommendations relevant to the work of the Task Force included:

1. Providing leadership for patient safety initiatives
2. Creating a culture of safety
3. Providing training and continuous education
4. Improving reporting systems
5. Establishing a national patient safety strategy

6. Next steps in research

Recommendation three is directly relevant to this section of the report, and therefore requires further elaboration. The authors identified four key recommendations[10] under this domain.

i. Hospitals must maintain up-to-date patient safety standards and protocols.
ii. Universities should train health sciences students in the prevention of adverse events.
iii. Professional associations, colleges and hospital associations should promote improved patient safety by disseminating information on best practices and giving professionals training in risk management.
iv. Provincial governments must finance training and development programs supporting safety in hospitals.

Recommendations of the National Steering Committee on Patient Safety

In 2004 the National Steering Committee on Patient Safety produced a report titled "Building a Safer System –A National Integrated Strategy for Improving Patient Safety in Canadian Health Care." The following recommendations of the report that focus on the establishment of educational and professional development programs are relevant to effective adverse health event management:

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

- Develop educational and continuing professional development programs to improve patient safety in collaboration with national accrediting bodies, academic institutions, provincial licensing authorities (for peer assessment reviews) and health-care facilities/organizations/scholarly societies.[11]

Canadian Patient Safety Institute – Safety Competency Framework

The vision of the Canadian Patient Safety Institute (CPSI) is to create one of the safest health care systems in the world. CPSI believes it is necessary to equip health care providers with the tools and knowledge during their training years to build and maintain such a system. In March 2007, CPSI announced a new initiative spearheaded by CPSI's Advisory Committee on Education and Professional Development. The development of a pan-Canadian framework for patient safety competencies would identify the key knowledge, skills and attitudes related to patient safety for institutions with an interest and responsibility for education and the professional development of practitioners in

medicine, nursing, pharmacy and the therapy groups (physical therapy, occupational therapy and respiratory therapy). CPSI partnered with the Royal College of Physicians and Surgeons of Canada to facilitate the development of the Canadian Safety Competencies Framework[12].

The objectives of developing the framework are:

- To identify the key knowledge, skills and attitudes related to patient safety competencies for all health care professionals.
- To develop a simple, powerful, flexible framework that will act as a benchmark training, educating and assessing health care professionals in patient safety
- To develop a framework that will allow for its smooth integration into curriculum at educational institutions, into the professional development programs of health care associations, and directly into patient care sites across the health-care delivery spectrum.
- To foster interprofessional and interorganizational collaboration in patient safety.
- To help make patient safety competencies easy for everyone to understand and apply. [13]

The draft Canadian framework consists of six domains:

1. Contribute to a culture of patient safety.
2. Work in teams for patient safety.
3. Communicate effectively for patient safety.
4. Manage safety risks.
5. Optimize human and environmental factors.
6. Recognize, respond to and report adverse events.[14]

The framework will be formally launched in September 2008 (Personal Communication, Chantal Backman, May 26, 2008). The ultimate goal is to incorporate the framework into the education of health professionals in Canada. It is anticipated that the development and integration of a framework of interprofessional patient safety competencies will expedite the development of regional patient safety curriculum.

In a July 2, 2008 news release, Health Canada announced the renewal of funding for the Canadian Patient Safety Institute.[15] Over the next five years CPSI will work in collaboration with its national and regional partners on four key areas: education, research, tools and resources, and interventions and programs. It will continue to promote patient safety as a focus in health sector education and training, and facilitate the development of curriculum competencies. CPSI will also

- enhance patient safety research capacity,
- provide tools to foster accountability, and
- improve patient safety practices and processes and develop pan-Canadian programs to enable timely implementation of patient safety practices. [16]

Patient Safety Education Curriculum – Newfoundland and Labrador

Centre for Nursing Studies

Information from the Centre for Nursing Studies as it pertains to teaching materials and/or curriculum descriptions the School of Nursing may use as it relates specifically to patient safety, safety culture, management of adverse events, and the code of ethics and standards of practice for registered nurses and licensed practical nurses is outlined verbatim below. Specific feedback from faculty included the following:

BN (Collaborative) Program

Year I

- Safe patient handling is taught in first-year theory, lab and clinical courses.

Year II

- The *Pharmacology* course includes sections on the "role and responsibilities of the nurse," "legal and ethical implications," "drug errors" and "self-administration and self-prescription." A guest speaker from the "Canada Vigilance Regional Office – Atlantic" does a presentation on "Reporting of adverse reactions: the role we play to ensure patient safety." Safety is a thread through all of our lab sessions and there is a full lab entitled "Medication Errors." Pharmacology content focused on safety is tested through theory exams and lab practicum.
- *Community Health* clinical addresses the safety of the nurse during home visiting.
- *Nursing Practice for the Care of Women and the Childbearing Family* includes the objective to "provide competent nursing care." Competent nursing care is evaluated using the Nursing Practice Appraisal Form, which includes the following: 1) [the nurse] administers appropriate aseptic technique when carrying out procedures; 2) maintains safety principles when providing all aspects of nursing care. Personal, colleague and client safety issues/concerns are emphasized and addressed in both lab and clinical settings in Nursing Practice for the Care of Women and the Childbearing Family.
- *Extended Practice* includes the objective for students to "provide competent nursing care to individuals and families who are experiencing health-related needs;" competent care is inclusive of "safe" care. Specifically, this implements preventive strategies related to the safe and appropriate use of medication; it implements other preventative and therapeutic interventions safely (e.g., positioning, managing intravenous therapies, oxygen administration and wound care); and uses safety measures to protect self and colleagues from injury or potentially abusive situations (e.g., aggressive clients, appropriate disposal of sharps, lifting devices). Extended Practice also includes the objective that students "apply legal, ethical and professional standards that guide the practice of nursing." Specifically, the nurse practices nursing according to agency and school policies; recognizes limitations of practice and consults with faculty in

new/unfamiliar situations; reports unsafe/unethical/illegal practices; questions, recognizes and reports errors (own and others); and takes action to minimize harm arising from adverse events.

Year III

- *Nursing Concepts for Middle and Older Adults*. In both theory and lab, students are taught and shown Eastern Health's "occurrence reporting" forms, including the multiple different types of occurrences (e.g. patient falls, medication errors, etc.). Also, in the lab and clinical there is a process in place should a student or faculty member be injured (e.g., needlestick). An occurrence form is completed and the appropriate people (e.g., Occupational Health) notified for any necessary follow-up/treatment.
- *Nursing Practice with Middle and Older Adults* uses a clinical incident report (Appendix IV Student Handbook – see faxed material) to report/track student incidents in the clinical area. When there is an actual error, a clinical incident form on the unit is also completed. Students are sent to the lab for remedial if there is an actual error. The lab faculty track medication errors and discuss/review the incident with the students.
- *Nursing Concepts and Nursing Practice for Mental Health* (theory and clinical) address the legal and ethical issues related to mental health nursing. The Mental Health Care and Treatment Act is discussed in both courses as it relates to safe patient practice. In the clinical course, issues related to safety, including clinical observations, how to report an incident, documentation and sharps policies are reviewed. All issues related to safety on individual clinical units are discussed. In theory, discussions focus on suicide, aggression and violence, medication as it relates to adverse health events, including prevention of adverse health events and psychiatric medication emergencies. Also debriefing after an incident happens is discussed as a means of reviewing the events and strategizing re future understanding and prevention.

Years I – IV

- Throughout the four-year nursing program, client safety, medical asepsis and proper body mechanics are guiding principles for every lab and clinical experience. It is stressed with students that they must wash their hands before and after every patient contact, and if they do not, for example, they would not be deemed independent for a particular skill, e.g., dressings. Any safety concerns would be documented on the student's appraisal, and if an unsafe pattern is demonstrated with no sign of improvement, the student could fail the clinical course.

The Centre's *Student Handbook* references the Clinical Incident Report. Faculty also reviewed each course in the BN (Collaborative) Program to determine the learning opportunities provided for students to apply the competencies required for entry-level practice, as identified by the *ARNNL (2006):* Competencies in the Context of Entry-Level RN Practice

2007-2010. The courses line up with the competencies (Ms. Joan Rowsell, personal communication, July 8, 2008).

Memorial University of Newfoundland - School of Nursing

The following information is included – often as threads – through courses offered from the first year through to fourth year (Ms. Karen Webber, personal communication, June 10, 2008).

(A) Patient Safety/Safety Culture

This topic is discussed in N1017, Fundamental Psychomotor Competencies & N2004, Pharmacology & Nutritional Therapeutics.

(B) Adverse Health Event Management

This topic is addressed in N2004, Pharmacology & Nutritional Therapeutics

- A guest speaker from the Canadian Adverse Reaction Monitoring for the Atlantic Region delivers a lecture to the students.

(C) Changing from a Culture of Blame to a Culture of Discovery

(D) Medication Errors: Identifying, Reporting, Assessing, Disclosing

(E) ARNNL's Protocol Regarding Concerns about Patient Care

- Topics C, D and E are covered through lectures and discussion in N3113, *Nursing Leadership and Management*.

(F) Standards of Nursing Practice & Code of Ethics

- These topics are introduced in N1004, *Introduction to Nursing*, as well as being addressed again formally in N4103, *Issues in Nursing & Health Care*.

Memorial University of Newfoundland - Faculty of Medicine

The Faculty of Medicine is currently in the process of a major curriculum revision. The Faculty is keen to incorporate the knowledge gained by the Task Force and translate that into a more specific patient safety approach that can be prominently interwoven throughout the new MD education program curriculum (Dr. James Rourke, personal communication, June 9, 2008).

At the current time, most of the specific patient safety and management of adverse events education takes place in the postgraduate residency training program. Dr. Rourke provided the Task Force with the following information:

- During the initial Post Graduate Medical Education (PGME) orientation for PGY1 (first-year residents), it is included in a session dealing with the Canadian Medical Protective Association (CMPA), which covers many patient safety issues.
- It is also dealt with contextually by each of the disciplines.
- The Faculty has a formal adverse incident report process involving the residents. The Assistant Dean for PGME meets with Dr. Oscar Howell, Vice-President of Medical Affairs for Eastern Health when such an incident occurs to discuss and address concerns and develop and take appropriate action.
- Avoiding adverse events has also been included as part of Medicine Grand Rounds as recently as May 9th 2008, and previously was the focus of an all-day professional development session involving external experts.

Dr. Rourke also addressed the Faculty of Medicine's commitment of incorporating patient safety into its educational curriculum. This is illustrated in the following quote:

> At both the postgraduate residency training and the MD education programs, the Faculty of Medicine is committed to incorporating the most up-to-date educational and management approaches to address patient safety issues and concerns in a most effective way. The timing of our curriculum renewal process and your work [the work of the Task Force on Adverse Health Events] will facilitate this.

Conclusion

The Canadian Patient Safety Institute, in collaboration with the Royal College of Physicians and Surgeons, is promoting the development and of a national interprofessional patient safety competencies framework. It is anticipating adoption of the framework into regional patient safety curriculum.

A recent submission to the Task Force on Adverse Health Events focusing on interprofessional education (IPE) and patient safety competencies highlighted "the potential for IPE to enhance interprofessional teamwork and other Patient Safety Competencies identified by the Canadian Patient Safety Institute."[17] At a provincial level, there is a window of opportunity to expedite the adoption of the framework, given that the Faculty of Medicine is reviewing its curriculum, with major changes planned in the coming year.

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Report on Leading Experts' Opinions of Adverse Event Management in Health Care Systems

Prepared for the Task Force on Adverse Events

Government of Newfoundland and Labrador

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July 22, 2008

Executive Summary

The purpose of the current study was to gather information from national and international experts to help inform the Task Force on Adverse Health Events about leading practices for managing adverse events in various health care settings. In-depth interviews were conducted with 15 individuals with similar and disparate levels of expertise in the components of the Adverse Event Management framework being promoted by the Task Force. Many of the key informants were either part of or responsible for risk management and/or patient safety departments in their institutions/jurisdictions. During the interviews, key informants were presented with multiple questions covering the six broad areas of the framework, specifically: identify and report; assess; disclose; action; communicate, coordinate and lead; and evaluate. This report outlines the findings that emerged from a synthesis of expert opinions on the leading practices in each area guiding the inquiry.

Based on the interview data, the general consensus is that current identification and reporting systems for adverse health events fall short of the ideal, and thus no one system can be viewed as a "gold standard". The limitations of existing identification and reporting systems revolve around the absence of an all-encompassing definition of adverse health events that has equal applicability for all health care sectors, as well as all local, provincial, national and international jurisdictions. Because of disagreements within and across jurisdictions about what falls under the realm of quality versus safety

issues, the resulting inconsistencies create problems, not only for the meaningful codification and rating of adverse events, but also for the identifier's/reporter's ability to sort through quality events, near misses and events causing actual harm, and then to record/report them appropriately within the system.

In recent years concerted efforts have been directed toward developing acceptable identification and reporting systems for all health care sectors. Despite significant accomplishments, much work still remains. Until greater clarity is achieved on what constitutes adverse health events and reliable identification and reporting systems become the norm, the opinion of several leading experts in the area is that health care institutions should be doing the following: 1) relying on a number of data sources for detecting adverse events, 2) ensuring that adequate mechanisms and resources are in place to facilitate meaningful integration of all relevant data bases dealing with adverse events, 3) investing resources into the training of front-line staff so that all levels of providers become not only willing participants in, but also skillful, at identifying and reporting adverse events, and 4) developing policies and procedures that promote a culture of safety that is based on justice, trust, non-punitive, multidisciplinary teamwork, effective communication and continuous learning.

Institutional protocols guiding investigations into health care events that have the potential for, or actually result, in patient harm varied across national and international

jurisdictions, but shared certain basic common themes. First, preliminary investigations are required to identify the appropriate category (system or performance failures or both) for classifying the event as well as its severity and pervasiveness. Second, initial assessments should be used to determine the responsible persons/body for conducting the review, the required skill base of the review team, and the most appropriate methods for undertaking more in-depth reviews. Despite these commonalities, it was apparent from the findings that significant differences existed among key informant opinions about the review process. Most important among these are the specific events that warrant full-scale investigations (case reviews versus peer reviews versus multidisciplinary team reviews), the degree of independence of the review team from front-line staff and managers (total independence versus consultative involvement versus integral team members), and the appropriate methods for investigating adverse events (system-based versus individual-based approaches; and root cause analysis versus failure mode and effects analysis versus health system safety, etc.).

It was apparent from the key informant interviews that there is unquestionable support for the presence of clear institutional policies and protocols to guide appropriate and timely disclosure practices, as well as adequate training for providers and managers directly involved in the disclosure process. Emphasis was placed on being knowledgeable of the facts prior to participating in disclosing, maintaining an open and transparent approach at all critical junctures in the disclosure process, acknowledging the seriousness of the situation, conveying regret to patients/families and being constantly supportive of

patients/families. Finally, great importance was attached to having adequate provisions in place to deal with any psychosocial and emotional issues that staff may experience as a result of being directly or indirectly involved with an adverse event.

Based on the key informant interviews, the action phase for the management of adverse health events identifies points of concurrence and opposition. Despite the clear differentiation between the roles of the assessment team and the action team, it is apparent that key informants recognized the need for collaboration between the two teams in order to develop logical, feasible and achievable recommendations for practice/system changes. An equally important point made by the key informants is the need to differentiate between individuals who are responsible for leading the action plan and those who assume responsibility for implementing it. Finally, key informants stressed that the recommendations of assessment teams and the implementation plans of action teams could become mere academic exercises without the commitment and dedication of senior management and the availability of adequate resources.

The communicating, coordinating and leading of managing adverse health events was perceived to interact with all the other components. A couple of things were stressed aspect of the framework and in some cases reiterated, by the key informants. First, priority should be given to effective internal and external communication of relevant information to all appropriate persons/bodies in a timely fashion and in a manner that

conveys how seriously the organization perceives the event. Second, emphasis should be given to ensuring that the organization has appropriate mechanisms in place to facilitate effective and efficient communications and that individuals/bodies responsible for communicating, coordinating and leading have the necessary skill base to do so.

The final component deals with the long-term evaluation of the impact of recommended system changes following adverse events. The emphasis here is on monitoring progress toward, and the ultimate achievement, of targeted outcomes. Key informants spoke about the necessity of “closing the loop” when moving from the review phase to the action phase and, finally, to the outcome phase. Importantly, all of the key informants acknowledged that long-term evaluation is probably the most underdeveloped component of adverse events management. The rationale offered for this is the absence of an exhaustive set of appropriate outcome indicators.

In conclusion, the information gleaned from interviews conducted with key informants augments the existing knowledge about concepts integral to adverse health event management and also provides new insights into them. It is apparent that further work is needed in this area, not only to make the health care environment safe for patients and families, but also to ensure that protocols are in place in all organizations for appropriate and timely responses to adverse events.

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1.0 Introduction

The purpose of the current inquiry was to elicit the opinions of experts in the management of adverse events to help inform the Task Force on Adverse Health Events about leading practices in the area. The process for selecting key informants was as follows: (a) review of invited speakers at symposiums/conferences associated with patient safety/adverse events, (b) review of relevant patient safety/adverse health event literature and policy publications (e.g., *When Things Go wrong – What do Patients, Clinicians and Families Want?*), (c) consult with national and international organizations to identify key individuals or their designates within an organization with expertise in the area, and, (d) consult with conference/symposium organizers. A list was subsequently compiled and a contact process established and implemented in May of 2008.

A senior researcher initiated contact with potential informants via email and provided them with a detailed explanation of the work of the Task Force, including its Terms of Reference. Potential informants were also directed to a link on the website of the Task Force at http://www.gov.nl.ca/ahe and encouraged to reflect on the Adverse Event Management Framework provided there. A generic consent form and an interview guide (Appendix A) were emailed to each individual who agreed to participate in the interview process. The interview guide was designed to explore issues related to the various components of the framework (identifying and reporting, assessing, disclosing, acting,

communicating, coordinating and leading, and evaluating adverse events) as they pertain to the health and community services system.

Key informant interviews were conducted with 15 individuals from diverse backgrounds who are directly or indirectly involved in the management of adverse events. Eleven of the key informants represented various Canadian provinces and four were from select international countries. The interviews averaged one and one-half hours and were conducted by telephone between May 12, 2008 and July 3, 2008 by one experienced interviewer (Dr. Christine Way, School of Nursing/Faculty of Medicine) to ensure consistency and comprehensiveness.

Permission was requested to audiotape the interviews to allow verbatim transcription, with the understanding that all tapes would be destroyed when the transcribed text was reviewed for accuracy. An individual from the Health Research Unit of the School of Nursing, Memorial University of Newfoundland, transcribed the interviews. Verbatim quotes are used anonymously in the final report. All key informants agreed to be listed as contributors in the final report.

Analysis of the interviews proceeded in a stepwise fashion according to the components of the framework. Transcribed texts were first read in their entirety. Subsequent steps

involved reading and rereading the text to identify themes defining each component, refining and differentiating these themes, and identifying commonalties and differences within and across national and international jurisdictions. During the final step, the relevancy and import of all themes informing each component was confirmed and synthesized for the purpose of the discussion that follows.

2.0 Identification and Reporting

This section is organized under two major headings: leading practices and reporting lines. The leading practice component contains the bulk of the discussion and deals with the approaches and measures to improve identification and reporting. The first focus is on the leading practices used to identify and report adverse events occurring in various health care sectors. These leading practices are based on the experiences and/or opinions of national and international experts. The second focus is on summarizing expert opinion on the best way to use data collected on near misses or close calls to help create a culture of patient safety. A third focus is on the patient complaints database which has received increased attention in certain jurisdictions because of its purported usefulness for identifying, verifying and clarifying near misses or adverse events (i.e., misdiagnosis). The final focus of this section is on presenting a brief overview of significant gaps in the identification and reporting of adverse events, as well as the expert opinion about how best to proceed in modifying or resolving them.

2.1 Leading Practices

During the interview process, it was difficult keeping the key informants focused on identification: many of them preferred to talk around it in terms of reporting. Rather than conjecturing possible reasons for this, it would be more fruitful to highlight the key points made about identifying and reporting in terms of the interlocking connections between them, while still highlighting the differences.

2.1.1 Approaches to Identification and Reporting

As noted by several key informants, many approaches exist for identifying and reporting, and are either retrospective or prospective in nature. Within the key informant jurisdictions, electronic or web-based systems are the most dominant reporting systems for tabulating data gleaned from identification of adverse events. These systems are also the most vulnerable, and require a great deal of concentrated effort and investment from organizations to make them efficient and effective. Other alternatives referenced by the key informants included patient complaint data, nursing/medical notes, case reviews, internal audits, morbidity and mortality data, diagnostic errors and malpractice or litigation claims.

Total reliance on one approach may not be a wise choice for any organization. In fact, most of the national and international experts were of the opinion that there should be multiple ways to identify and record adverse events. One informant had this to say:

> The self-reporting of adverse events has always been problematic because, of course, self-reporting just by its nature is variable and inconsistent. So even though it's important to have that, it's certainly not the best way to go in terms of understanding where the vulnerabilities for an organization are. So we stress to a very great degree that other data sets perhaps capture a little more of what's going on in health care organizations. [I 13]

A second informant also emphasized the use of multiple data sets for identifying potential adverse events and appropriately reporting them. The point is that what is gleaned from the interaction of diverse and complementary data sets is more helpful in assisting organizations in rating adverse events and directing them toward meaningful system change.

> What we find is that in an organization the patient-safety-incident people won't think of the other ways in which things go wrong for patients. We have some guidance called the seven steps to patient safety. What we try to stress is that there are numerous ways in which you'll know that things have gone wrong for your patients….What we've stressed is the vital way in which people should integrate all of that information.…An incident reporting system will never pick up all your adverse events for numerous reasons – mainly due to the barriers to reporting. So

> the leading practices for a good organization … integrates all the different ways in which things go wrong for their patients. [I 12]

What then are some of the leading practices in Canada regarding the identification and reporting of adverse events? The inevitable conclusion drawn from discussions with experts is that there is in fact no "gold standard", and what currently constitutes leading practices are at various stages of development. This position was summarized by one informant:

> Well, the first thing is the system in place to track adverse events. I think there is a lot of inconsistency in the way people are doing that across the country, even having the ability to do that from a technology point of view, and that could be either paper-based or something with IT support. I think people are a bit all over the map in terms of even establishing a reporting system. [I 7]

A second informant concurred, but also felt that the data on adverse events resulting from reports by front-line workers, particularly nurses and physicians, was not reliable.

> Now the problem is that the reporting of adverse events is not a systematic process in Canada. It falls short of a system that you can rely on to give you useful data. So there are some ways in which the system is trying to address it, for example, saying that certain things should have a mandatory reporting, but it tends to be a very kind of sporadic business. It's not reliable at all. [I 8]

Other informants approached the problem from a slightly different perspective: the limited usefulness of identification and reporting systems beyond acute care settings. What is significant here is that situational contexts are quite different in community settings and may pose additional barriers.

> I think the big challenge in home care is that an adverse event is not as cut and dry in the home environment as it is in the institutional setting. People choose to live at risk. For example, whereas in an institution a fall would be considered to be an adverse event of some kind, in the home [setting] it's an occurrence and may be caused by the fact that the individual chooses to live at home. You don't have 24/7 coverage by health care professionals of what's going on in that home. It's really distinguishing between what is and what isn't an adverse event, and what the health care professional team is responsible for as opposed to what the individual in the home is responsible for, because they provide the environment and we're a guest in their home providing a service. [I 11]

Other informants addressed the special challenges encountered in ambulatory and community settings. It is apparent that this area of health care has received very little attention from the perspective of having useful mechanisms available to help health care providers identify and report adverse events. One informant commented thus:

> I find that we're really good with the acute care groups and targeting them because we know where they are and they generally stay in one spot. It's trying to

> target the ambulatory care [that's difficult]. The clinics that move around and are remote from your site, not connected as closely to your main facility as other groups, or maybe don't have intermittent contact with the managers and supervisors because they work alone. I can tell you some of the stuff that we've done with our mental health program and what's reportable. For example, making sure that everybody consistently reports an attempted suicide, or suicide even in the community, so that it can be reviewed by the morbidity and mortality team. [I 4]

An equally problematic area identified by some key informants was misdiagnosis or diagnostic error. As one key informant noted, diagnostic errors are very important because they may have far-reaching consequences for a patient's health and well-being, but are, for the most part, invisible unless someone (e.g., patients, families, health care providers) lodges a formal or informal complaint against the attending physician or institution.

> The biggest gap that's out there is diagnostic error, I think.... If you take a closer look at what's going on in the health care system – for example, in primary care and acute, care the current estimate is about a 15% diagnostic error rate. That is extremely high, and the problem is that diagnostic errors are the most catastrophic and consequential. If I make a mistake with a medication, for example ... most of the time it's inconsequential. ... Yet they get a lot of attention because it's a very

> tangible event.... Diagnostic error is high up the tree and difficult to get at because it's the way that physicians think about what's going on with a patient and that's an invisible process. People aren't very good at fixing invisible processes. [I 8]

A second informant also commented upon the difficulties in identifying diagnostic errors and having them entered into a reporting system for adverse events.

> If it hasn't been reported electronically, then unless someone rings us or unless we've done some soliciting, then we may not find out about things until some time after they've been managed.... I guess what I'm thinking is that when a complaint arises, it's an adverse event which is brought to our attention from an external source, because clearly we don't have a system accessing mental health, where if we sent the patient home, and two days later they die, unless their general practitioner or someone tells us.... But in big cities, if somebody has died because they had been sent home with undiagnosed infarct and they re-infarct two or three days later, we won't know unless we're told, unless the coroner tells us or for some reason their family rings up and says, Why did you send this person home? [I 9]

This is obviously a very important area that increasingly is gaining the attention of individuals who are working in patient safety. It is also a very difficult area to target for change, because it means altering tradition by moving something that is guarded and sacred, physician rights to clinical decision-making, into the public domain for greater scrutiny and critical appraisal.

The inherent problem with misdiagnosis is that there is a crossover from acute care into the community setting. This is another issue that falls into that grey area present in every jurisdiction. As some key informants noted. both national and local bodies with patient safety responsibilities continue to struggle with how to resolve this issue.

> The journey of the patient is often one of hit and miss, so it's, you've got a few symptoms here and we're not quite sure what's wrong with you. So we think that we'll diagnose you with A. But as we go along the journey your diagnosis changes to B and then we might diagnose you to C. Along the way we might give you some treatment and therapy for those.… But … you'll have patients sometimes for quite some time, maybe years, being treated for something that isn't the thing they should be treated for, or the thing that they've got wrong with them is being missed.… So misdiagnosis is a key gap that's not reported very effectively, which brings me to the actual care setting – primary care or community care and general practitioner services. Independent practitioners very, very rarely feel the need to tell us about anything or their local organizations, because for one thing they don't see very many of these things, and, for another, quite a lot of time they're picked up elsewhere. So the people who picked them up from somewhere else don't tend to report about other people. [I 12]

The final area identified by key informants as being underutilized, but containing invaluable data on system and performance deficiencies, is patient complaints. Although sorting through patient complaints may be a labour-intensive activity similar to analyzing a near misses database, it is a process viewed by some institutions as constituting an important step in attaining a state-of-the-art system that is focused on high quality and patient safety. One informant argued for its potential usefulness in augmenting other data sets dealing with adverse events.

> Certainly patient complaints, every organization captures their patient complaints, those should be looked at with a very, very hard eye. They should be analyzed very, very closely even though a great many patient complaints are thought to be frivolous and perhaps about hotel type things. Others are actually very reflective of where some of the vulnerabilities are, where patients are worried about the safety of the care that's being provided to them, where they feel as though communication – particularly around problematic situations – that don't really occur very well, and they're upset about it. So patient complaints are important data and I think a little more dependable than the self-reporting of adverse events, at least in some categories. [I 13]

Some jurisdictions have taken an extra step and devised a formal mechanism to deal with patient/family complaints about potential quality and safety issues. One informant noted that her organization actually incorporated a statement on patient complaints in a newly

developed policy on reporting. The important is that patient complaints about safety issues are not only welcomed, but support the notion of patient-centered care.

> We've even put a statement, a policy statement, into our reporting of harm, close calls, and hazards, about encouraging patients and families, volunteers and visitors. We're not shutting the door, we're not saying these are the reports and these are the information from clinicians, from our staff. We're welcoming it from whomever, because really the reporting piece is a huge culture carrier that takes us then into assessment and learning and improvement. So the reporting piece of it is very important, but, of course, it's based on that culture piece and we actually have a policy about a just and trusting culture. [I 3]

A second informant described how his province moved to formalize an organization's attention to, and review of, patient complaints. What is important to note is that once complaints are received about critical incidents, the organization is obligated to do follow-up. This informant commented on the provincial system thus:

> As part of a CPSI research grant, initially we created a phone line, a single point of entry for people, including patients and families, to be able to report critical incidents.… Ideally we do get the name from people so that we can follow up as part of the actual critical incident investigation and analysis.… Our phone line is not governed by a statute, but if a health care provider or an organization becomes aware of a critical incident they have a duty to report it. Further, once we have ascertained that it actually is a critical incident and not, for example, a

complication of a procedure, we have a further duty to disclose that to the patient or family member. [I 1]

2.1.2 Measures to Improve Identification and Reporting

Despite the presence of diverse approaches for identifying and reporting adverse events, problems persist within and across organizations in developing reliable systems. Different jurisdictions are using several measures to help improve identification and reporting systems. The following factors were believed to be integral to success in this area:

- The presence of a guiding framework or taxonomy for separating "health care deficiencies" that constitute quality issues from events that pose threats to patient safety;
- the development of conducive rating scales to determine the severity of events/situations which embody potential (near misses) or actual harm;
- the presence of a culture of safety that encourages everyone to not only critically think about how health care delivered in certain ways may pose risks to patients' well-being, but also to feel empowered to do something about it, like documenting or reporting it; and,
- the stated intent to use identification and reporting systems as "learnings" to help improve the quality and safety of health services delivery.

Each aspect is discussed in more detail in subsequent paragraphs. What is important for the reader to be mindful of is that the separation of identification and reporting is arbitrary at best, and only done successfully when reference is made to appropriate reporting lines for adverse events of varying severity.

2.1.2.1 Definitional and Taxonomy Problems

One of the basic premises of a successful identification system is developing consensus on what constitutes adverse events that could or do lead to patient harm. This is a very important starting place because it provides the foundation for front-line workers' ability to detect when something could go wrong or has gone wrong, to know how to prevent the event from happening or intervene to minimize harm, and to critically analyze the act or situation in order to report it in a meaningful and timely fashion to appropriate authorities.

As noted by a number of informants, there is limited consensus on what constitutes an adverse event. Without intersubjective agreement, inconsistencies exist in what gets reported and how it is reported. One informant commented thus:

> What is an adverse event? And so once it's into that, do you include near misses, or good catches, do you leave them out? Sometimes people will gravitate more towards a sentinel piece as opposed to the broader definition. But I think that first

> and foremost definition is the key. Then a system to collect that information, from the identification point of view; I'd say that's probably a major gap. [I 7]

A second informant also agreed that definitional problems constitute major barriers to adequate identification and reporting. This informant felt strongly that near misses and actual harm should be viewed as separate entities.

> I think it's important to distinguish between actual harm and potential harm. I think that has led to considerable confusion, which has allowed some providers not to identify and therefore not to report. So, personally, I am quite favourable to a definition which at the first step focuses on real harm to the patient. In other words, the topic of near misses or, more appropriately, near hits does not belong in this area. I think the approach to identifying them and reporting them and learning from them is very different than the approach for those events where there actually has been harm to the patient. [I 15]

Equally important are the implications for patients' and families' understanding of harmful acts or harmful situations. That is, if health care providers and managers fail to agree, then this compromises their understanding. One key informant articulated the key issues quite well.

> We've really worked hard here in [city] to get the language in terms that the man on the street can understand. What's a critical incident? I don't know. It sounds bad but what is it? Suffered an adverse event: I'm not sure what that is? I don't think the average [citizen] knows what it is.… Some people still talk about

> adverse events, but we are really talking about *reporting harm*. I find the disclosure of harm definition – it's an outcome that negatively affects a patient's health and/or quality of life – Now, that's still written in the Oxford dictionary as hurt or damage, and that's what patients understand. [I 5]

It became quite apparent from the interviews that jurisdictional differences not only existed in the terminology selected to label adverse events (e.g., critical incidents, patient safety events, patient safety incidents, potential for or actual harm, etc.) but also in the defining criteria for classifying such events.

Some organizations have concentrated intensive efforts on developing a classification system for capturing all possible variations of adverse events. For the most part, conducive taxonomies for operationalizing adverse events have been reviewed and components selected and/or modified to accommodate the particular idiosyncrasies of the local environment. One informant summarized organizational work of this type in the following manner:

> Overall we rolled out this reporting system and developed a framework. I won't say it's particularly based on any specific taxonomy. There are several taxonomies. I know the World Health Organization has promoted an international classification for patient safety of reportable events. We've looked at that but we have more of a system of space [situational context, i.e., geography and political climate] on the things that staff has been reporting, and expanding on those and

> the things that are important to this district. It's built on that and we add things based on accreditation standards or what we see as patient safety goals. [I 4]

What, then falls, within the purview of an adverse event versus a quality issue? Safety issues were differentiated from quality ones in the following manner by one key informant:

> What we try to do is get the bulk of patient safety events, things that might be near misses, predominantly near misses or things that we'd like to prevent from happening again.… There are lots of nonconforming events out there, things that have missed a little step or might be near misses or quality events. We're looking at those so we can present the big things. If you look at it like an iceberg or a big triangle, what we want to do is prevent it from getting to that point. There are lots of things that happen before you get to the sharp end where you have the big adverse events. [I 4]

The separation of quality and safety however, is a rather complicated process, due to what is shared by the two. Another key informant commented on the inherent problems with this:

> If a patient experiences harm because they have a terrible condition… I don't think we should consider that a critical incident. If they experience harm because they have a terrible condition that we did not handle in the usual intended way, I think that's a critical incident. Similarly, if somebody has a complication or

> encounters a risk that's associated with a procedure and we responded to that in the appropriate, intended or reasonable way, I don't think that should be considered a critical incident. But if they encountered a risk or complication and we did not recognize it or respond appropriately, I think that is a great example of harm occurring during the provision of services as a result of some breakdown in the way we provided those services. [I 15]

It is apparent that differentiating quality from safety issues is not an easy exercise and one that is often fraught with difficulties. It could be that what first presented as a minor event or close call could later manifest as something more serious. The problem is that if near misses or close calls go unreported and/or are not rated within the system, then there is no way to retrospectively track their progress over time. One informant emphasized the importance of reporting near misses and augmenting these with additional data recorded in nursing/medical notes:

> We have a schema here in [city] in that basically, a close call means that you weren't harmed at the time of reporting, but you could go on to develop harm. So if a patient falls out of bed or slips on the floor and picks himself or herself up or is picked up … and says, No, I think I'm fine. Well, they weren't harmed at the time of reporting. You can report a patient fell, but we need to keep an eye on that patient because what if that patient is taking warfarin and three days later is a bit confused, . . . then found to have a subdural.… So what happened at the time? How was the patient when you found the patient on the floor? Not what do you

anticipate will happen to the patient. One of the problems that we had here with our old reporting system is that it asked the reporter to judge what the outcome would be. [I 5]

2.1.2.2 Rating Scales

Besides the definitional and taxonomy work, efforts have been focused on developing rating scales to facilitate operationalization of the severity of potential/actual harmful events. Again, this can be quite variable across provincial/national jurisdictions, institutions and health care sectors. What is important here is that systems of this type attempt not only to capture the movement from non conforming events (quality issues) to near misses or close calls to events that actually result in variant levels of harm to patients, but also to quantify this progression.

Rating scales are useful tools for classifying the severity of adverse events because they require that the rater critically think about what has occurred in terms of the potential for, and actual level of, harm to patients. Although different institutions vary the number of scale steps, the basic principles remain the same, with scores ranging from “no harm to permanent harm or death.” The problem with rating scales occurs primarily on the low end, with minor events or near misses. In this instance the rater often encounters difficulty separating quality from safety issues. Another closely related problem is that there tends to be a predominance of data on the low end and very little in the mid- and

upper-ranges. This reality creates a third problem that relates to the rather time-consuming and labour-intensive efforts required to sort through the aggregated data to identify meaningful events that together could be symptoms of greater system problems, but if left alone could threaten patient safety.

Although a number of informants commented upon the problems with rating scales, overall the general sense was that this is the best way to proceed, because it forces front-line staff to engage in critical thinking about incidents and occurrences and to make clinical judgments about quality or safety issues. One informant commented upon the problems in rating near misses and then finding the time to look at this data in a meaningful way.

> We have four levels of rating the severity of an adverse event. So often a level 3 or a level 4 … is, in fact, embodied in near misses. It was this far away from being catastrophic, but it's only because something actually happened that it didn't get to that point. Usually they identify the gaps in process where it was leading towards that outcome but didn't because of some chance intervention.… We are trying to characterize those. The short answer is we'd like to know more about our near misses. We do capture our near misses in our identification system … and we know there are many more … 3s and 4s reported than …1s and 2s. At this stage we're planning to evaluate those more comprehensively, but we just haven't had a chance to do that in any systematic way yet. [I 9]

A second informant addressed the problems in training front-line staff to exercise critical judgment concerning quality and safety risks, and at the same time documenting these in a useful manner. The struggle highlighted here is one of convincing people that thinking time is important to achieve quality professional practice.

> What we've got is our national reporting and learning system, if you imagine the hub or the central system as a national system, which is linked electronically to every local organization, local risk management system … that has a risk manager. Every organization has to have a risk manager and their responsibility is to all new staff … and existing staff … to train them in what they should or shouldn't collect. What they do is speak to every single staff member, whether it is a doctor or nurse or physiotherapist or whoever, and explain what they define as an incident and what should be collected. What you find is that you still have people who will say, No this is a side effect of the clinical care I'm giving, or this is a complication we could have expected. So people struggle with the incidents that naturally occurred and were possibly expected to those that most definitely should have been prevented and shouldn't have occurred. [I 12]

Rating scales which require critical thinking and judgment calls by the rater raise important questions about their overall utility in busy clinical areas. Certain jurisdictions have attempted to ameliorate this problem by requiring that providers and/or patients/families who identify adverse events report such occurrences by telephone.

These reports are forwarded in a timely fashion to a safety team which determines their status. One key informant described this system as follows:

> The reporting of critical incidents now in [city] only occurs by telephone. We have a 24-hour-a-day live coverage by trained, university graduate operators, who take the call and follow up with a very simple ten step protocol. The person taking the call does not make a decision about whether this is or isn't a critical incident. The information is emailed within two or three minutes to the regional patient safety team, characters like me, and appropriate people at the facility and within affected clinical programs. A number of people know about this in a timely fashion. [I 15]

The rationale for total reliance on a telephone-based system is the anticipated benefits from having the reporter "tell a story" as opposed to forcing him or her to "check a box". The following quotations attempt to capture this:

> We will not accept paper reports. We will not accept email reports. The only way you can report here is by telephone, and that requires you to tell us a story — an account that we think is a much more powerful indicator of what really was happening. Whether or not it gives us the answer as to what specific factors led to this, it does give us a clear understanding of the event as the reporter experienced it. [I 15]

> We're seeing some interesting diversification of reporting, and we think that's partly because in the old system first of all you had to find the piece of paper and that was often a challenging task.… Then you had to tick off a bunch of boxes. What we've concluded, and this is based to a great extent on the experience of the National Patient Safety Agency in the UK, that tick boxes don't tell you the story and don't give you a clear understanding of what happened. They limit the options for the reporters. The protocol that the operators use encourages them to include as much information as their story requires. It's, I think, one of the reasons we're happy to use that system. [I 15]

2.1.2.3 Creating a Culture of Safety

Several key informants discussed at length the problems encountered in preparing different levels of staff to sort through and think about what has occurred and how to rate its import for reporting purposes. Given the increasing importance of near misses for improving patient safety, all of the key informants were of the opinion that further work is required on the front lines to not only create a culture of patient safety, but also to educate and train staff to effectively identify and report adverse events in a timely and consistent manner. It was also apparent from the key informant interviews that the identification process is crucial in the successful development of an effective reporting system. Several jurisdictions have devoted a lot of time and effort and resources to ensure this.

Many suggestions were made by the key informants on how an organization might go about achieving a culture of safety. The commentary revealed that this is indeed a tedious process that requires a core group of dedicated people to lead the initiative, as well as the commitment of top management. One of the first areas requiring attention is that of existing policies and procedures that should be modified to fit the new mandate. New ones may also need to be developed. As one informant noted so this process can be quite cumbersome and take on a life of its own:

> I'm not a big one for rules and regulations, although it may be that there needs to be some rewriting. Having worked on the four safety policies that we now have here in [city], it took us three years of unbelievably hard work and writing and rewriting and consulting and reading and rewriting and consulting and churning and arguing and discussing and rewriting yet again. Writing policy and legislation is a slow, cumbersome process that maybe is not the best way to go. I'm not going to say that you should completely rule it out. It is going to depend on what you've already got on the books, but let's look and see what's on the books first because maybe you can just write an amendment. [I 5]

In fact, some of the informants noted that they learned from the experiences of others and moved to seek permission to adopt their policies and procedures with minor modifications.

The next priority is to work with staff and management to promote understanding and acceptance, and also to provide them with the required expertise. One key informant described staff acceptance as being the foundational for everything:

> I think you have to do some underground or baseline work before you get to the reporting system, which is to convince people that it's worth their while to report because somebody is going to actually do something about it, and that it's going to be safe for them to. If I've made an error that, fortunately, … didn't harm somebody, but you can sure see that it could harm somebody and I decide to report that, am I going to be disciplined for that? We tend to use the phrase "appropriate accountability," and we don't think it's appropriate to hold people accountable for making errors. [I 6]

Without exception, all key informants supported the notion that staff have to be convinced that identifying and reporting system and performance issues that threaten patient safety is necessary. They must also, however, receive assurances that by doing so they will not have their rights or those of their co-workers violated.

The significant components of a culture of safety identified by the informants included justice and trust, nonblaming, supporting the team concept and learning. This aspect was summarized by one key informant who referenced the work done in aviation by James Reason and its applicability to health care delivery systems:

> So people have to trust that you're not going to be reprimanded if you find an adverse event and report it. It's not the tattletailing on your colleague, your team member, it's putting the patient first. You're putting the team first by actually identifying it. The whole purpose of identification is really to learn and, based on the learning … to improve. So if you don't report, and if you don't have a culture that supports reporting, then you can't learn because you don't know really that it happened or others don't know that it happened and can't make the kind of improvements that the system, not just on a one-off basis, would need to help the organization make it safer for the next patient. [I 3]

The approach to ensuring staff that they would not be reprimanded for identifying and reporting adverse events was quite different across jurisdictions. Most of the informants noted that electronic reporting systems are now the norm in many jurisdictions. Although severe adverse events must be reported everywhere, reporting of minor events and/or near misses is voluntary but highly encouraged as a useful means to improve the system. One informant had this to say about the difference between mandatory and voluntary reporting systems:

> It's a voluntary reporting system in all situations other than fatal or severe harm, in which case, it's mandatory. It could be a medication error, it could be an unlocked medication cabinet, it could be a chart left lying around, or it could be a procedural error. By making it voluntary, with the exception of severe and fatal

> harm, we're enabling people to report in, and we're encouraging the reporting at the units and at the team level so that it's not being perceived as tattletailing.… So what could we set up… I guess as a unit or a department with that learning to know… [it] just hasn't happened once to that particular nurse, but it's happened five times on that unit, or it's happened on ten units. The reporting system is really a learning tool. [I 3]

For some informants complete anonymity was the preferred approach in their institutions. In certain jurisdictions this philosophy had actually been incorporated into the system, whereas in others it was still at the discussion stage. The following quotations from two key informants working in different health care sectors capture this aspect:

> It is a totally anonymous system in that we don't identify the staff.... We ask them to identify the patient so that we can track it back, review charts and look at a particular clinical case. But we don't ask them to identify themselves because … They find the thing that has happened or they are the ones that it skips to a halt in front of. So we ask them to review those events, put them in the system and then look at them to identify what needs follow-up. [I 4]

> In our setting we have an events reporting system. At this time it doesn't allow for anonymous reporting. I am pushing for anonymous reporting for the next stage. The organization didn't feel that they could handle anonymous reporting right off

> the bat. We've been building a just culture. We went away from the no-blame to a just culture because you always get into these arguments around accountability when you talk no-blame I think a just culture is a better description of what you need. [I 11]

Another informant presented a contrasting perspective on the merits of anonymous reporting, preferring to ensure that the organization maintained the confidentiality of the reporting person:

> I think the basic philosophy is that, number one, you have to make it safe. So there has to be some confidentiality. Some people would say you go to anonymous reporting. We don't support anonymous reporting in [city] but we do support confidential reporting. How you devise a system where it will truly be confidential is a big challenge. [I 6]

Work on creating a supportive culture for identification and reporting systems was often initiated concomitantly through education and training initiatives. In order for policy change to be realized in practice, a tremendous amount of work is required in educating both front-line staff and all levels of management. This process can take years as one informant noted:

> So as you can imagine, if there had been a culture where inadequacy is a norm, then the fact that we might fail a patient and if it's been occurring for 20 years, it might take a bit to get people to be thinking, Well, in fact, that shouldn't be

> happening and that constitutes an adverse event.… When we did our huge educational push in 2005-2006 around adverse event reporting, we actually saw an increase in adverse events reported, mostly in the … 3s and 4s which mightn't suggest that we weren't getting worse in our performance, we were just getting better in our reporting. [I 9]

Even with intensive training in identification and reporting, problems may still occur following the introduction of a new system. This aspect is captured in detail in the following quotation:

> My colleague and I did 88 one-hour sessions in a three-week period to train the trainers just for the major site here. Every other site we went out to in person, set up in a central room for days on end with one-hour sessions following right after each other. One of us would do everybody that came down to train the trainer, and one of us would circulate in the units to help people who couldn't come down or were having a problem with reporting. We ran a question line through a general phone-in system and we have a generic email where they can send us questions. That takes a lot of time.... Folks who say they're going to flip the switch and launch the whole system in one day, [that's] not realistic, not realistic. You need to really pilot it. We piloted it for six months in three smaller sites before we started rolling it out to the rest of the district, and [we] really, really worked on making sure that everything worked well …. Right now the issue we're having with network traffic is really turning people off.… Whatever you do, make sure

that you have lots of capacity before you go out there because they took to reporting like ducks to water. [I 4]

2.1.2.4 Leading Practices and "Learnings"

The desired outcome following work on a culture of patient safety is the creation of a critical mass of front-line providers who are motivated to actively engage in identifying and reporting events that compromise the quality and safety of care delivered within an organizational setting. Despite the tremendous efforts across national and international jurisdictions, there are still many deficiencies and gaps in systems designed to manage the identification and reporting of adverse events within health care. As with any system, innovations designed to facilitate improvements will fall short of set goals unless there are committed individuals at all levels to facilitate their implementation. Commitment alone, of course, is insufficient without adequate resources to support the implementation process.

Many of the experts interviewed had considered how to best improve existing mechanisms and institute innovative strategies so that they become guiding standards that have global applicability across provinces and countries. The basic idea is that opportunities exist for everyone to learn from each other and not have to keep making similar mistakes. One informant had this to say:

> What you need is a national databank of adverse events, and it will have to be a reliable databank.… Without reliable feedback you cannot really calibrate your behavior. I do believe that CPSI is working on this. The reason that I would like to see a national data repository is because provinces can then learn from other provinces and, not only that, but countries can learn from other countries. In some cases there is no need for us to reinvent the wheel every time. [I 8]

Even in the presence of national standards and a national repository for adverse events, problems still occur with independent practitioners who do not fall under the guidelines of any particular health care organization. The target group here is physicians, who account for most of the misdiagnoses or diagnostic errors. The important question is how to convince this group to become willing partners in improving the quality and safety of health care systems. One informant commented thus:

> We'd like to start with the general practitioners but they are not interested in communicating with us…. They believe they're autonomous practitioners who don't need to listen to a national organization. We truly struggle with misdiagnosis even though there are numerous conferences that talk about it and a large number of very nice research studies.… I think again that is a key gap: very few solutions for thinking about what's the root cause of misdiagnosis. Clearly, it's understanding the latest evidence, and good observation or lack of it. Picking up a deteriorating patient is one way we've been looking at it, communicating between mainly somebody who is low in the hierarchy to somebody higher in the

> hierarchy of a team, usually nurses to doctors, and trying to improve the way that they communicate and explain what's wrong with patients. [I 12]

Another key informant stressed the importance of working on forging more effective communication between members of the clinical team. The goal should be to minimize the hierarchy and to give every member a voice in questioning clinical judgments that threaten patients.

> We have been pushing hard on clinical units to undergo team training because we believe that those management concepts have been shown to be very effective, particularly in acute-care-type clinical units. In labour and delivery it's been just phenomenally effective, but we think it also should happen in places like the OR, the emergency department, the critical care unit, the recovery room. Those are the places where there needs to be very crisp communication between providers. There needs to be understanding as far as what's being communicated. There needs to be accountability as to what people have agreed to do, and there needs to be immediate response. There also needs to be the ability of every voice to be heard. Somebody who has noticed something, if they can't be heard, if no one is paying attention to their voice because hierarchally they're too low on the totem pole, that's a problem. The wide variation of communication difficulties are the things that we see in malpractice cases that we think are very, very reflective of some pretty serious issues that are going on, on a broader scale in our health care organizations. [I 13]

Some key informants were concerned that too much emphasis is being placed on the use of reporting tools at the expense of thinking about and writing up what actually happens to patients. There was some support for improving communication by having a backup system that details what happened to a patient in his or her chart. One key informant summarized the sentiments of many others with the following commentary:

> I think that whatever happens to a patient has to be written in the record. We're obviously talking about acute care, and we always focus on that because it's easier and tidier and neater and we can count the number of individuals within the walls of the institution, but I think it applies anywhere. You need to write down somewhere in some kind of patient document what happened at the time. Unfortunately, a lot of health care providers have become afraid and don't want to write in the records. They say, Oh well, I'll put it on the critical incident form and that will be okay. Well, that's no good because when I come on shift, how do I know what happened to the patient? [I 5]

Other informants approached communication deficiencies from a slightly different perspective. In a busy acute-care setting, it is often difficult finding time to not only reflect upon about what has occurred during one's shift, but also to synthesize it in a written form. The position taken by one informant is that organizations need to allocate

resources for “thinking and writing time” if front-line staff are to support initiatives to create a culture of safety.

> Throughout the health care system, people have to recognize the value of a reporting system.... Unless you find a way of dedicating resources to this system … then it won’t get done. It’s no good saying to physicians, you guys never report anything…. We are losing a huge amount of data simply because the resources are not given to the people who are at the front line, which is where all your valuable data is being generated. ... So the way it should work is something like this.... You come in and you work for seven hours, clinical work ... and then ... you will dedicate 30 minutes of your time at the end of the shift to systematically record any adverse events or near misses or things that you might think would be of value to the health care system in terms of improving patient safety. You have to take the step to create the resources to do this. [I 8]

A similar position was articulated by a second informant who felt that organizations should make greater use of front-line workers’ perceptions of vulnerable clinical areas by engaging them in focus groups on a regular basis. By using such an approach to data collection, opportunity exists for review of what has occurred in conjunction with prospective data collection on what is currently happening in the clinical setting.

> I think every organization should be on the constant march to say hypothetically this is where we were vulnerable at such and such a period of time.... What every organization needs to do much more routine around is having focus groups with

> their front-line providers. In other words, bring that data to them and say, Look, this is what we saw from the past. Are we still vulnerable right now? Is this still going on? Are we likely to still see these kinds of things recur? Even though that's a more informal, unstructured data gathering process, organizations ought to be doing that a whole lot more. [I 13]

2.2 Reporting Lines

A final area under identification and reporting relates to the types of reporting systems and reporting lines followed for adverse events rated at different levels of severity. The level of governance for reporting adverse events is very similar across jurisdictions for those receiving a mild to moderate severity rating. Normally, the first-line manager or supervisor of the area initially informed and then deals with it directly, if minor. If the event is of sufficient importance to require system changes or improvement, then it is also reported to a risk management team or patient safety team depending on the institutional structure. These events may move up to the vice-president who is responsible for services within a department. The following quotation captures some of this movement:

> This is just a question of we rely on everybody to look at the situation and say, Can you at your level in the organization handle this by yourself? And if the answer to that question is no, then you need to notify the person one level above you. And then they ask the same question, and if it's too big for them, then they

> notify the person above them. So we don't have an IT system to support … applied common sense, knowing that common sense isn't always prasticed. [I 6]

As well, if institutions have risk management or patient safety teams, they are assigned the responsibility of creating a database template or aggregate of quality and minor adverse events that is shared with top management, the governing body and government. The following quotations capture this routine:

> We do quarterly breakdown on events for them [the board] based on the reporting system — what's coming through the reporting system— and if they have any questions.… They are [All low-rating events are] summarized and they get a numerical summary. We also [identify] the top five events at our site and by the district overall to show them what the top events are and how we handled that through the quality perspective. [I 4]

> We like to think that not everything has to go to the board for review and assessment; that's not the role of a governing body. [I 3]

> Sometimes our patient safety officers who also have access to it may see it before the front-line manager. If it's happened on the weekend … the patient safety officer will see it first, but usually it would be the front-line manager. [I 9]

Most informants were also in agreement on the reporting lines for events of increasing severity. The following quotations attempt to capture some of these differences and commonalities.

> But what we really try to say is most of the time for anything serious, and we've actually defined what we mean by serious, it needs to go to the very top. So it needs to go to your operational vice president. And that operational vice-president, we would assume, would know enough to let our chief operating officer know, who would then let our chief executive officer know. And then they would decide at that level whether they now need to let our provincial government know through the deputy minister's office. So it's really a question of everybody at every level looking at this and saying, Who above me needs to know? [I 6]

> Well, depending on the … rating, we have an area patient safety manager who reviews all 1s and 2s [severe]. Fortunately, we don't have so many that they can't manage that. But the severe incidents will get reviewed by at least one or two other people outside the clinical or corporate setting in which it's taken place. So there is some sort of independent review of it– as independent as you can be while working for the same organization.… We're compelled by [name of health authority] to report within 24 hours of it occurring, which means it has to move very quickly within our organization. It gets escalated from their manager to their

> manager to their manager to the chief executive, with staff in the directorate of the clinical governance assisting him. [I 9]

With regard to the various reporting levels within a particular institution, a significant differentiating factor was the pervasiveness of a culture of safety throughout the institution and other institutions aligned with it. When the emphasis is placed on learning from system deficiencies and failures, the intent is to maximize sharing in order to facilitate improvements in quality and safety. The following quotation captures this position:

> We want to keep decision making closest to where the patient is receiving care, and where the health care providers can actually make a change and make an improvement. But we want to be able to feed that up so that improvements being made in one department, in one unit, and in one service area … get shared too.… So it's so important to capture not only what the potential harm is, what the hazards are, what the adverse events and situations for patients harmed are, but also to capture the learning and to share that learning, so that others can make the changes and improvements that they need to make before patients are harmed. [I 3]

3.0 Assessment

The protocols and/or policies guiding assessment of adverse events evidenced more commonalities than differences on the national and international stages. There were a couple of significant factors that determined the type and degree of initial and follow-up assessments: 1) severity of the event and pervasiveness of its impact and, 2) performance versus system deficiencies. Although these areas may overlap, an attempt is made to highlight the unique particulars of each.

The important question that every organization has to ask is What kind of adverse events will be the subject of an investigation? Concomitantly, it must also pose the question concerning the status of near misses or close calls, especially when there is a clustering effect that may be indicative of deeper and far-reaching systematic issues. The answers to these questions are not always clear-cut, and may be a function of available resources and expertise, as well as the strategic direction of the organization in the short- and long-term.

Key informant positions on the appropriate mechanisms for organizations to have in place to conduct preliminary assessments and, if necessary, more in-depth investigations, tended to evidence greater variability. It was possible to draw clear lines in terms of not only the required structures, but also the expertise the personnel comprising them. One informant highlighted some of these differences within her jurisdiction:

> What they tend to have for minor events is either a peer review, with somebody coming from another ward to have a look, or the risk managers will do a small investigation. Very, very typically a risk manager could have ten or so investigations on the go at the one time. They tend to reserve the root-cause analysis for severe events and deaths, and usually have an independent expert to come in and chair the whole thing. [I 12]

A second informant also spoke to the different situations where a case review by a manager would be required versus a multidisciplinary case review or a root cause analysis, and how that selection is made within her organization. The following quotation highlights the importance attached to the severity and pervasiveness of the event (s) under question:

> We will do case reviews. It may be something where we simply need the manager to review it. It may be non-compliance with existing policies, a matter of maybe a little bit more education and coaching with staff members as opposed to an incident that requires a more thorough, detailed, broader review because of larger system issues. So we pick the tool that fits the best. Otherwise, you just get bogged down. [I 10]

A few informants favoured the notion of patient safety teams over risk management teams. One informant provided his rationale for this choice:

> One thing that worries me a little sometimes is that the risk management departments of hospitals get involved in this, and I don't think that risk managers

> traditionally have been patient safety people. They've been people who have been worried about the hospital being sued and minimizing the risk to the hospital, but the emphasis should really, obviously be on minimizing the risk to the patient.… So unless risk management departments change their make-up and change their attitudes, I'm not sure they should be the people involved here.… There should be patient safety officers at the front line, there should be patient safety departments within hospitals. There should be a provincial patient safety department that can sort of devolve the recommendations of CPSI. [I 8]

The experts interviewed were much closer in agreement on appropriate protocols for severe events than near misses, which tended to be weighted differently across jurisdictions, especially which regard to their learning potential. Points of difference between the key informants were more reflective of underlying philosophical stances than hard-core evidence. The following comments made by one informant summed up the perspectives of many others:

> You have to prioritize, so how do you decide? The institution has to make a decision. There will be some things, and some people will take a list from elsewhere and apply it. That's fine, but I think top management has to say, This is our list. It can't be the nurse on the ward or the doctor in the operating room to say this is the list. I think it has to come from top management. It has to be an informed decision.… I mean, that's their job – their job is to run the institution,

> their job is to decide what sort of things. They may have good help…. I hope they have good informed help, but ultimately the decisions stem from them. [I 5]

The basic problem identified by many of the experts who had knowledge of, not only their own but other jurisdictions, was the absence of a core group of skilled individuals to conduct preliminary and in-depth assessments. Although there were variations on what is available in different organizations, there was a greater consensus about what ought to be present in practice. One informant made the following comment:

> I was with a large group of people yesterday, the risk managers across the country. Not all of them have been trained in root cause analysis [but they] should be. Not all of them have been educated in the cultural discipline of closing the loop from adverse events. And not all of them have supports for communicating, when an adverse event takes place, to patients and families and that's a real hot topic for us at the moment. It's very variable and some of that variation depends on the inclination of the organization and how important it sees it. There isn't a formal national program to educate people, which there should be. [I 14]

In contrast, a second informant commented on the skill base of the risk management team with regard to conducting multidisciplinary case reviews or root cause analysis:

> We've got our staff with training in doing multidisciplinary case reviews, and so we certainly rely on their assistance. Depending on the case we'll bring in others, some of our more senior people, to actually participate in the review as well. We

> may bring someone in externally as well.... They [the risk management team] assume responsibility for initiating the case review. They report it and then normally talk to whomever, whether it's the department head or the manager, to say, We think that a case review is required. And then they'll work through who needs to be involved, how soon it can be done, and try to get it set up. [I 10]

Other key informants also discussed the qualifications needed by the review team. The severity of the adverse event was the main differentiating criteria. One informant described his perspective in the following manner:

> Well, they need to obviously have a broad administrative perspective and know how the organization functions. They need to understand how the clinical safety committee structure works – how reviews are actually done, the process for how that will happen efficiently and effectively, and the expectation from that process of recommendations for fixing the system. They need to understand how it works and have people who can do an administrative review of individuals and get appropriate recommendations for how to deal with them. They need to know how to deal with families and patients and how to support them. And they really need to know how to deal with staff so they don't feel isolated and left out to dry for some of these events. So it's a really varied skill set. [I 6]

Besides the disparate perspectives on the required skill base of the review team, there were additional differences noted about the appropriate assessments methods. A number

of participants voiced concerns over the heavy reliance on root cause analysis. A couple of them had this to say:

> I think that root cause analysis is okay in principle, but I don't think it works very well in practice. Because what tends to happen is that people go off and take courses in root cause analysis and they come back with a fairly rigid approach to understanding an event. ... I think it is one tool that we can use. I think a better tool is critical incident analysis, the approach that's been advocated by Charles Vincent. It was published in the BMJ and they've got what they call the London Protocol. I think it's a far more comprehensive instrument because it takes account of everything from the individual patient to the organization, the system. [I 8]

> There are a number of quality review tools and we feel that root cause analysis has been given too high a profile by CCHSA that it's a be-all and end-all. It's an extremely time-consuming process. I have looked at an event, done my follow-up and come to the same conclusion that the root cause analysis team did in three months, and I did it in two hours. So we really try to be careful about what type of events you put that into. We'd rather see if some events can go to a team-based morbidity, mortality quality review process where the multidisciplinary team looks at it and sees what needs to be rectified, because they will do it with a much quicker process. If this is a type of event which is just the tip of the iceberg and a

> symptom of the system, that's where you need something like failure mode and effects analysis, which is also a very, long and time-consuming tool. [I 4]

A third key informant also commented on the limitations with root cause analysis and how her organization decided to accept an alternate approach, the health system safety analysis, developed by an expert on-site:

> Through the relationship that we have with [expert] ... we developed something that we call a health system safety analysis. It takes us away from just looking at the individuals and it takes us away from trying to find a root cause. The connotation in root meaning is that ... one thing caused the harm. Through many conversations, through much research, [expert] has helped us create ... a new way of trying to assess, especially very complex situations from a systems approach. You not only look at the environment, the workplace, the organizational factors, but you're also looking at the people involved. The starting point is really the patients and the families.... Sometimes it's in those discussions with the patients and families that you find things that really can make the biggest difference. [I 3]

When key informants were queried about the logistics of involving health care providers and site managers associated with a particular adverse event, there was evidence of support for both sides of the argument. It might be helpful to briefly describe the rationale for each position. First, support for the inclusion of clinical staff and front-line managers rested on the assumption that individuals comprising these groups are more adept at

understanding the contributing factors responsible for the occurrence of adverse events and knowing the best approach to modifying or resolving them. One key informant articulated this perspective in the following manner:

> Well, I think the people involved in the event are the closest to it. They can speak to what the issues are and how to piece together where the breakdowns may have occurred and what led to that particular event occurring. I think the manager or the leader has that level of importance or credibility, and probably has the ability to filter that information to those who have the power to make those changes. So I think both need to be there, and both play a very particular role around the outcome of that. [I 7]

A similar perspective was articulated by a second informant:

> There is a policy framework called the Incident Management Policy ... we're just a local health authority [and] we're compelled to implement it and that guides everything we do. ... It relies on severity of system code rating, which I think is fairly widespread. It's very accessible, and I would be surprised if there were any managers or clinicians who didn't know about it.... Yes they do [site manager must be involved in review]. In order to discharge it as something that's been dealt with, they certainly have to explore it and put in an explanation about what they've done about it. [I 9]

Second, key informants who opposed the inclusion of the site clinical and management teams did so for a variety of reasons, but the most important of these related to the potential for negative repercussions and the need for a suitably qualified team that has been invested with the power and authority to not only recommend improvements, but actually oversee their implementation. A number of informants articulated these positions quite well:

> You must keep the investigators separate from those who are in operations. Absolutely, it's like church and state. You have to keep them away because they have to be free to investigate everything, and they should be able to investigate to the level of the feds. [I 5]

> No, no. I mean it can happen depending on the level of severity. You could have a supervisor looking at things related to their department, but that would be only if we're on the lower levels of that scale [severity of event] we're talking about. I think when you get up into the other areas, it needs to be certainly removed. [I 2]

> In my experience people who are front-line managers are not high enough up in the organization to be able to see everything that needs to happen. I'm talking for the more serious ones. [I 6]

> The manager on the unit where it occurred cannot be the investigator because of potential conflict of interest. Not in the sense of covering up, but they have lived the environment of that unit for quite some time and may have come to accept as normal a certain way of doing things that an outsider would say, Goodness, is that how you do things? We always involve the manager and other people from the unit very directly in the investigation process, but they cannot be part of the investigating team.… I think that it helps also for staff to feel more comfortable that the person who is coming to talk, to have this protected conversation with, is not their immediate supervisor. [I 15]

The final area addressed by the key informants was related to the type of assessments needed for system versus performance contributors to adverse event occurrences. In every jurisdiction concerted efforts are directed toward separating performance deficiencies from those more systematic in nature. One informant described the thinking around this in his jurisdiction:

> I guess from our perspective here in [city] we'd say that you need to have a policy that says how you're going to review an adverse event, who would do it, what tools would they use to do it, and would you be looking at a system-based approach or would you be looking at an individual-based approach. So in [city] we try to do both where it's necessary.... [It's best to] Have different people doing it, and be quite clear to people that when we're doing a system review ...

> questions around knowledge and competence of individuals does not come into play. And if they need to come into play it will be done through a separate process.... I think the other thing that is really important is to train the people who are doing the reviews both from a system perspective and an individual perspective to avoid hindsight bias. [I 6]

A second informant also spoke about the importance of separating performance and system issues:

> They're [risk managers] asked to do that very specifically by looking at the individual factors within the system, the direct care related incidents and the system related incidents. So it's very Reason Model by looking at the active and then the latent conditions, decision making and so on. I think what we've encouraged them to do is look at the system and look at the processes. The individual and their competency, their ability to perform and their ability to do the role that they were asked to do is something that is seen as a bit of a no-no, because everyone is saying we should look at the system. We're now coming back and having to say to people Look it's a balance. You can't have somebody who is incompetent within that system however hard you try to make the system work. The competency has to be addressed and people are struggling with that now. [I 12]

4.0 Disclosure

The content in this section focuses on the disclosure policies supported by the experts interviewed. It was evident from the various discussions that there were philosophical similarities among the experts with regard to the ethical and moral right of organizations and health care providers to disclose to patients and families in a timely, honest and comprehensive manner. It was also apparent that great importance was attached to achieving a sense of balance between and among health care providers and management who assume responsibility for interacting and working with patients and families harmed by adverse events. The final noteworthy point was the emphasis placed on "taking care of patients and families" beyond the short-term impact stage, by continuously disclosing to them at critical junctures in the process as new information emerges and new understandings are constructed.

All of the Canadian experts supported, in principle, the disclosure guidelines of the Canadian Patient Safety Institute. It is interesting to note that in some jurisdictions a differentiation is made between disclosing to patients and families, notifying staff in the organization, reporting to other health care providers in the region and informing the public. One key informant described these differences in the following manner:

> We use the word "reporting" to mean only that conversation between health care providers or staff, or it could be patients, but they're reporting to their health region, so the recipient is the health region. "Disclosure" is the conversation that

> providers in the health region have with patients. "Informing" is basically the conversation that the health region then decides to have with people outside of the inner family circle, either with their own staff or with health care agencies, regulatory agencies, etc. Then for that piece of how do you actually let people in the organization know that something has happened and need to know, we try to stick to the term "notify". [I 6]

A second key informant took exception to the use of the word "disclose" to describe the interaction that occurs between providers and patients and families following an adverse event. She commented thus:

> I know there has been a lot of discussion in the literature because the word "disclose" means to make something plain in view which was previously hidden. There is a certain negative [connotation], and there has been a bit of writing in the literature, this isn't really a good term. On the other hand it's the term we've got, so I think it's a process, it's not a one-off. [I 5]

A third informant was of the opinion that insufficient attention has been given to important issues like apology and compensation in disclosure guidelines. The connotation here is that avoidance of such issues sends the message that organizations are not taking full responsibility.

> I think books like Matthew Berlinger's *After Harm* gives you a clear, brilliant assessment of the situation. If we've made a mistake that has harmed you, we need to make an apology of responsibility, and be willing to sit down and talk

> about compensation. Lucien Lee wrote an article in 2006 in *Physician Executive* and sets out very clearly the four conditions of disclosure. There has to be a program in each facility, and training for the staff, because it's not easy to do. There has to be support for the staff, the patients and the family, because that's an important element. And there has to be willingness to talk about compensation. We took those four principles to our board and they've accepted them and I'm proud of that. Are we necessarily doing that all the time? Absolutely not, but that's the direction we have to go in. [I 15]

Besides the appropriateness of the terminology used, all of the key informants discussed at length what should be conveyed to patients and families, how this information should be conveyed and when it should be done. In cases of multi-patient and multi-jurisdictional events, there is a time-delayed preparation time to allow all parties involved in the disclosure process to assimilate the facts and determine the best way to respond to them. One key informant summarized her perspective on this process thus:

> You have to assess each situation based on its merits. How quickly do you have to get the message out? What are the ramifications? How severe is it? How will it impact the patient? Mainly 99% it's going to impact their psychological well-being because of fear, and fear takes control. Can you send them a letter? It's great to send them a letter no matter if you do phone calls first and then send a letter, because you give them the information that they need in writing.

> Guaranteed that if you send them a letter, within 48 hours it will be in the newspaper, so make sure your message is good, there are no inconsistencies or errors and it's well vetted before it goes out. [I 4]

A second key informant also stressed the importance of thinking through things and working together before proceeding with disclosure:

> I'm nominated as the contact person for the organization, so if anyone has difficulty with this, I'm just a phone call away and I can talk them through it, and I do. Sometimes I meet with a team beforehand. Sometimes we get some very tricky issues but we usually know how to handle it. If for some reason a SAS 1 [severe event] becomes apparent long after a patient has passed away, in the interests of being mindful of the sensitivities of that family, we will still disclose the event, but we may wait until we actually know what's happened so that we're going back to them only once or twice. [I 9]

A third informant commented on the importance of developing consensus among team members on the what, how and when of disclosure:

> As long as you take the approach of we're not here to blame people, we're here to understand, I think what should happen is somebody should take the lead and say, Either we're going to do this or you're going to do this. But somebody is going to be accountable for being the liaison with the patient and talking with the patient. This isn't a case of saying, well they screwed up and we didn't. It's a case of here are the facts of what happened. So I think the parties need to get together and

> agree to work together for the sake of the patient and agree on who is going to be the spokesperson, what are the facts, and what can we reasonably agree on about our facts. We will agree when we decide what the facts are, that those will be disclosed in their entirety to the patient. [I 6]

Some organizations have also developed disclosure policies that staff is expected to adhere to at all times. In situations where policies have been developed, a great deal of attention has been given to educating health care providers and managers about these policies and training them in the art of disclosure. One key informant described this process in the following manner:

> As I said, in SAS 1 and 2s [severe adverse events] we are compelled, and we have an actual obligation, clearly to disclose to the patient and/or their family about what's gone wrong. We take that very seriously, and in the last year [we've] undertaken a comprehensive training program for our senior managers and clinicians about how to do that. We have an open disclosure policy in [health authority], but we've turned that into a local policy-compliant procedure for staff to comply with the policy, which sets out precisely how we do this in our organization. [I 9]

A second informant stressed the importance of having mechanisms in place to adequately prepare the organization and all staff in disclosure policies and procedures:

> We have a very robust training program teaching providers and organizations about the fine balance of making sure that you're doing the ethically right thing and really meeting human needs. That you're following up on things that you promised to deliver as a result of this. That you recognize you are probably roller boat to a lawsuit but that fear needs to be put aside in terms of making sure you're doing the right thing, first and foremost. We're actively training all of our organizations on how to achieve that fine balance, that right balance and how to do this appropriately and sincerely. [I 13]

Besides disclosure to patients, there are obligations to notify or inform health care providers who work in some capacity for the organization or the larger regional health authority. As one key informant noted, staff are sometimes omitted from the list of who needs to know:

> The other key thing we've learned is that sometimes we do the piece to the media before we've adequately done the piece to our own staff. There's nothing worse than your staff finding out about something big and bad from reading the front page of the newspaper or hearing about it on the TV, [rather] than hearing it directly themselves first. [I 6]

As well, many of the experts referenced the need to have supportive structures in place for those who are directly involved in the event and/or work in the particular clinical area. The experts concurred that being attentive to health care provider needs was often a

neglected area in the past, but is now receiving much needed attention as a result of the "just culture" wave.

> For families, patients and also for the . . . the nurse or any health service provider that was involved in that particular incident, that there is some support from the point of view of disclosing that information but also dealing with that. It can create a lot of stress in the provider, and I think it's important to have those kinds of support mechanisms to be able to talk through what's happened and deal with that particular provider's feelings associated with that. [I 7]

A second key informant described the mechanisms in place in her jurisdiction for ensuring that the staff involved receives adequate support following an adverse event

> Depending on the nature of the event the operational management is responsible for that but there are two things. One is reporting back to the people who have been involved [in] what we have found to have happened. Secondly, before that is the management of their mental health, as you may find, when a preventable adverse event occurs which has resulted in harm, the staff is obviously devastated. We have internal mental health counseling programs for that kind of situation. We will refer them to those. We are sympathetic to that kind of thing because we don't take a blame approach. The thing in teaching open disclosure is that error is really, if ever, just one person's fault, so we do see that as part of our context. [I 9]

The area of the disclosure policy that evidenced less agreement among the experts was in relation to an organization's obligations with regard to informing the public and government agencies/departments. The major arguments for and against this level of disclosure relate to the patients'/families' right to privacy and the criteria which should be used to judge the value of health care systems, especially with regard to the adequacy of care delivery. The basic underlying premise of both arguments is the importance attached to accountability and justice. One key informant described his perspective on this in the following manner:

> I have real mixed thoughts about informing the public. In my mind when an adverse event happens, it's between the organization or the provider and the patient and the patient's family. It's a private situation. I don't think the public necessarily needs to know about that, because every one of these situations has complexities to them that would suggest that they're not very clear-cut. [I 13]

A second key informant also differentiated between the type of events that should and should not be disclosed to the public:

> If you're talking about a particular event, that's really tricky because I think in general the public wants to feel assured that particular institutions are safe, and if I get care there I'm in a safe place. So producing information to show that level of accountability, I think, is important from a public point of view, but to disclose a particular event, that's tricky. I don't think the public necessarily needs to know about the event. [I 7]

A third informant also stressed the importance of exercising caution when dealing with the public. As noted, the public can be very unforgiving, especially when they do not have sufficient information to promote adequate understanding:

> The public has a mentality from my experience that they want to be able to pin it on somebody as opposed to understanding that, in this type of an environment, with all its complexities and equipments and hand-offs, things are not at a succinct level all the time. ... But yet when it happens, they have to have a level of understanding that by going after somebody, you're promoting this whole protect-yourself mentality, that you hide your mistakes, keep your head down, kind of thing. I think the public has to be educated in that regard. I went through a couple of experiences where they didn't care about learning, they didn't care that you're trying to open up the culture and build trust so that people would report and that you could really get at the big issues. They want heads to roll. [I 2]

The final area under disclosure deals with the policy around informing the government when an adverse event has taken place in an organization. Again, there were differences of opinion among the experts concerning the what, how and when of disclosing to government representatives and departments.

> All external communication is done through Public Affairs. They pick the spokesperson, the person best able to discuss the event and who is appropriate for a particular event, especially an adverse event. But the communication done to the

> Department of Health and to any other external body, we would determine who that would be or we have a group meeting to decide the action list. [I 4]

A second key informant made this comment about the involvement of government:

> It depends on what the information is going to be used for. That would be my question. I'm not sure how I would answer that to be honest. Various provinces have taken different approaches to that. Whether one is better than the other, I really think it depends on the objectives, how it ties around wanting to know that information. [I 7]

5.0 Actions for Management of Adverse Events

The content in this section focuses on experts' perspectives on what actions should be taken by an organization in managing adverse events. The content here does overlap with that of other sections, especially assessment and communicating, coordinating and leading. What is different here is that the focus shifts to highlight the specifics of the overall operational plan guiding the implementation phase, and who is ultimately responsible for leading it.

The responsible body and/or persons for developing and leading the action plan for managing adverse events varied considerably across jurisdictions. Again the experts expressed views that supported or differed from the organizational norms that they have

experienced or were currently experiencing. For the most part, though, there was support for the separation of the group of individuals responsible for the review and implementation processes. One key informant provided the following rational.

> We believe that if an event is either a close call or an actual adverse event of substantial risk, then it should be reviewed by a properly constituted group of people – multi-disciplinary with some training. Their role is basically two things. Number one is to understand what happened, and number two is to come up with recommendations for trying to fix the system. Those recommendations usually need a vetting process from people more experienced in organizational matters than the committee that reviews the event, because sometimes they are not practical or feasible. But at some point people with [administrative] authority ... have to make a decision about following these recommendations … and then it's their accountability to assign people to carry out the plan. In our organization that's usually the vice-president level. [I 6]

Another key informant made similar remarks about the importance of separating the recommendations of the review process from the actions taken by the organizations to address them. Significant here is the differentiation made between the roles and responsibilities of the patient safety team and the program manager, while also emphasizing the collaborative efforts required in shaping recommendations that are logical, feasible and achievable through action plans:

> A patient safety consultant would typically be the person analyzing/investigating a critical incident and will write recommendations. Now their job is not to create an action plan for how those recommendations will be achieved. Part of their job is to meet with the people who would be creating those action plans to first of all see if it's feasible, to see if it makes sense, to see if there are specific things that they might word into that recommendation that might help them to achieve that goal.... They will create a recommendation that they think will help prevent this from happening again. They will meet with the program manager or director.... So the accountability of the patient safety consultant who has investigated is to make recommendations that can actually be implemented, and the program manager has an accountability to identify what can be implemented and [to] work within that framework to make sure that it gets done. [I 1]

One important point made by the key informants is the responsibility of senior management in facilitating the action process and ensuring that the necessary resources are allocated to achieve the objectives of the action plan. As such, a clear line is drawn between individuals leading the action plan and those ultimately responsible for its successful implementation. Although organizational structures vary across national and international jurisdictions, the basic principles underlying the positions of different experts in the area are very similar. One key informant summarized the perspectives of many others on this issue in the following manner:

> My ideal on this is that who should take the lead would be the chief of the department or chair working with, hopefully, a very, very well-structured performance improvement department for the hospital. The coming together of those two should really be the key.... The chief medical officer and the chief nursing officer ought to be the overseers to make sure that the clinical chair is working with performance improvement and pushing forward an initiative that responds to a very important understanding that a vulnerability has been identified that needs to be resolved. [I 13]

A second informant clarified what senior management would be responsible for concerning the implementation of the action plan:

> They [senior executive] would need to know, but would not necessarily be immediately involved or directly involved with every case review. They would know about it, they'd need to know what the outcome was, and ultimately they would be accountable for insuring that the recommendations were acted on, but they would not be sitting in the room with every case review.... So what we have put in place is a process where every VP as part of their annual review will be questioned on critical incidents from their reports – what high-priority critical incident review recommendations are they responsible for, and what's the status of them. [I 10]

As many of the key informants noted, somebody in the organization must assume ultimate responsibility. Regardless of who does this, it is also imperative that the appropriate mechanisms are in place to help this individual or body to be accountable. One informant commented upon the shortcomings of existing systems and how efforts should be directed towards their improvement:

> There is always a sponsoring VP. The VP whose portfolio that [the incident] mainly occurred in is responsible for ensuring that any recommendations are followed up on. They [administration] were trying to develop a tracking tool that would go to our executive team to ensure those recommendations were done in a timely fashion. That's all part of this quality review process that we're trying to get in place. That really does need to be tightened up, because that's where I think it falls down. To be perfectly honest, I don't think they have that as tight as it could be. There are certain things that we do get in place and are handled, but I don't know that all the recommendations are necessarily acted on. [I 4]

A second informant also emphasized the importance of "closing the loop" when moving from the review phase to the action phase, as well as the short- and long-term monitoring of actions taken.

> We emphasize the need to close the loop to make sure that communication is complete. The next step which we are just starting to do is not only to monitor the implementation and recommendation, but to monitor outcomes in response to the implementation and the recommendation.... So not only do we monitor that we've

> actually changed it, but we want to make sure that it's preventing a repeat of the adverse event or it's diminishing the risk of the adverse event that was there in the first place. [I 9]

A final focus of this section is the degree to which the board of the regional health authority and/or organization should be involved in the management of the actions directed towards resolution of adverse events. The general consensus of all experts was that this should be limited to information updates only. The comments made around this by a couple of key informants are exemplary:

> I think there should be a line in the sand saying, these are the types of events that senior management and the board should hear about as a regular update. How many have happened, the nature of what's happened, how the system has analyzed them, the recommendations that have come forward and have been approved to fix the system, and what the update is on those fixes. I think a regular reporting to senior management and a board quality-committee or a quality-and-safety committee should be put together as a part of accountability to the governance structure. [I 6]

> We never involve them [the board], we would report to them. I would be accountable to the board.... Of course, I may designate the operations of it to one of my VPs, but ultimately I'm accountable to the board. [I 10]

6.0 Communication, Coordination and Leadership

Relevant content for this section has been documented elsewhere during discussions of other aspects of the model. When asked to specifically focus on the integral aspects of good leadership and coordination, and who should take the ultimate lead throughout the entire process, the experts consistently made referral to the governance structure For the most part, organizations referenced had clear protocols in place to guide internal and external communications around adverse events. It was clear that most of the experts interviewed were of the opinion that guidance, direction and the lead should come from senior management.

One common theme expressed by many experts is the important role played by senior management in communicating and coordinating both within and external to the particular organization. One key informant made the following comments about what is required of senior management when the organization is confronted with an adverse event:

> It's the senior group of the health authority that has to take control and identify all the players who need to know – whether it's clients, or physicians, or support groups, or the government – and make sure that everybody gets the information that is appropriate to them, and when in doubt err on the side of information. You have to then find ways of making sure that the message does get out, that it is received. You got to have it at a level in the organization that people will respect

> and recognize that this is it, we're at the top of the chain here now. Because if they feel like it's down lower, they're going to feel like we're not taking it serious, we're not hearing what's going on, that we don't realize the gravity of the situation. [I 2]

A second informant expressed a similar sentiment about top leadership needing to lead the coordination and communication.

> [It's best] the higher it is in an organization. It can't be at the CEO level –it is way too busy and distracted. But one or two levels down … it communicates that we take this seriously … having our very top administrators actually in charge of this and accountable for it. [I 6]

Key informants identified a variety of mechanisms that have been established in different jurisdictions to facilitate internal and external communications. Regardless of the mechanism, the experts agreed that the goal should always be to promote openness and transparency. One informant commented upon the importance of internal communications for the benefit of all front-line providers and managers.

> I think for the most part the non-safety managers [senior managers] have a role to create in their teams the idea that this is an important initiative; that it is a non-threatening initiative, even though on the surface at times it may be seem threatening. But creating an air within a team that this is not about blame but it's about learning; that we all make mistakes and that sometimes within health care

> these issues can lead to severe harm; so it's only by understanding how they occur that we're going to mitigate them; and it's only by talking about them that we're going to understand them. So creating those conditions where difficult conversations can be held and, in some instances, I suppose, giving time to the people within their program or teams to have those deep and sometimes difficult conversations, would be a role that they could or should play. [I 1]

An important part of the governance structure identified by many of the experts interviewed is the public relations or communications department. The presence of qualified individuals to help management personnel and front-line staff effectively deal with communications around adverse events was highlighted by one key informant:

> We've been constantly challenged by not only relations with our own internal staff… So how do we set that up so that we can communicate effectively with our own staff but also the public and government quite frankly? I think there needs to be some skill or expertise around those three different areas. [I 6]

In fact some organizations have dedicated resources to ensure that senior management, as well as other organizational representatives, is equipped to communicate in a meaningful fashion the message that the organization wishes to convey to the general public and relevant stakeholders. A couple of key informants described the approach taken by their organizations:

> Most of our senior leadership has had communication training to make sure that they come across as credible about what they're saying in the message, and to communicate well. Our Public Affairs people make sure that nobody goes on the camera that doesn't look professional. We dress the doctors up, we get them new lab coats, new ties and make sure that they're not appearing in greens and looking sloppy. That's part of the message. You want to instill trust and you want the public to see that they're respectful and professional and know what they're doing and what they're talking about. [I 4]

> We actively train our senior leaders how to communicate. Communication, as you know, is indeed the principle, single, root cause of all adverse events – a lack of communication, miscommunication, inadequate communication, or just omitted communication. So communication, we know in our organization is very key. We can't emphasize enough how important it is to have, not only developed skills amongst our managers and clinicians, but to provide support with particular tools to communicate. That can be a two-way thing – communicating up or it can be communicating down and out. [I 9]

It was also obvious that health care organizations in all jurisdictions recognized the importance of maintaining public trust and confidence. If communications around

adverse events is not done properly from the onset, then it can be a difficult road back. One of the informants particularly emphasized this point:

> We're very mindful that we don't want to undermine confidence in our organization, so we take steps to make sure that we don't. However, of course, that might still occur, we can't control how other people see us. But our view is that we are very much a public service organization, so we try and serve the public. [I 9]

In general, most of the experts interviewed noted that conveying the right message to the general public is not only the responsible thing to do, but also that it has to be done in a transparent and open manner. The following comments made by a couple of key informants captured this sentiment:

> We've had a number of incidents here, and sometimes it's a breach in confidentiality. It may be just a case that someone has gone to the press and the local talk show. You gain absolutely nothing by being secretive about it. So my mantra has been accountability and transparency. Well, you got to tell the truth. I think people understand that to err is human, systems are imperfect, and I think the sooner you get it out there the better. [I 10]

> I think at the end of the day it comes down to being as transparent as you possibly can, even though it's super hard to do and it makes everybody feel really uncomfortable. The natural inclination of most people and most large organizations is to hope this one doesn't get out there, because that's just going to be a whole lot of heartache and headache. But you just got to resist that urge. [I 6]

In general, most of the experts felt that poor coordination, communication and leadership are symptoms of weak organizational governance. A couple of informants commented thus:

> When you have strong leadership, you have strong governance, and when you have poor leadership you have poor governance. If you've got poor governance it may well go back to having poor leadership…. [I 9]

> Yes, most definitely. It's also evidence of a weak safety culture of that organization.... A good safety culture is one where you've got leaders who drive safety and keep everybody communicated, informed and coordinated and so on. So it's culture as well as governance. [I 12]

However, not all those interviewed agreed with this position. One key informant discussed in detail why he felt that the situation confronting the governance structure is really much more complex.

> In a lot of cases it's symptomatic of complex processes. I mean in any situation there are always going to be coordination challenges, communication challenges, people may be overlooked or something. ... Health care is so complex. There are so many opportunities for someone to be missed or [for] a communication breakdown. You're dealing with different types of professionals, from different types of cultures, language barriers and challenges. It's an emotional issue. Lots of times you say something and people are hearing something else. You then have lawyers involved, and vested interests come into play. There are so many opportunities for things to go wrong. So it's not necessarily, I think, poor or a weak organization. [I 2]

A second key informant was also of the opinion that it is not just a simple matter of equating the two concepts.

> It's not that people don't want to do the right thing or aren't kind. But sometimes you just get overwhelmed, and either it's under-resourced or the people don't have the skills or the tools to do this, or the processes aren't in place. So it's not necessarily that a board or a management team aren't competent or doing the job well. Sometimes you got to look at what supports are in place to help them do the right thing. [I 10]

The final area in this section deals with the role of the board of directors in communicating, coordinating and leading following an adverse event. One informant captured the views of what many others conveyed at some point in their interview:

> Oh, their [the board members] role is to ask the questions, to represent the community, really. They need to sit through some of the medical jargon, the complexities. They have to hold the management team and the CEO accountable in a way that they understand. Lots of times they can play a big role in asking the simple questions. Why did it happen? What are you doing about it? I don't understand that. I can't tell my neighbor that. That doesn't make any sense to me. They need to have a comfort level with the issue. [I 2]

7.0 Evaluation of Overall Management

The final component of the model addresses the evaluation of the overall management of adverse events. The experts participating in the interviews were asked to express their views on the measures required to evaluate what has been accomplished after an organization has gone through all of the processes associated with identifying, reporting, assessing, disclosing, managing, and communicating, coordinating and leading. Special consideration was given to the type of outcome measures, who should be responsible for this phase, and should it be conducted by an internal or external body to the organization.

It was apparent from the interview data that all of the experts supported ongoing evaluation of an organization's performance following adverse event. Despite recognition of the inherent value of evaluation, most acknowledged that this was an underdeveloped area in many organizations. The reasons for this state of affairs varied, but there seemed to be a common underlying theme that referenced the gaps in identifying appropriate outcome indicators or performance markers for assessing quality/safety linkages within health care organizations. One key informant commented thus:

> Now it depends on what you're evaluating. I mean, do you have system markers — this goes to what you are measuring in your system and how can you track the performance of your system? For example, the HSMR, which is the standardized mortality rates, does your health region participate in that now through QI and what markers are you using?... The unit of responsibility, whether it be the doctor's office or the ward or the hospital or the region, has to have some system performance markers. [I 5]

Although many organizations are aware of what needs to be done in this area, it is a matter of developing a strategic plan around it and prioritizing it for immediate and ongoing action. One informant discussed where things are in her organization:

> We do not do this well, and what we are now focusing on first of all is just closing the loop to make sure we are implementing the recommendations that come out of these reviews. Then the next step is evaluating in a formal way the whole thing:

> we do not do that well, that's still work ahead of us.... One of the things that we've identified is we need a link to basically connect the dots between this whole process with some of our quality improvement and patient safety initiatives, including accreditation. [I 10]

The second important theme under evaluation related to experts' perceptions of the need for an external evaluation to complement the internal assessment process. There were differing perspectives on the merits of having an external body to do follow-up. The following quotations capture key aspects of these contrasting perspectives:

> I don't know that there necessarily has to be an external agency involved in that. I would advocate, though, that there is a component of evaluation to ensure that, number one, the changes have been made and they fit, and that people aren't falling back into the original trap that led to that event. I think it's similar to basic quality improvement philosophy that there are some final checks, and you just keep going through that process. [I 7]

> If you go back to the original idea that we talked about of having a national rapid response team, if they were involved in a major disaster and they were mobilized and sent there and did their assessment and made all the recommendations about what should happen, they would be in an ideal position to evaluate it three months later or so on and see what had happened. I'm not very keen on foxes doing the

> chicken count. I do think you need some sort of outside observation. People within established systems tend to pat themselves on the back too much and not be critical of what they do. [I 8]

What surfaced as important qualifying criteria is the presence of an internal/external regulatory body that is responsible for ongoing evaluations in the aftermath of adverse events. Certain jurisdictions have established a "policing body" of sorts that uses select outcome markers which are time driven. One informant described the responsibility of the department located within a regional health authority for ongoing evaluation:

> Ultimately, the chief executive is responsible in our organization. But the chief executive is clearly supported by the director of safe governance. The outfit that we try to run is that we identify threats to quality and safety, and part of that is making sure that we're doing the best we can possibly do. We're pursuing safety, quality and excellence to the greatest extent possible, and so we're constantly reviewing how we do things and whether or not we actually can or can't go just one step better. [I 9]

As this informant also noted, there are the specifics that the evaluation team looks for regarding the recommendations made by the initial review team, but there are also more general things that relate to the long-term mandate for the organization:

> Usually on our root cause analysis report we'll have a causal statement, a recommendation to the response of the causal statement, and then some

> measurement outcome. So we'll say 60% of staff doing this by February, 2009. That's exactly what we'll look for: we have to have a measurable outcome.... We're very mindful in actually making a difference instead of just activity for activity sake. We want to see that we've made a change, ultimately, to reduce risk in our organization. [I 9]

Comparatively, the presence of regulators (i.e., provincial, state or national bodies) automatically means that at some point in the process an external evaluation will be completed on the initiatives taken by the organization to resolve systematic and/or performance issues that created the situational context for the adverse event(s). A detailed example is provided by a key informant on what an external evaluator is required to do in one jurisdiction:

> We're the first line; we're the first organization to consider whether or not we undertake an investigation. The legislation that established us states that we can either be requested to undertake an investigation by the minister [of health] or the main provider, or we can instigate an investigation.... Our criteria are around whether a serious adverse event has been investigated by the provider. If it's already been investigated by the provider to a satisfactory level then we wouldn't get involved. If it's been investigated and there is still a lack of confidence, then we consider undertaking an external investigation.... So obviously it's up to the provider to undertake or commission its own external investigation. We're

> satisfied with that as long as it's for the right reasons, and an appropriate group of specialists are doing it. But if we're not happy with that, then it will be us: we will consider whether or not we are the ones that should do it. [I 14]

Although the relevant local institution and its administrative structure must assume responsibility for implementing any recommendations made by the regulatory authority, this regulator still does follow-up to ensure that actions have been taken, assessments have been done and there are ongoing evaluations of system changes and their ability to promote patient safety. On a cautionary note, this key informant stressed that it is imperative that regulatory authorities try not to case manage.

8.0 Conclusion

By triangulating information from the opinions and concerns of individuals with experiential and theoretical knowledge in the management of adverse health events, it was possible to profile achievements in this area as, well as the important aspects that continue to pose challenges for health care institutions. It is apparent from the commonalities and differences in expert opinions that parts of the health care system are in serious need of redesign in order for institutions to achieve optimal quality and safety in all health care sectors.

One of the most important areas that require ongoing attention is training and support for all health care providers, to empower them to identify and report near misses and adverse events causing harm, to engage in meaningful and timely preliminary assessments of events posing potential/actual harm, and to change care processes so that they reflect the highest quality and safety standards. A corroborating area is the importance of having ongoing commitment from senior management to ensure that the necessary human and physical resources (e.g., core group of appropriately skilled individuals for review, implementation and evaluation teams, tracking mechanisms to monitor progress with adverse health event management, etc.) are in place to support a work culture focused on quality and safety. Finally, it is apparent that more than ever health care systems require seamless systems that flatten the hierarchy and promote effective and efficient communication and coordination among all members of the health care team.

Appendix A

Key Informant Interview Guide

Adverse Event Management Framework Interview Guide

The purpose of these interviews is to assist the Task Force in its preparation of a final report to the Ministry of Health and Community Services. Information obtained may be used as a catalyst for the recommendation, development, implementation, adoption and evaluation of a provincial strategy addressing the management of adverse health events across the continuum of health and community services.

Please feel free to expand on any of the questions that will be asked. Before we begin, I would like to ask you if you wish to have your name listed as having contributed suggestions.

Before I commence, I would ask your permission to turn on the digital recorder?

Definition of an Adverse Event

An unexpected event in health care delivery that results in harm to the patient and is related to the care and/or services provided to the patient, rather than to the patient's underlying medical condition. (Canadian Patient Safety Institute. Canadian Disclosure Guidelines, March 2008).

The series of questions are based on the *Adverse Event Management Framework* (http://www.gov.nl.ca/ahe) promoted by the Task Force, and consist of identifying, reporting, assessing, disclosing, taking action, communicating, coordinating and leadership, and evaluating the overall management of the adverse event. Some questions may overlap.

Identification and Reporting of Adverse Health Events

Identification

1. In your opinion, what are the leading practices used to identify adverse events in the Canadian health care system?

2. Should near misses or events with potential harm be reported, assessed and so on, with the same level of diligence as an actual event? If not, what factors should distinguish a lesser response?
3. Where are the gaps in the identification of adverse health events?

Reporting

4. How would you define "reporting" of an adverse event?
5. What types of reporting systems are necessary for informing patients/families/team/government and so on, and informing events internally and externally, if required?
6. In your opinion, to what level of governance (e.g., internal audit committee of the board of directors of a regional health authority) should adverse events be reported?
7. Who should be responsible for reporting such events to the regional health board of trustees?
8. Under what circumstances should adverse events be reported within an organization (e.g., degree of severity/significance) to the board of trustees?
9. In your opinion, when an adverse event is identified, should mandatory reporting of the event to the provincial government/state occur?
10. Where are the gaps in the reporting of adverse health events?
11. What suggestions do you have to address the gaps?

Assessment of Adverse Health Events

12. What protocols/policies should be in place to allow for the assessment of adverse events?
13. It is possible that the assessment of minor events will be done by the leader/manager on-site only. What are the characteristics of an event that would justify a more detailed assessment process? Further, should the assessment process include people involved in the event, or just people uninvolved in the event?
14. Broadly speaking and depending on the level of seriousness of the adverse event, in your view, who should be delegated the responsibility of conducting the assessment?
15. What qualifications and skill sets are necessary to make an assessment? If a team approach is taken for the assessment, what players should constitute the team?
16. What types of analyses and assessments (probe – root cause analysis or other appropriate forms of investigation; peer review; interviews and so on) are useful in evaluating single and multi-patient adverse health events? What types of assessment guides do you believe are the most effective?

17. How and by whom should any updates associated with the assessment of the adverse event be made?

Disclosure of Adverse Health Events

The recent publication of disclosure guidelines by the Canadian Patient Safety Institute is a significant aid to the work of the Task Force. Rather than duplicating this effort, we will consider its applicability to the Newfoundland and Labrador setting.

Multi-patient and /or multi-jurisdictional event

18. What experience, if any, have you had in the disclosure of multi-patient and multi-jurisdictional disclosure? For clients with special needs?

Disclosure to patient/family

19. From a patient/family perspective what is your opinion on how the disclosure process should unfold?

Disclosure to the public

20. One of the key questions for a multi-patient event is, At what point should the RHA disclose the event to the public? Should it be determined by the number of people; the severity of harm (even if a few people); the potential for harm to others? Other factors?
21. Should disclosure be made public after all affected patients are notified? Or are there some circumstances (and what are they) which would justify public disclosure before all the patients are notified?
22. What is the best channel (meeting, phone, letter, registered letter, through the media) of informing a patient about an adverse event? What are the factors that would dictate using one rather than another?

Actions Taken in the Management of Adverse Health Events

23. In your opinion, what individual or individuals should assume the responsibility of developing an action plan and leading the implementation of identifiable actions?
24. Should the board of trustees and senior management be provided with regular updates on the implementation of the action (s) taken? If so, how should the trustees be updated?

Communication, Coordination and Leadership

25. When adverse events are initially reported, what role should management of an organization or regional health authority have in the coordination and communication processes?
26. When large-scale adverse events occur, diminished public trust and confidence in the system can occur. In your opinion, what are the key challenges of communicating, coordinating and leading when such an adverse event occurs?
27. How should information be shared internally (e.g., within an organization or regional health authority) and externally (e.g., across the health and community services system, public, media, and so on)?
28. In your opinion, is poor communication, coordination and leadership a symptom of weak organizational governance?
29. In your view, what is the role of the board of directors when an adverse health event occurs?

Evaluation of the Overall Management of the Adverse Health Event (s)

30. In your opinion, who should be responsible for conducting follow-up evaluation? External agency? Internal audit committee?
31. Who should be responsible for assessing the status of corrective actions?
32. Who should be responsible for communicating lessons learned?
33. What methods for evaluation should be used?
34. What measurements of effectiveness should be used?
35. In what time frame should the follow-up evaluation be conducted?
36. How will the results of the follow-up evaluation of the entire process be communicated (internally/and/or externally – if necessary)?

Government – When should it be informed that an adverse event has occurred and what should be its role?

37. At what point should the Department/Minister/Ministry be informed of an adverse event?
38. Is there any role for the Department in a multi-patient event if confined to only one site?
39. Is there a role for the department in a multi-patient, multi-RHA adverse event to ensure coordination?

Other

Is there anything else you have to say, or anything I have missed, that you feel would be useful or can improve how adverse events are managed?

ADVERSE HEALTH EVENT MANAGEMENT

International and Canadian Practices

A Background Document Prepared for the
Task Force on Adverse Health Events

Deborah Gregory, Ph.D.

Table of Contents

Executive Summary

Introduction

Studies' related to medical error in Canada[1], Australia[2], the United Kingdom[3], and the United States[4] have resulted in growing awareness and heightened concerns related to patient safety within the health system. In response to these concerns, global effort has been placed on patient safety in general, and more specifically, on adverse event management.

Background

The Secretary to Cabinet (Health Issues) in his role as Chair, Task Force on Adverse Health Events, has been mandated by the provincial government of Newfoundland and Labrador to address the following objectives in its terms of reference: (1) to examine and evaluate how the health system identifies, evaluates, responds and communicates with regard to adverse events within the health system; and (2) to examine relevant best practices in other jurisdictions.

Objective

The objective of this paper is to facilitate an understanding of the international, national, provincial and organizational "leading practices" in adverse health event management.

Methods

A scan of existing practices and an extensive review of the literature inform the composition of this paper. In addition, the Task Force sought to learn from the experiences of experts in the field of adverse health event management. Fifteen expert consultations were conducted from five Canadian provinces (Alberta, Manitoba, Saskatchewan, Nova Scotia and Ontario) and four countries (Australia, Ireland, the United Kingdom and the United States). Valuable insight was gleaned from the interview transcripts of these experts who so willingly gave of their time. The dialogue with key informants will comprise a separate but complementary report to the literature review.

Findings

A review of the relevant literature suggests that there are many lessons to be learned from the pioneers (UK, US and Australia) in the field of adverse health event management. In Canada, a tremendous amount of work has been done at the national level and within the provinces and territories. However, in order to learn from adverse health events it is necessary to have in place standard definitions, a standardized adverse health event taxonomy, standardized methods of reporting and timely and appropriate feedback mechanisms to ensure that changes are made to improve patient safety. The Calgary Health Region is considered by many as the country's most progressive.[5] It can be used as an exemplar of adverse health event management.

Conclusions

In undertaking a review of relevant "leading practices" in other jurisdictions, we were afforded the opportunity to examine and learn about the management of adverse health events from international, national, provincial, regional and organizational perspectives. Clearly, the pioneers in the field of adverse health event management (i.e., the UK, Australia, and the US) have much to offer in the way of lessons learned. The WHO is providing leadership in the area of adverse event reporting, learning systems and the standardization of taxonomy for classifying adverse events.

At a national level, the Canadian Patient Safety Institute (CPSI) has taken a lead role in the development and publication of Canadian Disclosure Guidelines, developing a strategy to create a Pan-Canadian reporting and learning system. It has also developed the Canadian Root Cause Analysis Framework, a quality improvement tool to help individuals and organizations determine all of the contributing factors and root causes that led to an event (e.g., critical incidents and close calls). CPSI is currently engaged with key stakeholders and partners in the development of a Canadian inter-professional, competency-based framework for patient safety.

At the provincial level, a variety of initiatives have been undertaken to address the reporting of "critical incidents" or accidents. A number of these initiatives are tied to legislation and regulations. However, a major limitation is the lack of standardization of definitions and terminology used within and between provinces, within and between regions, and between organizations. It is difficult to say, with any degree of certainty, whether one practice or policy is leading the way in the field of adverse event management, in part, because of the paucity of evaluative outcomes research being conducted in this area.

Introduction

Studies' related to medical error in Canada[6], Australia[7], the United Kingdom[8] and the United States[9] have resulted in growing awareness and heightened concerns related to patient safety within the health system. In response to these concerns, global effort has been placed on patient safety in general, and more specifically, on adverse event management.

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Findings

Recommendations of the National Steering Committee on Patient Safety

In 2004 the National Steering Committee on Patient Safety produced a report titled *Building a Safer System –A National Integrated Strategy for Improving Patient Safety in Canadian Health Care*[10]. The following recommendations of the report are relevant to an effective response system.

- Adopt nonpunitive reporting policies within a quality-improvement framework across the health care system.

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

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

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

- Recommend the types of surveillance systems, including relevant patient-safety indicators, to be developed and supported in Canadian health care. The recommendations would be based on the findings of the review proposed in the previous recommendation outlined above.

- Publicly report measures of health care quality and safety.

Recommendations of the Baker and Norton Report

Baker and Norton[11] completed a review of patient safety initiatives elsewhere in the world and provided recommendations for initiatives within Canada. The relevant recommendations for the Task Force are:

Develop better reporting systems:

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

acute, chronic and community.

- There should be expanded support for the existing and developing national and provincial Adverse Drug Event (ADE) reporting systems.
- Health care organizations should be strongly encouraged and supported in heightening their focus on errors, adverse events and near misses, and to link this to improvement work and system change.
- Support should be provided to develop curricula and learning experiences in patient safety at all educational levels (undergraduate and postgraduate and continuing professional education).
- Canadian professional colleges and organizations should be encouraged to be active in the areas of disclosure policy and legislation and to lobby for appropriate legislation to enable them to expand their efforts.
- Patient safety programs and initiatives should be integrated into the Canadian Council on Health Services Accreditation standards and other health care accreditation standards.
- Legislation change could enhance the reporting of errors and near misses and should be encouraged and supported.

Adverse Health Event Management at the National Level

At the national level, a number of organizations are taking lead roles in the optimization of patient safety and adverse health event management, including the Canadian Council on Health Services Accreditation, the Canadian Patient Safety Institute and Health Canada, among others. A brief overview of three organizations and their current and potential future roles is discussed in this section.

Health Canada

The Canada Vigilance Program collects data on adverse reactions (AR), defined as harmful and unintended responses to a health product. Guidelines for health professionals and consumers have been created for the voluntary reporting of suspected adverse reactions to health products. Adverse reactions to Canadian marketed health products include prescription, nonprescription, biologic, natural health and radiopharmaceutical products. An adverse reaction may include *any* undesirable patient effect suspected to be associated with health product use. An unintended effect, health product abuse, overdose, interaction (including drug-drug, and drug-food interactions) and unusual lack of therapeutic efficacy are all considered to be reportable adverse events.

Canadian Council on Health Services Accreditation

The CCHSA (renamed Accreditation Canada in May 2008) is a not-for-profit, independent organization that has provided national and international health and social service organizations with voluntary, external-peer review programs and guidance for over 50 years.

In May 2003, the CCHSA Board approved Phase 1 of its Patient Safety Strategy, which focused on four domains: (1) accreditation program, (2) information, communication and education, (3) research, and (4) partnerships. The accreditation program was enhanced with the development of a list of reportable sentinel events and among other things the implementation of a mandatory reporting policy.[12]

In October 2004, the CCHSA's Patient Safety Advisory Committee (PSAC) was established to provide direction and advice on the implementation of the Patient Safety Strategy. PSAC consisted of key stakeholders and the CCHSA's partners in safety, including the Canadian Patient Safety Institute (CPSI), Institute for Safe Medication Practices (ISMP, Canada), Health Care Insurance Reciprocal of Canada (HIROC), Canadian Medical Protective Agency (CMPA) and the Canadian Institute for Health Information (CIHI).

In 2005, CCHSA developed standards promoting adverse event[13] and near miss[14] reporting- and-learning (the reference guide for sentinel events and near misses is presented in Appendix A).

- An adverse event is "usually negative or unfavourable reactions or results that are unintended, unexpected, or unplanned."
- A near miss is "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.
- The CCHSA's sentinel event policy is meant to improve the reporting and sharing of information across organizations. The CCHSA defines a sentinel event as "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. * Major and enduring loss of function refers to sensory, motor, physiological, or psychological impairment not present at the time services were sought or begun. The impairment lasts for a minimum period of two weeks and is not related to an underlying condition."

In January 2005, the CCHSA's Patient Safety Goals and Required Organizational Practices (ROP) came into effect. An ROP is defined as "an essential practice that organizations must have in place to enhance patient/client safety and minimize risk."

Five ROPs are directly related to patient safety culture.[15] More specifically, Canadian health care organizations seeking accreditation are required to

(1) adopt patient safety as a written, strategic priority/goal;

(2) provide quarterly reports to the board of directors on patient/client safety, including changes/improvements following incident investigation and follow-up;

(3) establish a reporting system for actual and potential adverse events, including appropriate follow-up, in compliance with any applicable legislation and within any protection afforded by legislation;

(4) implement a formal (transparent) policy and process of disclosure of adverse events to patients/families, including support mechanisms for patients, family and care/service providers;

(5) conduct one patient-safety related prospective analysis per year (e.g., Failure Modes and Effects Analysis) and implement recommended improvements/changes.

In 2007, CCHSA released its Patient Safety Strategy – Phase 2 and vision for 2007-2010. A review of the roles of adverse and sentinel events in the CCHSA accreditation program is currently underway. A provincial and national review of reporting requirements will be part of the process and the roles of adverse and sentinel events in the accreditation process will be clarified further).[16] A major limitation is that accreditation is completely voluntary for Canadian hospitals and long-term care facilities. This may change based on the advice of the Health Council of Canada that all health care facilities be accredited as a condition of funding, and that the findings of the accreditation reports be made public.[17] [18]

Canadian Patient Safety Institute (CPSI)

One of the recommendations of the National Steering Committee on Patient Safety report, *Building a Safer System*[19], was the establishment of the Canadian Patient Safety Institute (CPSI). The CPSI was created to provide leadership and coordination for patient safety and quality improvement across the Canadian health care system. The federal Minister of Health announced the establishment of the CPSI on December 10, 2003. The institute is funded by Health Canada, but has an independent board of directors responsible to its members, including the provincial ministers of health and the public.

In March 2008, CPSI launched *Canadian Disclosure Guidelines*[20] after two years of extensive effort and collaboration by a number of experts from key national organizations representing physicians, nurses, pharmacists, health care providers, patients and others. The Guidelines are intended to assist and support health care providers, inter-professional teams, organizations and regulators in developing and implementing disclosure policies,

practices and training methods across Canada.[21] A summary of the CPSI Disclosure Guidelines is presented in Appendix B.

CPSI is also exploring a pan-Canadian strategy for reporting and learning from adverse events.[22] The CPSI, in collaboration with the Institute for Safer Medication Practices Canada and Saskatchewan Health, also developed the Canadian Root Cause Analysis Framework, a quality improvement tool to help individuals and organizations determine all of the contributing factors and root causes that led to an event (e.g., critical incidents and close calls).[23] Finally, CPSI is engaged with key stakeholders and partners in the development of a Canadian inter-professional competency-based framework for patient safety.[24]

Reporting and Learning Systems

> The primary purpose of reporting is to learn from experience…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.
>
> Lucian L. Leape, MD
> *New Eng J Med*, 2002

Adverse health event reporting and learning systems hold much potential for improving patient safety in general. However, the emphasis must be on lessons learned and sharing of the same, otherwise, the reporting of adverse health events will only result in the collection of interesting statistics.

In 2007 a review of relevant literature on adverse event reporting and learning systems from technology, implementation, learning and classification perspectives was performed. The author classified the review into seven themes: (1) governance and legislative frameworks for national reporting systems (2) taxonomy and classification systems used in data reporting and analysis (3) technical/design considerations and user issues (4) anonymous and confidential reporting systems (5) reporting by professionals and/or patients (6) financial implications, and (7) feedback systems to improve safety. Governance and legislative frameworks must be considered as well as incentives and barriers to implementing reporting systems. An overview of the national reporting systems in the UK, US, and Japan was provided. The author also emphasized the importance of a standardized taxonomy for coding and classification of events such as the WHO *International Patient Safety Event Classification (IPSEC)* currently being developed. Some of the technical/design considerations and user issues one must take into account include paper-based adverse event reporting systems versus electronic,

use of information technology (e.g., personal digital assistants by physicians at the patient beside), categories of detail that should be included in a patient safety database (e.g., what, where, when, how and why an event happened, what action was taken or proposed, what was the impact of the event (e.g., harm to the patient, organization, etc.), and factor that did, or could have, minimized impact. The choice of anonymous or confidential reporting and learning systems needs careful consideration. Importantly, anonymous reporting does not allow the opportunity for follow-up if questions arise during the course of an investigation, sometimes making it difficult to get at the root cause (s) of the adverse event. The literature review addressed the barriers to reporting by health care professionals, and the differences in physician and nurse preferences for reporting systems. The author suggests that in order to overcome the barriers to reporting, a learning and nonpunitive culture of safety must be promoted, and legal protection provided for those reporting incidents. White states that very little information has been published about the specific costs associated with the development, implementation and maintenance of incident reporting databases. However, the author suggests that to properly prepare for the "financial implications" of an adverse event reporting and learning system, the following areas and their associated costs should be taken into account: feasibility testing, legal advice, computer form design, hardware, software, development of taxonomy/classification systems, user education, user awareness, user acceptance testing, data coding, data analysis, feedback reporting, external promotion of systems and incentive programs. Finally, White highlights the importance of providing frequent "feedback" to staff and notification of any changes made to improve the system.

Leape (2002) suggests that successful health care adverse event reporting systems are exemplified by the following characteristics: (1) nonpunitive (2) confidential (3) independent – data are analyzed by independent organizations (4) expert analysis (5) timely feedback provided to system users (6) systems-oriented solutions to reported problems, and (7) participant organizations are responsive to suggested changes.

In this section of the paper, attention is given to the initiatives that have been undertaken by a number of countries. Although the Task Force is cognizant of the fact that many countries have reporting and learning systems in place (e.g., Japan, Denmark, the Netherlands, the Czech Republic and so on), it will focus only on the World Health Organization and three specific countries (the United States, the United Kingdom and Australia). Finally, several Canadian initiatives, either underway or being considered at a provincial or national level, will be presented.

International Initiatives

World Health Organization

Adverse event and critical incident reporting and learning systems have been developed in several countries and summarized by others.[25] The WHO draft guidelines on adverse event reporting and learning systems were developed in collaboration with Dr. Lucian Leape from Harvard's School of Public Health.[26] The goal of the development of such guidelines was to help countries develop or improve existing systems.[27] The draft guidelines highlight a number of key characteristics of successful reporting and learning systems: reporting is safe for the individuals who report; reporting leads to a constructive response; expertise and adequate human and financial resources are available to allow for meaningful analysis and learning and the reporting system is capable of disseminating information and recommendations for change.[28]

United States

In 1999, the Institute of Medicine released its landmark report *To Err is Human: Building a Safer Health System.*[29] One of the report's recommendations was the establishment of a national mandatory reporting system in hospitals, followed by an expansion to all sites engaged in patient care. As of 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; however, the requirements for these reporting systems vary from state to state.[30] In addition, there is limited evidence of the sharing of information at the national level.[31]

United Kingdom

A landmark report published in 2000, *An Organization with a Memory*[32], and the UK's government response, *Building a Safer NHS* [33]led to the establishment of the National Patient Safety Agency (NPSA). The NPSA was created to coordinate efforts to report and learn from mistakes and problems that affect patient safety in health care. It is a system for reporting and tracking adverse events and near misses. The NPSA tries to promote an open and fair culture in the NHS, encouraging all health care staff to report incidents without undue fear of personal reprimand. It collects and analyzes information on patient safety incidents from NHS organizations, staff and patients. A core function of the NPSA was the development of the National Reporting and Learning System (NRLS), an anonymous mandatory reporting system that is responsible for collecting reports of patient safety incidents (actual and potential adverse events) from all service settings across England and Wales, and, importantly, learning from such reports. All reporting by individuals is anonymous, but it is mandatory for NHS Trusts to submit any reported

adverse event to the NRLS. The NRLS was launched in February 2004.

An evaluative report reviewing the progress of the NRLS was released by NPSA in February 2008.[34] Over 800 staff participated in the review. A major finding was the insufficient progress in improving patient safety. The staff suggested that the NPSA (1) build on the system currently in place but improve it (2) make the system quicker and easier to use (3) get to the most serious issues quickly (4) streamline routes of reporting, and (5) provide more targeted feedback for organizations and specialties.

Australia

The Australian Advanced Incident Monitoring System (AIMS) is a confidential error reporting system. Patient Safety International, a subsidiary of the Australian Patient Safety Foundation, developed the AIMS software tool to consistently capture information on close calls and critical incidents, allowing for in-depth analysis of both types of events. Patient Safety International (PSI) is a leading provider of incident management software to help health care services improve the quality of care by reducing medical errors, waste and harm to patients. The AIMS consists of a confidential incident report form completed at a local level, and an anonymous monitoring system.

The AIMS incident management software is used by over 400 Australian hospitals, as well as at sites in South Africa, New Zealand and the United States. AIMS captures adverse event and near miss information across acute care, community care, disability care, mental health and residential aged care (nursing homes). Unlike other systems, AIMS includes a standardized classification (ontology) that is recognized by the World Health Organization and the US Institute of Medicine. The software is currently in use in over half the Australian public health system and allows a comparison of critical incidents and appropriate interventions to reduce the risk of recurrences among those participating in the surveillance system. A national reporting system, therefore, does not truly exist in Australia.

Canada

Canadian Institute for Health Information

The Canadian Institute for Health Information (CIHI) collects information on a number of patient safety indicators: (1) obstetrical trauma during childbirth, (2) foreign objects left in after a procedure, (3) post admission pulmonary embolism or deep-vein thrombosis and (4) in-hospital falls and hip fractures. In a 2006 survey of primary care physicians the findings suggested that almost three of five primary care doctors reported that there was no documented process for follow-up and analysis of adverse events.[35]

Canadian Medication Incident Reporting and Prevention System

The Canadian Medication Incident Reporting and Prevention System (CMIRPS)[36] is a system that reports, analyses and manages voluntarily reported medication incident data on a national basis. The Canadian Institute for Health Information, Health Canada and the Institute for Safe Medication Practice Canada are collaborating parties of CMIRPS. The CMIRPS coalition is comprised of the Canadian Association of Chain Drug Stores; the Canadian Healthcare Association; the Canadian Institute for Health Information; the Canadian Medical Association; the Canadian Nurses Association; Canadian Pharmacists Association; Canada's Research Based Pharmaceutical Companies; Canadian Society of Hospital Pharmacists; College of Family Physicians of Canada; Consumers Association of Canada; Health Canada - Marketed Health Products Directorate, Health Products and Foods Branch (Secretariat); Institute for Safe Medication Practices Canada; and The Royal College of Physicians and Surgeons of Canada. CMIRPS promotes an open, "blame-free" system that encourages health care practitioners to voluntarily share their medication incident experiences.

The purposes of the CMIRPS program are to coordinate the capture, analysis and dissemination of information on medication incidents; enhance the safety of the medication-use system for Canadians; and support the effective use of resources through the reduction of potential or actual harm caused by preventable medication incidents.

The goals of the CMIRPS information system are to collect data on medication incidents; facilitate the implementation of reporting of medication incidents; facilitate the development and dissemination of timely, targeted information designed to reduce the risk of medication incidents facilitate the development and dissemination of information on best practices in safe medication use systems.

The CMIRPS collects reports on potential and actual incidents related to any medication and occurring at any stage of the medication-use system: prescribing, order communication, product labeling and packaging, compounding, dispensing, distribution, administration, monitoring, documentation or use. Incident reports can be submitted by health care professionals, institutions such as hospitals, and from patients themselves. Medication incidents may involve improperly prescribed medication, improper administration or incorrect dosage or protocol.

Canadian Adverse Event Reporting and Learning System (CAERLS)

The Canadian Patient Safety Institute is currently engaged in a process to establish the Canadian Adverse Event Reporting and Learning System (CAERLS), one of its strategic business plan goals. As an initial step, a review of leading national and international practices was conducted in the reporting of adverse events, medical error and critical incident reporting, and related improvement mechanisms designed to facilitate knowledge transfer, learning and, ultimately, to improve patient safety. [37]
A comprehensive review[38] of the published literature on adverse event reporting and learning systems in health care for the Canadian Patient Safety Institute encompassed an examination of governance and legislative frameworks; taxonomy and classification systems; technical/design considerations and user issues; anonymous and confidential reporting systems; reporting by professionals and/or patients; financial implications; and, feedback systems to improve safety.

In 2007, CPSI commissioned a separate review[39] focusing on provincial, territorial and federal legislation and policy related to the reporting and review of adverse events in health care in Canada. As part of the review, the authors addressed key enablers and barriers for the reporting and review of incidents on a national scale. The authors (1) analyzed the application of provincial and federal legislation, (2) reviewed policies at provincial and regional levels, (3) conducted surveys of health care regions, hospitals and other health delivery organizations, and (4) interviewed experts and key stakeholders interested in the reporting of incidents. The report's findings indicated that while some provinces have enacted legislation for the mandatory reporting of adverse health events, the reporting of adverse events remains at the institutional level in many other provinces. Importantly, the prohibition of the sharing of patient safety information, both within and outside of the province, would act as a significant barrier to the creation of a national reporting system. Other factors that would prove to be challenging include "a lack of a common approach, shared definitions, and other elements need to collect and compare data on a provincial basis, let alone on a pan-Canadian basis" (page 2). [40] The authors recommend the development of local capabilities to collect and analyze reports within organizations and regions. They suggest the establishment of a provincial body (e.g., Minister or other separate body) responsible for reporting in each province. The provincial body would be responsible for coordination of the reporting by institutions and professionals in health care in compliance with legislation within that province. De-identified information would be shared by the provincial body with a national body (i.e., a pan-Canadian body) that had the capacity to disseminate information and warnings on a national basis. Finally, in order to learn from lessons across the country, a framework for the classification of incidents on a pan-Canadian level would be required.

The collaborating organizations of CMIRPS (Health Canada, Canadian Institute for Health Information, and the Institute for Safe Medication Practices) are exploring the possible integration of CAERLS and CMIRPS.[41]

Regional and Provincial Initiatives

Several initiatives are currently underway in a number of regional health authorities/ health care organizations including the British Columbia Incident Reporting Information System (IRIS) Project; Regional Occurrence System Enhanced (ROSE) Project, Eastern Health, Newfoundland and Labrador; and Patient Safety Reporting System (PSRS), Capital Health (Halifax), Nova Scotia.

Incident Reporting Information System (IRIS) project

The IRIS project[42] is an initiative of the British Columbia Patient Safety Task Force. It is a collaborative effort of all six BC Health Authorities and the Health Protection Program. The project is funded by Canada Health Infoway, British Columbia Ministry of Health and the Health Authorities. The project will consist of four stages: (1) feasibility study 2003/04 (2) package selection, 2005/06 (3) pilot implementation, and (4) provincial rollout 2007-2010. The exercise will cover all facilities in the community. The objective of the project is to enable the identification, management, analysis, learning and sharing lessons acquired. DATIX[43] software, a web-based incident, complaints and claims reporting tool, will be used in all regions of the province. Anyone with access to an organization's intranet will be able to report incidents directly into the DATIXWeb software using easy-to-use web pages. Managers receive an automatic email with details of incidents. They can complete the details of the investigation through the web and also run analyses incidents. DATIX uses a standard coding system for clinical and nonclinical adverse events and near misses. The Calgary Health Region is also a client of DATIX and will be implementing the reporting tool across its region in the near future.[44]

Regional Occurrence System Enhanced (ROSE) Project

The Regional Occurrence System Enhanced (ROSE) Project[45] proposed by Eastern Health will entail the development and implementation of an electronic occurrence reporting system (OCR) across the continuum of patient care encompassed by the Eastern Health Regional Authority in Newfoundland and Labrador. The project will consist of three stages: (1) requirements finalization and implementation planning (2) staged implementation and testing, and (3) benefits determination/evaluation. The project has five broad objectives (1) to enhance the development of a patient safety culture through intense education and ongoing support initiatives (2) to improve the efficiency and effectiveness of the occurrence reporting system(3) to improve communications related to occurrence reporting and implementation of action plans (4) to support related quality, research and evaluation activities (5) to explore opportunities for collaboration throughout development, implementation, evaluation, and knowledge transfer.[46]

Patient Safety Reporting System (PSRS)

Findings from two patient safety culture surveys conducted in 2003 and 2005 at Capital Health (Halifax) suggested that staff believed that they "… would probably be treated in a negative way for reporting or discussing errors or serious occurrences" by 45.4% in 2003 and 50.4% (p=0.03) in 2005. Capital Health recently developed and launched an in-house incident reporting system. The Patient Safety Reporting System (PSRS), an intranet-based online reporting and data retrieval system created on a network platform provided by CCD Systems, was implemented at three pilot sites in June 2007, and in 2008 the system was expanded across the region. The program allows computerized reporting of patient safety issues from a network-ready computer. Report completion and delivery occurs immediately after the clinical staff or physician completes the report online, thereby eliminating the handling of paper forms and time-intensive data entry. The system will, upon completion of the event entry, send an email notification to the responsible clinical leaders and/or physician, allowing them to review and follow-up their reports immediately and enhance system accountability. Past practice included Risk Management assigning a severity rating to the event; however, with the new system the individual entering the event is able to assign the severity or patient impact to the actual event or near miss. Confidentiality of the new reporting system is anticipated to increase staff/physician confidence in the reporting system.[47]

Summary

> Learning is more than the analysis of an adverse incident – it is about ensuring there is a change based on well-designed action plans. These must be realistic, achievable and sustainable, with all stakeholders involved in their development.[48]

Adverse health reporting and learning systems have been developed and implemented in a number of countries. Canadian organizations and institutions that have adopted or are engaged in the development of reporting and learning aspects of adverse health care management should remain cognizant about the challenges experienced by other countries and organizations (e.g., National Patient Safety Agency –UK – National Reporting and Learning System). More specifically, an evaluation observation coming out of the UK in relation to the NRLS suggests that

> despite the high volume of incident reports collected by the NPSA … there are too few examples where these have resulted in actionable learning for local NHS organizations. The National Reporting and Learning System (NRLS) is not yet delivering high-quality, routinely available information on patterns, trends, and underlying causes of harm to patients (p.6). [49]

Provincial reporting and learning initiatives are slowly beginning to emerge. Each province and territory has established individual policies and guidelines for reporting

adverse health events. Furthermore, in many areas policies and guidelines vary between jurisdictions and or regional health authorities and or organizations. Finally, the focus of adverse health event reporting has been on the acute-care setting (i.e., institutions). Gaps in patient safety and adverse health event reporting have been identified in long-term care[50] and home care[51]. The Health Council of Canada's 2007 Annual Report stressed the importance of implementing standardized, systematic reporting of adverse health events across the continuum of health care (i.e., acute care, long-term care, and community). The Council cautioned that without such an approach jurisdictions would be "unable to collect and monitor information, understand the extent of the errors, and share learning and knowledge" (page 47). [52]

It is important to remain focused on the purposes of establishing national reporting and learning systems: to collect information, disseminate lessons learned and transfer the knowledge and learning to all health system stakeholders. Lessons learned from pioneers (the US, the UK, and Australia) in the field of adverse health event management will be very helpful in the planning and implementation of a pan-Canadian reporting and learning system.

Provincial Legislation – Quality of Care Committees

Legislative and regulatory frameworks focused on quality of health care services exist in all Canadian provinces and territories. A detailed listing is provided in Appendix C. Details associated with various pieces of legislation specific to the Newfoundland and Labrador setting are presented and discussed elsewhere in this report.

Information related to quality of care committees is protected by legislation. The intent of the legislation is to protect and prevent the information from being used in subsequent legal or disciplinary proceedings, thereby encouraging full participation of health care providers in quality improvement. Quality improvement programs in hospitals/ institutions often use quality of care committees to analyze clinical outcomes, adverse events and close calls. Recommendations arising from the analyses are used to help correct any system failures that are identified. Some jurisdictions explicitly prohibit the sharing of any findings, conclusions or recommendations of a quality improvement committee to persons other than in management responsible for their implementation.[53]

Provincial Incident Reporting and Investigation Legislation

Three provinces (Saskatchewan, Manitoba and Quebec) have legislation that requires the reporting of various types of incidents that occur in health care facilities (hospitals, long-term care, child care, personal care homes). Saskatchewan and Manitoba, in particular, have moved from a voluntary reporting of adverse events to a more comprehensive

legislated process, including mandatory reporting and shared learning, in an effort to reduce the potential of critical incident reoccurrence. As of July 1st, 2008, Ontario will become the most recent province to amend legislation, thereby mandating the disclosure of critical incidents to patients.

CPSI engaged a group to conduct a review of provincial, territorial and federal legislation and policy related to the reporting and review of adverse events in health care in Canada.[54] A legislation reference table is presented in Appendix C. The review identified only three provinces that address adverse events/critical incidents in their legislation. The key provisions of the statutes summarized by Baker, Grosso, Heinz et al are included in Appendix D.

In this section of the paper, an overview of established provincial incident reporting, the investigation legislation of three provinces (Saskatchewan, Manitoba and Quebec) and new legislation in Ontario as of July 1st, 2008 are discussed.

Saskatchewan

In 2002, Saskatchewan became the first Canadian province to enact legislation requiring mandatory reporting of adverse events to the provincial Department of Health.

On September 15, 2004, the government of Saskatchewan passed legislation requiring the reporting and investigation of occurrences of critical incidents in health care. The aim of such legislation is reporting for learning to enhance patient safety. A critical incident is defined as:

> 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, or a program operated by, a regional health authority (RHA) or a health care organization (HCO).[55]

Saskatchewan's Personal Care Homes Regulations (R.R.S. 2000, c. P.-6.01, Reg 2 amended by Saskatchewan Regulations 69/2002 and 89/2003), mandate reporting of "serious incidents." This includes "any occurrence, accident or injury that is potentially life threatening" as well as " any harm or suspected harm suffered by a resident as a result of unlawful conduct, improper treatment or care, harassment or neglect on the part of any person" (s.13 (1)). Licensees must notify the "resident's supporter," their physician, the department responsible and the regional health authority. They are also obligated to provide a written report to the government department responsible, outlining a number of things including "any actions taken…to solve the problems…and to prevent recurrences of the serious incident" (s.13(2)(b)).

The *Saskatchewan Critical Incident Reporting Guidelines*[56] lists the critical incidents

that must be reported to the Department of Health. Since 2004, notification of "critical incidents" must be made by health care organizations to their regional health authorities. This guideline was adapted from the US National Quality Forum, *Serious Reportable Events in Health Care: A Consensus Report* published in 2002.[57] It is the responsibility of the authority to directly notify the minister. Investigations and written reports are to follow (*Act to Amend the Regional Services Act*, (2004); *Critical Incident Reporting Guideline and Saskatchewan Critical Incident Regulations*). Details of the report must include a description of the circumstances surrounding the incident, the identification of potential contributing factors that upon modification could prevent a reoccurrence of the event, actions taken and future plans of action the organization or authority might identify as a result of the critical incident investigation. The names of patients, health care providers or any other individuals with knowledge of the critical incident are protected by a confidentiality provision in the legislation, and therefore cannot be named in any report arising from the investigation of the critical incident.

Manitoba

In 2005, the Manitoba government passed legislation to amend the *Regional Health Authorities Act* and the *Manitoba Evidence Act.*[58] The amendments contained mandatory critical incident reporting requirements. A critical incident is defined as:

> Unintended event that occurs when health services are provided to an individual and result in a consequence to him/her that (a) is serious and undesired, such as death, disability, injury or harm, unplanned admission to hospital or unusual extension of hospital stay, and (b) does not result from the individual's underlying health condition or from risk inherent in providing the health service.[59]

Manitoba does not have a "common list" or guideline of reportable critical incidents similar to the one used in Saskatchewan. However, once identified, the channel for reporting a critical incident is similar to that of Saskatchewan, the health care organization would report the event to the regional authority, which in turn would report the incident directly to the Minister of Health. If a critical incident occurs, the regional health authority, health corporation or health care organization must ensure (1) that appropriate steps are taken to fully inform the individual, as soon as possible, about the facts of what actually occurred with respect to the critical incident (2) its consequences for the individual as they become known, and (3) the actions taken and to be taken to address the consequences of the critical incident, including any health services, care or treatment that are advisable. A complete record must be made about the critical incident, which must address the preceding points. The individual who experienced the critical incident may examine the report and receive a copy, free of charge.

Quebec

The government of Quebec amended legislation in an effort to mandate when and what a patient should be told after an accident or incident occurs in institutions. The amended legislation ensures a specific right to be informed of an accident. An "accident" is defined as "an action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user, a personal member, a professional involved or a third person".[60] An "incident" is defined as "an action or situation that does not have consequences for the state of the health or welfare of a user, a personal member, a professional involved or a third person, but the outcome of which is unusual and could have had consequences under different circumstances". [61]

Health care facilities' obligations concerning disclosure of accidents, declaration of accidents and incidents, allowance of support for patients, their families and health care workers involved in the accident, creation of a risk- and-quality management committee, accreditation on patient safety, quality and risk management and the development of a local registry are addressed in Bill 113. The Bill also makes provision for a province-wide registry of incidents and accidents.[62]

Ontario

In February 2003, the Council of the College of Physicians and Surgeons of Ontario approved a policy that mandates disclosure of a critical incident.[63] The disclosure of a critical incident in Ontario was addressed at a provincial level in July 2008, with a new regulation that amends Regulation 965 under the Public Hospitals Act. [64] The amendment mandates the disclosure of a critical incident to a patient.

A critical incident is defined as

> any unintended event that occurs when a patient receives treatment in the hospital, (a) that results in death, or serious disability, injury or harm to the patient, and (b) does not result primarily from the patient's underlying medical condition or from a known risk inherent in providing the treatment.

Hospitals are expected to adopt and implement the regulation; however, they may also retain or develop expanded disclosure policies that exceed (but do not contravene) the requirements of the Act. The boards are responsible for ensuring that hospital administrators establish a system for ensuring the disclosure of every critical incident. Policies and procedures for staff reporting will be based on what is most appropriate for their particular facility.

Summary

The definition of reportable incidents varies between the three provinces that have legislated adverse event reporting requirements. The most inclusive definition is in the *Saskatchewan Critical Incident Report Guideline*. In each of the provinces, the minister must be notified of a critical incident occurrence, and a report must follow. While detailed reporting guidelines are available in Saskatchewan, institutions in Quebec are responsible for developing written recording and provision of information procedures as they relate to adverse event occurrences. Manitoba and Saskatchewan have very similar requirements when it comes to reporting critical incidents; however, Manitoba does not have a detailed reporting guideline process such as the one used in Saskatchewan. In Ontario, the boards will be responsible for ensuring that hospital administrators establish a system for ensuring the disclosure of every critical incident. The policies and procedures for staff reporting will be facility-specific.

Disclosure

A number of comprehensive overviews of open disclosure are available in the literature (Canadian Patient Safety Institute, 2006; Australian Commission on Safety and Quality in Health Care, 2008).[65] [66] Open disclosure policies have been developed and implemented in a number of countries over the last five years:

- *Australia - Open Disclosure Standard: A National Standard for Open Communication in Public and Private Hospitals, Following an Adverse Event in Health Care* (2003); [67]
- *UK - Being Open -Communicating Patient Safety Incidents with Patients and Carers: NHS* (2005); [68]
- *US - When Things go Wrong: Responding to Adverse Events* (2006)[69] and;
- *Canada - Canadian Disclosure Guidelines* (2008). [70]

Most recently, CPSI launched the *Canadian Disclosure Guidelines* (CPSI, 2008). [71] The guidelines are based on a national and international environmental scan and review of the literature. The purpose of the guidelines is to provide support for the development and implementation of policies, procedures and training methods (e.g., Canadian root cause analysis) as they relate to adverse health events disclosure processes to health care providers, interdisciplinary teams, organizations and regulators. The approach to the disclosure process in these guidelines is purported to occur in two stages: (1) initial disclosure and (2) post analysis disclosure. During the initial disclosure, consideration should be given to the following: (a) participants in the disclosure discussions (b) when disclosure should take place (c) the setting and location of the disclosure (d) what to disclose, and (e) how will disclosure occur. During the initial disclosure, the guidelines suggest providing facts, explaining the care plan, avoiding speculation, expressing regret, outlining expectations, arranging follow-up, identifying a contact and documenting.

During the second phase of disclosure, further facts and any actions taken are provided to the patient/family with an appropriate expression of regret. The information is documented. The Task Force will not be duplicating the extensive efforts of CPSI on identifying an appropriate disclosure process; rather, the Task Force will review the applicability of the CPSI *Disclosure Guidelines* to the Newfoundland and Labrador setting.

Additionally, the Newfoundland and Labrador Commission of Inquiry on Hormone Receptor Testing in Breast Cancer has a policy focus and includes a review of both the policy and legal issues raised in its Terms of Reference. The Commission engaged six experts to prepare disclosure obligation papers to assist the Commission with its policy development role. The papers are available at http://www.cihrt.nl.ca/partIIoftheinquiry.html.[72] The papers focused on the following topics:

1. Legal and Ethical Obligations of Public Health Authorities and Government (Dickens, G.);
2. Examining Disclosure Options: Procedures for Disclosing Adverse Events: A Literature Review (Espin, S.);
3. Disclosing Unanticipated Outcomes to Patients: International Trends and Norms (Gallagher, T.H.);
4. Disclosure: Ethical and Policy Considerations (Hébert, P.C.); and
5. The Legal Duty of Physicians to Disclose Medical Errors (Robertson, G.B.).

Adverse Health Event Management – Policies of Select Canadian Organizations

As part of the work of the Task Force, we identified and examined a number of policies related to the management of adverse health events at the organizational, regional, provincial and federal levels. A complete listing of the policies reviewed is presented in Appendix E. The Task Force has decided to focus on three regional policies only in this section. The policies are presented in Appendix F.

Alberta

Calgary Health Region

The Calgary health region is considered by many to be the country's most progressive.[73] A quality improvement framework - with patient safety as a focal point- and a supporting program were developed after the region's first full accreditation in 1999.[74] A number of regional safety policies exist between the region/providers and patients (i.e., disclosure of harm policy), between providers and the region (reporting hazards, close calls and harm policy), between the region and its providers (i.e., just and trusting culture policy) and

between the region and its principal health care partners/stakeholders (i.e., informing). Detailed procedure manuals complement each of the regional policies. Reporting focuses on all types of incidents (i.e., harm, close calls and hazards) and is done on a voluntary basis to the Calgary Health Region. Sharing of information for the purpose of learning and making system improvements within the region and in other health care organizations is fostered.

One of the guidelines used in the region focuses on the "Immediate and Continuing Management of Serious (Potential) Adverse Events." The purpose of the guideline is "to outline the immediate and continuing roles and responsibilities of senior administrators or medical leaders in the Calgary Health Region when potentially serious adverse events have or may have occurred" (page 4). The guideline is used as a framework to assist senior administrators/medical leaders in decision-making, planning and taking actions. The initial and critical steps in the immediate management can be captured in the acronym RESPOND. The RESPOND checklist addresses the following steps:

R esuscitate/react – to the patient's immediate needs
E nvironment – ensure that it is safe for patients and providers
S ecure equipment – for examination and evaluation
P rotect other patients – that they cannot be immediately harmed
O ffer support - to the patients/families and health care providers involved
N otify – appropriate clinicians/administrators and complete a Safety Learning Report
D isclosure – acknowledge the adverse event

Actions associated with RESPOND are outlined in the procedure manual.

Once the immediate management of the potentially serious adverse event has been addressed, a senior administrator/medial leader is accountable for the continued management of the event (i.e., patient/family, health care provider(s) involved, region). A second checklist focuses on advocacy, communication and evaluation (ACE) and actions that may or may not be taken.

A dvocate – and continue to support the patient/family and health care provider(s) involved:

- Assigning a patient advocate, providing ongoing support for the patient/family and health care providers are key actions.

C ommunicate – important information to the patient/family, health care providers and/or other stakeholders:

- Disclosing to the patient/family, completing a safety learning report (required in the event of a patient suffering fatal or severe harm, but also strongly encouraged when a patient has suffered from moderate or minimal harm or experienced a close call), and informing principal partners and stakeholders.

E valuate – the potentially serious adverse event so that the Region can learn and make improvements, where appropriate, for the safety of the next patient.

- Key actions include:
- Conducting a safety analysis (if there is reason to suggest that system contributing factors may be associated with the potentially adverse event or risk thereof (close call)). The Safety Analysis does not review or assess the performance of individuals, and would not be conducted by persons who have administrative responsibilities for the area and health care providers involved.
- And/or an administrative review (when there is evidence or probable reason to suggest that individual contributing factors may be associated with the potentially adverse event or risk thereof (close call)). An administrative review is conducted by individuals with administrative responsibilities for the actions of the individuals involved. The reviews are not conducted under the direction of the clinical safety committee; therefore, Section 9 of the *Alberta Evidence Act* does not apply to these documents. The provincial privacy legislation does not permit the release of the outcome of the administrative reviews.

A summary of three presentations by Dr. Ward Flemons, VP Health Outcomes that focus on the operational response to an adverse event, acting on the management of an adverse event and embracing a culture of safety are presented in an accompanying document – *Provincial Forum on Adverse Health Events – Summary Proceedings.*

Manitoba

Winnipeg Regional Health Authority

The Winnipeg Regional Health Authority (WRHA) Patient Safety team[75] develops and supports programs and initiatives with the goal of reducing unnecessary patient injuries and deaths in the region. The regional team is led by Dr. Rob Robson, Chief Patient Safety Officer and Harvard-trained health care mediator. A comprehensive strategy to improve the region's capacity to effectively manage and learn from adverse events – or what the region refers to as Critical Clinical Occurrences (e.g., medication errors, misdiagnosis, equipment failures and so on) – was implemented by the authority. The Regional Integrated Patient Safety Strategy has four focal points: (1) promoting culture change with the aim of moving from a culture of blame, fear and retribution to a safety culture that encourages openly discussing adverse events, asking questions and making improvements (2) directly involving patients by way of a Patient Safety Advisory Council (3) learning from clinical practice (e.g., Critical Clinical Occurrence), and (4) promoting change in care delivery with the aim of enhancing acceptable standards of care.

The WRHA has two regional policies available on its website that apply to all WRHA governed sites and facilities (including hospitals and personal care homes), and are

specifically related to reporting, investigating, disclosing and learning from critical incidents. The policies, Critical Incident Management and Learning[76] and Disclosure of Information Related to Care and Treatment[77], were adopted by the WRHA in 2007. The Disclosure of Information Policy mandates the disclosure of pertinent clinical information, not only following critical incidents but in other patient-centered care circumstances. The Reporting of critical incidents or provisional critical incidents within the regional authority for any individual including employees and medical staff is mandatory. Provincial legislation dealing with critical incident reporting provides protection from litigation for the work of committees created to investigate such incidents. It is also mandatory for the regional authority to report critical incidents to the Ministry initially (i.e., after the event has been confirmed as a critical incident), to submit a status report on the critical incident within 30 days to Manitoba Health, and to submit a copy of the final report within 90 calendar days of the critical incident or upon completion of a critical incident review.

In 2008, Dr. Robson and Elaine Pelletier, a patient safety process analyst for the region, published an article in *Health Care Quarterly* that focused on the factors that led the WRHA to develop a process to identify cases involving patient harm following critical incidents in the health care system. The coauthors described the main steps that would lead to early compensation discussions with patients in cases when preventable contributing factors were under the control of WRHA.[78]

Saskatchewan

Saskatoon Health Region

All critical incidents are reported through a region-wide reporting process in compliance with Section 58 of the Regional Health Services Act and its corresponding regulations- The Regional Health Services Critical Incident Regulations – and the Accountability Agreement with Regional Health Authorities and Saskatchewan Health.

Critical incident is defined according to the legislation and regulations. The Saskatchewan Critical Incident Reporting Guideline (2004) is adapted from the 2002 *National Quality Forum Serious Reportable Events in Health Care: A Consensus Report*. The guideline provides a list of reportable events including surgical events (e.g., surgery performed on a wrong body part, on the wrong patient), patient death or disability associated with product or device events (e.g., contaminated drugs, devices or biologics), patient protection events (e.g., an infant discharged to the wrong person), care management events (e.g., patient death or disability associated with hemolytic reaction due to the administration of ABO-incompatible blood or blood products), environmental events (e.g., patient death associated with a fall while being cared for by an RHA or Health Care Organization), and criminal events (e.g., sexual assault of a patient that occurs on the grounds owned or

controlled by an RHA or HCO).

The Saskatoon Health Region Critical Incident Reporting Policy was revised in September 2007. Critical incidents must be reported immediately to the Director of Risk Management or designate. During the weekend or night shift, the most senior administrator on call is contacted through the Switchboard or the appropriate on-call process. The administrator then notifies the Director of Risk Management and appropriate senior managers. The event is entered into the Safety Reporting System (computer-based) or a confidential Safety Report is completed by staff member, physician, volunteer or student of the service/dept/area who was involved in, witness to, or became aware of the critical incident. This must happen within 24 hours of the critical incident occurring or when the incident is recognized as a critical incident and be in accordance with the procedures outlined in the Safety Reporting Policy (#7311-50-006).

When the Safety Report form is completed, it must be submitted to Risk Management within 48 hours of the critical incident. Other reporting forms or documentation that may have been completed (i.e., a medication error report) must accompany the confidential Safety Report. When the Safety Reporting System (computer-based) is used, automatic notification of the appropriate individuals will occur. Safety Reports are not part of the health record. The original report is filed in Risk Management. A factual note of the event and the patient assessment must be documented in the patient's/resident's chart.

Risk Management notifies the appropriate senior management that a critical incident has occurred. Risk Management, according to the legislation, shall notify the Minister of Health of a critical incident within three business days following the incident or the date the regional health authority becomes aware of it. Notification to the Minister of Health by Risk Management shall include de-identified, factual information about the critical incident.

Saskatoon Health Region shall investigate the critical incident through a nonpunitive, multidisciplinary review (Appendix B – Multidisciplinary Case Review) The investigation includes:

- the circumstances leading up to and culminating in the critical incident;
- any current practice, procedure or factor involved in the health service that contributed to the critical incident;
- actions considered, developed or required as follow-up to the critical incident; and
- implementation of any recommendations resulting from the critical incident review.

Risk Management, according to the legislation, will provide a written report of de-identified factual information including actions taken, planned and the quality improvements the RHA will be implementing as a result of the critical incident review.

The report must be submitted within 60 days of the RHA becoming aware of the critical incident.

Appropriate senior managers within SHR will receive a copy of the written report of de-identified factual information including the actions taken, planned and any quality improvements that will be implemented as a result of the critical incident multidisciplinary case review. Feedback/direction will be provided to appropriate stakeholders to implement quality improvements as required.

The region and its affiliates also have a *Disclosure of Adverse/Unanticipated Events Policy* that became effective in October 2007. The policy addresses multijurisdictional disclosure and multiperson disclosure. Further details are provided in Appendix F.

Apology Legislation in Canada

Apology legislation may be divided into three categories:

1. Expressions of sympathy, regret or benevolence;
2. Limited apology legislation; and
3. Comprehensive apology legislation.[79]

Derwin elaborates on the differences among the three categories. The first type of legislation makes expressions of sympathy, regret or benevolence inadmissible in court actions. A number of American states have passed laws protecting "expressions of sympathy, regret or benevolence". According to Derwin, such laws are not true apology laws and serve a very limited purpose.[80] As many as 36 states have adopted "apology laws", thereby providing legal protection related to disclosure; however, the degree of protection varies.[81] The second category of legislation protects apologies, but is limited in scope. Limited apology legislation may exclude apologies offered in certain types of actions, such as sexual assault lawsuits, tobacco litigation or intentional torts. The third type of apology legislation is comprehensive, protecting all forms of apologies, including apologies which admit liability. The Apology Act of Manitoba[82], the Uniform Apology Act[83], Apology Act, S.B.C. 2006, Chap. 19 (British Columbia)[84] and the Evidence Act, S.S. 2006, c. E-11.2, Section 23.1(1) (Saskatchewan)[85] are all forms of comprehensive apology legislation. Health Care providers' fears that information, opinion or speculation offered during the course of an investigation would be used against them in a medical malpractice lawsuit, inhibited reporting in the past. The intent of the legislation was to provide the protection to do so without fear of reprisal. It was felt that the legislation provided by the Apology Act would encourage health care professionals and institutions to apologize for their errors without that apology being admissible as evidence of fault.

On May 18, 2006 British Columbia became the first province to enact apology legislation.[86] This was followed by Saskatchewan in 2006 and Manitoba in 2007. In 2006, the British Columbia Ministry of Attorney General carried out a review[87] of the academic literature, and focused on factors in favour and against apology legislation. Theses factors are listed below.

Factors in favour of apology legislation include:

a. *To avoid litigation and encourage the early and cost-effective resolution of disputes;*
b. *To encourage natural, open and direct dialogue between people after injuries; and*
c. *To encourage people to engage in the moral and humane act of apologizing after they have injured another, and to take responsibility for their actions.*

Negative factors include:

a. *Public confidence in the courts could be adversely affected if a person who has admitted liability in an apology is not found liable;*
b. *Insincere and strategic apologies could be encouraged; and*
c. *Apologies encouraged by such legislation might create an emotional vulnerability in some plaintiffs who may accept settlements that are inappropriately low.*

In the British Columbia and Manitoba Apology Acts,[88] [89]apology is defined as

> an expression of sympathy or regret, a statement that one is sorry or any other words or actions indicating contrition or commiseration, whether or not the words or actions admit or imply an admission of fault in connection with the matter to which the words or actions relate.

The Yukon Legislative Assembly is also considering an apology act.[90] As was the case for the Manitoba Apology Bill, Bill 103 is modeled after the British Columbia legislation. The apology for an adverse event is inadmissible in court for the purpose of proving liability in British Columbia, Manitoba, and Saskatchewan. The legislation in British Columbia, Manitoba and the Yukon addresses the issue of insurance in the following manner:

> an apology does not, despite any wording to the contrary, in a contract of insurance, and despite any other enactment, void, impair or otherwise affect insurance coverage that is available, or that would, but for the apology, be available to the person in connection with that matter.

Ontario was the fourth and most recent province to consider an Apology Act. In April, 2008, A Private Members Bill (Bill 59) entitled the Apology Act, 2008, was tabled by Sault Ste. Marie Liberal MPP David Orazietti.[91] The intent of the Act is to allow an individual to express an apology in connection with any civil matter, without that apology

being considered an implied or expressed admission of fault or liability, or admissible as such in any court of law. It is anticipated that by removing the threat of litigation from an apology, more open communications in the health care environment will occur. The Ontario Medical Association and the Canadian Medical Protective Association welcomed the introduction and passing of Bill 59.[92]

The Uniform Law Conference of Canada was held in Prince Edward Island in 2007. The Conference, founded in 1918, harmonizes the laws of the provinces and territories, and also where appropriate, federal laws. At the 2007 Conference, recommendations on the Uniform Apology Act were adopted. The Act provides that an apology is not admissible in civil proceedings for the purpose of proving liability and that an apology is not an admission of liability. The conference suggested that: *"As* an alternative to a separate statute, a jurisdiction may wish to enact the provisions of the Uniform Apology Act as an amendment to its Evidence Act." [93]

A section common to all existing and draft apology legislation in Canada provides that an apology will not disentitle a person to insurance coverage, even if their policy or provincial legislation stipulates otherwise. Another similarity is the use of the term "person". Person, under provincial interpretation legislation, is defined as a person or corporation.

The existing and draft apology legislation in Canada is generally consistent, although there are some minor differences in wording. Some legislation for example uses the term "notwithstanding," while other legislation uses the term "despite." Saskatchewan's legislation refers to an event or occurrence, while the remaining legislation uses the term "matter."

Another distinction arises the Manitoba legislation and the draft Yukon legislation, neither of which include a clause that precludes an apology from being considered an acknowledgement of a claim for purpose of their respective limitations legislation.

The Canadian Patient Safety Institute supported the enactment of the Ontario Apology Act and is advocating that apology legislation be adopted by all Canadian provinces and territories.

Conclusions

In undertaking a review of relevant "leading practices" in other jurisdictions, we were afforded the opportunity to examine and learn about the management of adverse health events from international, national, provincial, regional and organizational perspectives. Clearly, the pioneers in the field of adverse health event management (i.e., the UK, Australia, and the US) have much to offer in the way of lessons learned. The WHO is

providing leadership in the area of adverse event reporting and learning systems and the standardization of taxonomy for classifying adverse events.

At a national level, the Canadian Patient Safety Institute (CPSI) has taken a lead role in the development and publication of Canadian Disclosure Guidelines and developing a strategy to create a pan-Canadian reporting and learning system. It has also developed the Canadian Root Cause Analysis Framework, a quality improvement tool to help individuals and organizations determine all of the contributing factors and root causes that led to an event (i.e., critical incidents and close calls). CPSI is currently engaged with key stakeholders and partners in the development of a Canadian interprofessional competency-based framework for patient safety.

At the provincial level, a variety of initiatives have been undertaken to address the reporting of “critical incidents” or accidents. A number of these initiatives are tied to legislation and regulations. However, a major limitation is the lack of standardization of definitions and terminology used within and between provinces, within and between regions, and between organizations. It is difficult to say, with any degree of certainty, whether one practice or policy is leading the way in the field of adverse event management; this in part, because of the paucity of evaluative outcomes research being conducted in this area.

Appendix A Canadian Council on Health Services Accreditation

In January 2005, the CCHSA's Patient Safety Goals and Required Organizational Practices (ROP) came into effect. An ROP is defined as "an essential practice that organizations must have in place to enhance patient/client safety and minimize risk". These goals and required organizational practices are meant to be widely applicable (i.e., acute care, long-term care, community settings). Five ROPs are directly related to patient safety culture. CCHSA conducts an evaluation of implementation and evidence of compliance of the ROPs as part of the accreditation process. Information is provided by the participating organization to surveyors to test for compliance and evidence that must be in place for each practice. Surveyors are provided with suggested methods (e.g., team interviews, staff interviews, documentation review, and so on) to assess compliance. The test for compliance and the required evidence are highlighted below. Methods for surveyors are not addressed in this report.

The ROP for Patient Safety Area[94] are as follows:

1. *to adopt patient safety as a written, strategic priority/goal;*

Tests for compliance
Is patient/client safety written as a strategic priority/goal?
Are resources allocated to support the organization's implementation of the patient safety strategic priority/goal?
Required evidence
Documentation to ensure that patient/client safety is a written, strategic priority/goal, e.g. review strategic plan, annual report, and/or list of organizational goals.

2. *to provide quarterly reports to the Board of directors on patient/client safety, including changes/improvements following incident investigation and follow-up;*

Tests for compliance
Is there written evidence of patient/client safety-related quality reports provided to the Board?
Do the quarterly reports demonstrate activities and accomplishments that support the strategic priority/goal?
Is there evidence of the Board's involvement in supporting activities identified in the quarterly reports?
Required evidence
Review self-assessment info for L&P 5.4. {Board receiving useful, timely, and accurate information so that it can identify issues, address concerns, and make informed decisions]
Documentation re: quarterly reporting to the board.

3. *to establish a reporting system for actual and potential adverse events, including*

appropriate follow-up, in compliance with any applicable legislation and within any protection afforded by legislation;

Tests for compliance
Is there a reporting policy and process for actual and potential adverse events?
Are improvements made following incident investigation and follow-up?
Required evidence
Reporting policy and process in place and used.

4. *to implement a formal (transparent) policy and process of disclosure of adverse events to patients/families, including support mechanisms for patients, family, and care/service providers;*

Tests for compliance
Is there a policy and process for disclosure, including support mechanisms for patients, family, and care/service providers?
Required evidence
Policy and process for disclosure is implemented.

5. *to conduct one patient-safety related prospective analysis per year (e.g., Failure Modes and Effects Analysis) and implement recommended improvements/changes.*

Tests for compliance
Has at least one prospective analysis been completed within the past year?
Documented evidence of at least one prospective analysis completed in the past year.
Required evidence
Evidence of improvements/changes.

Non-compliance with any one ROP results in a conditional award. Organizations have six months to follow-up by putting the appropriate processes and systems in place to meet the requirements of the ROP. The organization is required to demonstrate compliance through a report or focused visit within six months. Four categories are used to assess compliance with ROPs: (1) not in place (2) in development (3) fully implemented, and (4) a leading practice.

Appendix B Canadian Patient Safety Institute Disclosure Guidelines

Released in March 2008, the Canadian Patient Safety Institute disclosure guidelines[95] are the product of a national working group. They were designed for an audience of health care providers, organizations, ministries and regulatory and professional bodies, to support and encourage the development or enhancement of disclosure guidelines in each such organization, and recognizing that the CPSI guidelines would be adapted as appropriate in each setting.

Principles of the CPSI guidelines: 1) patient centred health care; 2) patient autonomy; 3) safe health care; 4) leadership support; 5) disclosure is the right thing to do; 6) honesty and transparency.

In some cases a patient may be defined as the substitute decision maker. All aspects of disclosure must be governed by applicable privacy laws and policies.

CPSI recognizes the importance of disclosure as a basis for respecting patient rights, as the basis for ethical professional behaviour, to ensure trust and confidence in providers and health care institutions and to reduce legal liability. It points out that the CCHSA requires accredited health care organizations to adopt a transparent and formal disclosure policy what includes supports for patients, family and care or service providers.

The term “error” is not used in the guidelines because it suggests negligent action that can be attributed to specific people. Often, disclosure needs to happen before complete assessments of causation have been completed, so it may be too early to call the cause an error. Usually adverse events are the product of system factors or the interplay of events. Avoiding the term “error” allows for a more supportive environment for disclosure and learning from adverse events.

Creating a culture of patient safety includes ensuring that there is a channel for the reporting of adverse events, whether inside or outside the organization. A safety culture recognizes that systems failure is often the main cause of an adverse event. The lessons learned from an AE are used to repair system components so that the adverse event can be prevented in the future.

Patients should be supported by providing them with timely access to further health care, including clinical investigations, treatments and transfers; designating a staff person to provide emotional and practical support; facilitating support from family, friends, etc; and assisting patients to access other professional support, such as social workers, counselors and community services.

Providers also need training in how to properly undertake disclosure; they also need support when adverse events occur and disclosure becomes necessary. Guidance and instruction on how to effectively communicate and respond to unintended patient outcomes should be integrated into undergraduate and graduate curricula for all health care providers.

The first priority after an adverse event is to attend to the patient, deal with any emergency, and ensure the prevention and mitigation of harm.

The disclosure process may consist of more than one conversation with the patient; it may be a dialogue over time. The initial disclosure should occur as soon as possible after an event; this is principally the obligation of the provider, but sometimes the organizational leadership or management may provide advice or assistance. The discussion will generally focus on the medical condition, further investigations and treatments, and associated risks. At this stage, even if an adverse event is recognized, it is unlikely that all the contributors may be known. The facts that are known should be communicated and, if appropriate, a commitment made to learn more. If the plan for further investigation is known, it should be communicated. Also appropriate is an expression of regret, avoidance of blame and speculation, and the provision of emotional and practical support.

The second stage is post analysis disclosure. Additional facts and the reasons for the events, if known, may be discussed. The involvement of leadership/management is likely to be more significant at this stage in determining what is disclosed. Leadership/management and providers must consider not only "the information needs of the patient, but also any restrictions or requirements on information exchange that might arise from the application of national or provincial legislation, regulations or local institutional/hospital by-laws and policies. The advice of legal counsel may be required." Patients may be told of what improvements have been made, and as appropriate further expression of regret, an apology or an acceptance of responsibility may be included.

When an investigation is conducted by a legally protected quality of care or similar committee, it is important to be aware of how the law around this process will impact information exchange. Providers and patients should be aware of the limitations in discussing some of the investigative information.

An organizational policy for disclosure may be flexible in order to recognize the different levels of harm and the varying levels of administrative response and communication support. The organization should support the patient-provider relationship by implementing an organized and practical disclosure process. Disclosures should be appropriately documented according to established policy.

Close calls need only be disclosed depending on their circumstance, although each event has its own unique issues and sense of whether the event could happen again. In general,

if an event did not reach the patient, there may be no requirement to disclose. But if the event reached the patient, and there is potential for harm, the event should be disclosed. Even if it reached the patient but there is no potential for harm, the event generally should be disclosed. Depending on the circumstances, a consultation with an ethics committee may be advisable.

Regarding multiple-patient disclosure, disclosure should be one patient at a time, and in-person, if possible. If not, it should be done by registered letter or by telephone with opportunity for follow-up. "In addition, disclosure should be timed, if possible, to occur with all patients involved at approximately the same time and, if possible, prior to any informing process, especially media coverage, being considered."

Where more than one RHA is involved, the RHA involved in the actual adverse event should if possible lead the disclosure process. Ideally, representatives from both jurisdictions should participate. Effective communication and consultation regarding the facts should occur first. The matters should be addressed on a case-by-case basis.

Appendix C Legislation Reference Table

Legislation Reference Table

	Evidence	**Health Information Privacy/ Freedom of Information and General Privacy**	**Adverse Event/Critical Incident**
AB	*Alberta Evidence Act,* R.S.A. 2000, c. A-18.	*Health Information Act,* R.S.A. 2000, c. H-5. *Freedom of Information and Protection of Privacy Act, R.S..A 2000, Cf-25.*	N/A
BC	*Evidence Act,* R.S.B.C, c. 124.	*Freedom of Information and Protection of Privacy Act,* R.S.B.C. 1996, c. 165.	N/A
MB	*The Manitoba Evidence Act,* C.C.S.M. c. F52. E150.	*The Personal Health Information Act,* C.C.S.M. e. P33.5. *Freedom of Information and Protection of Privacy Act,* C.C.S.M. c. F175.	*The Regional Health Authorities Act,* C.C.S.M, c. R.34. *Critical Incidents Regulation,* Man. Reg. 211/2006.
NB	*Evidence Act,* R.S.N.B. 1973, c. E-11.	*Protection of Personal Information Act,* S.N.B. 1998, c. P-19.1.	N/A
NL	*Evidence Act,* R.S.N.L. 1990, e. E-16.	*Access to Information and Protection of Privacy Act,* S.N.L. 2002, c. A-1.1.	N/A
NT[1]	*Evidence Act,* R.S.N.W.T. 1988, c. E-8.	*Access to Information and Protection of Privacy Act, S.N.W.T.*.1994, c.20.	N/A
NS	*Evidence Act,* R.N.S. 1989, a 154.	*Freedom of Information and Protection of Privacy Act,* S.N.S. 1993, c. 5.	N/A
ON	*Quality of Care Information Protection Act,* S.O.2004, C. 3, Sch. A.	*Personal Health Information Protection Act* 2004, S.O.2004, C. 3, Sch. A. *Quality of Care Information Protection Act, 2004,* S.O.2004, c. 3, Sch. B. Freedom of Information and Protection of Privacy Act, R.S.0.1990, c. F.31.	N/A
PE	*Health Services Act,* R.S.P.E.I. 1988, e. H-1.5	*Freedom of Information and Protection of Privacy Act,* R.S.P.E.I. 1988, c. F-15.01.	N/A
QC	*An Act Respecting Health Services Social Services, R.S.Q.,* c. S-4.2.	*An Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information, R.S.Q.,* c. A-2.1.	*An Act Respecting Health Services Social Services, R.S.Q.,* c. S-4.2.
SK	*The Evidence Act,* S.S. 2006, c. E-I 1.2.	*The Health Information Protection Act,* S.S. 1999, c H-0.021. *Freedom of Information and Protection of Privacy Act,* S.S.1990-91, c. F-22.01	*The Regional Health Services Act, S.S.* 2002, C. R-8.2. *The Critical Incident Regulations, R.R.S.* 2000, c. R-8.2, Reg 3.
YT	*Evidence Act,* R.S.Y. 2002, c. 78.	*Access to Information and Protection o Privacy Act, R.S.Y. 2002, C.1.*	N/A

[1] All statutes also as enacted for Nunavut, pursuant to the *Nunavut Act*, S.C. 1993, c.28.

Appendix D Adverse Event/Critical Incident Reporting Laws

Table 1: A Review of provincial, territorial and federal legislation and policy related to the reporting and review of adverse events in health care in Canada: Appendix 5, Adverse Event/Critical Incident Reporting Laws. [96]

	What is reported?	How is the event reported?	To whom is the event reported?
MB	53.1 "Critical Incident" means an unintended event that occurs when health services are provided to an individual that 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 hospital stay, and (b) does not result from the individual's underlying health condition or from a risk inherent in providing the health services. (<<incident critique>>) "Critical Incident Review Committee" means a committee of one or more individuals established under subsection 53.3 (1) or 53.4 (1). (<<comité d'examen des incidents critiques>>)	53.2 (2) If a critical incident occurs when a regional health authority, health corporation or prescribed health care organization is providing health services to an individual, the authority, corporation or organization must ensure that (a)appropriate steps are taken to fully inform the individual, as soon as possible, about (i) the facts of what actually occurred with respect to the critical incident (ii) its consequences for the individual as they become known, and (iii) the actions taken and to be taken to address the consequences of the critical incident, including any health services, care or treatment that are advisable; (b) a complete record is promptly made about the critical incident, which includes (i) the facts of what actually occurred with respect to the critical incident (ii) its consequences for the individual as they become known, and (iii) the actions taken and to be taken to address the consequences of the critical incident, including any health services, care or treatment that are advisable; (c) the record described in clause (b) is available to be examined and copied by the individual at no cost.	53.3 (1) Except as provided in subsection (6), if a critical incident occurs when health services are provided to an individual by a health corporation or a prescribed health care organization, the corporation or organization must promptly (a) notify the regional health authority for the health region in which the critical incident took place about the critical incident, in accordance with the guidelines established by the regional health authority, to investigate and report respecting the critical incident. 53.3 (2) Promptly upon being notified about a critical incident under subsection (1), the regional health authority must notify the minister about the critical incident. 53.3 (3) A critical incident review committee established under subsection (1) must, in accordance with the health corporation's or prescribed health care organization's directions, (a) investigate the critical incident and, during the investigation, provide information and reports to the corporation or organization as requested; and (b) upon completing the investigation, report its findings and recommendations to the corporation or organization in writing. 53.3 (4) In accordance with guidelines established by the regional health authority, the health corporation or prescribed health care organization must provide information and reports to the authority about the critical incident and the critical incident review committee's investigation, including a written report upon completion of the investigation. 53.3 (5) The regional health authority must provide information and reports to the minister about the critical incident and the critical incident review committee's investigation, including a written report upon completion of the investigation.

	What is reported?	How is the event reported?	To whom is the event reported?
QC	8. "Accident" means an action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user, a personal member, a professional involved or a third person. 183.1 The organization plan of an institution must also provide for the creation of a risk management committee. The number and members of that committee and the rules governing its functioning shall be determined by by-law of the board of directors of the institution. The composition of the committee shall ensure a balanced representation of the employees of the institution, of users, of the persons practising in a centre operated by the institution and, if applicable, of the persons who, under a service contract, provide services to users on behalf of the institution. The executive director or the person the executive director designates shall be ex officio a member of the committee. 183.2 "Incident" means an action or situation that does not have consequences for the state of health or welfare of a user, a personal member, a professional involved or a third person, but the outcome of which is unusual and could have had consequences under different circumstances.	8. The user is also entitled to be informed, as soon as possible, of any accident having occurred during the provision of services that has actual or potential consequences for the user's state of health or welfare, and of measures taken to correct the consequences suffered, if any, or to prevent such an accident from recurring. 183.2 The functions of the committee include seeking, developing and promoting ways to 1) identify and analyze the risk of incidents or accidents in order to ensure the safety of users and, in particularly in the case of nosocomial infections, prevent such risks and reduce their recurrence; 2) make sure that support is provided to the victim and the close relatives of the victim; and 3) establish a monitoring system including the creation of a local register of incidents and accidents for the purpose of analyzing the causes of incidents and accidents, and recommend to the board of directors of the institution measures to prevent such incidents and accidents from recurring and any appropriate control measures.	223.1 Any employee of an institution, any person practising in a centre operated by an institution, any person undergoing training in such a centre or any person who, under a service contract, provides services to users on behalf of an institution must, as soon as possible after becoming aware of any incident or accident. report it to the executive director. Such incidents or accidents shall be reported in the form provided for such purposes, which shall be filed in the user's record. The executive director of the institution or the person designated by the executive director shall report, in non-nominative form, all reported incidents or accidents to the agency at agreed intervals or whenever the agency so requires. 235.1 The board of directors of an institution shall, by by-law, establish rules to be followed on the occurrence of an accident, so that all the necessary information is disclosed to the user, to the representative of an incapable user of full age or, in the event of the user's death, to the persons referred to in the first paragraph of section 23. 278. Every institution must transmit an annual report of its activities, including activities related to risk and quality management, to the agency and to the minister within three months after the end of its fiscal year. The report must be filed in the form determined by the minister and must contain any information required by him and by the agency. 431. With a view to improving the health and well-being of the general public, the minister shall determine priorities, objectives and orientations in the field of health and social services and see to their implementation. He shall in particular… 6.2) from the content of the local registers referred to in section 183.2, establish and maintain a national register of incidents and accidents having occurred during the provision of health services and social services for the purpose of monitoring and analyzing the causes of incidents and accidents, ensuring that measures are taken to prevent such incidents and accidents from recurring and ensuring that control measures are implemented, where appropriate …. [6.2 is not yet in force].

	What is reported?	How is the event reported?	To whom is the event reported?
SK	58(1) In this section: (a) "critical incident" means an incident that: (i) arises as a result of the provisions of a health service by a regional health authority, a health care organization or the cancer agency; and (ii) is listed or described as a critical incident in the *Saskatchewan Critical Incident Reporting Guideline*, 2004 published by the department, as amended from time to time, or any subsequent edition of the Saskatchewan Critical Incident Reporting Guideline; Reference should be made to the *Saskatchewan Critical Incident Reporting Guideline, 2004* for a list of critical incidents that must be reported to Saskatchewan Health.	58 (2) A regional health authority shall, in accordance with the regulations: (a) give notice to the minister of the occurrence of any critical incident that arises as a result of a health service provided by the regional health authority; and (b) investigate any critical incident mentioned in clause (a) and provide a written report to the minister with respect to that critical incident and investigation. Similar provisions require reporting by health care organizations (58(3)) and the cancer agency (58(4.1)). From the *Critical Incident Regulations:* 4(1) A regional health authority shall, in accordance with sections 6 and 7, give notice to the minister of any critical incident that occurs: (a) in a facility that the regional health authority operates; or (b) in relation to a health service that the regional health authority provides or a program that the regional health authority operates. 4(2) Notice pursuant to subsection (1) must be given within three business days, or as soon as possible thereafter, after the day on which: (a) the critical incident occurs; or (b) the regional health authority becomes aware of the critical incident. Similar provisions set out notice to be provided by health care organizations (5(1) and (2)). 6 For the purposes of sections 4 and 5, notice may be given: (a) orally by telephone or in person; or (b) in writing, including transmission by facsimile or electronic mail. 7 Subject to section 10, notice required by section 4 and 5 must include: (a) a summary of the facts that led to the critical incident; (b) a summary of the health status of the person to whom the critical incident relates; (i) before the critical incident; and (ii) after the critical incident; (c) the actions that the regional health authority or health care organization, as the case may be, has taken or will be taking to investigate the critical incident; and (d) a statement as to whether the critical incident has been reported to any organization that is not part of the regional health authority or health care organization, as may be the case, and the names of those organizations, if any.	From the *Critical Incident Regulations:* 8(1) A regional health authority shall investigate any critical incident described in subsection 4(1) and prepare a written report with respect to each critical incident described in subsection 4(1) and prepare a written report with respect to each critical incident that it investigates. 8(2) A written report required by subsection (1) must include: (a) a description of the circumstances leading up to and culminating in the critical incident; (b) a statement identifying any current practice, procedure or factor involved in the provision of the health service or the operation of the program that: (i) contributed to the occurrence of the critical incident; and (ii) if corrected or modified, may prevent the occurrence of a similar critical incident in the future; (c) a description of the actions taken and the actions intended to be taken by the regional health authority as a result of the investigation; and (d) any recommendations arising from the investigation 8(3) The regional health authority shall submit the written report to the minister immediately on completion of the report. 8(4) If an investigation and a written report required by subsection (1) cannot be completed and the report submitted to the minister within 60 days after the day on which, the regional health authority became aware of the critical incident, the regional health authority shall advise the minister of the delay, the reasons for the delay and the anticipated date of completion of the report, which is to be not later than 180 days after the day on which the regional health authority became aware of the critical incident. Similar provisions set out how a critical incident must be reported by a health care organization (9(1)-(4)).

Ontario	Note: In February 2003, the Council of the College of Physicians and Surgeons of Ontario (CPSO) approved a policy that mandates disclosure of a critical incident, and the Canadian Medical Protective Association (CMPA) encourages appropriate disclosure of harm. Subsection 1 (1) of Regulation 965 of the Revised Regulations of Ontario, 1990 is amended by adding the following definition: "critical incident" means any unintended event that occurs when a patient receives treatment in the hospital, (a) that results in death, or serious disability, injury or harm to the patient, and (b) does not result primarily from the patient's underlying medical condition or from a known risk inherent in providing the treatment; ("incident critique")	Section 2 of the Regulation is amended by adding the following subsections: The board shall ensure that the administrator establishes a system for ensuring the disclosure of every critical incident, as soon as is practicable after the critical incident occurs, (a) to the affected patient; (b) if the affected patient is incapable, to a person lawfully authorized to make treatment decisions on behalf of the patient; or (c) if the affected patient has died, (i) to the patient's estate trustee, or to the person who has assumed responsibility for the administration of the patient's estate if the estate does not have an estate trustee, or (ii) to a person who was lawfully authorized to make treatment decisions on behalf of the patient immediately prior to the patient's death, or who would have been so authorized if the patient had been incapable. (5) The disclosure referred to in subsection (4) shall include, (a) the material facts of what occurred with respect to the critical incident; (b) the consequences for the patient of the critical incident, as they become known; and (c) the actions taken and recommended to be taken to address the consequences to the patient of the critical incident, including any health care or treatment that is advisable. (6) Subject to the Quality of Care Information Protection Act, 2004, the board shall ensure that the administrator establishes a system for ensuring that at an appropriate time following a disclosure of a critical incident under subsection (4), there be a disclosure to the person referred to in clauses (a) to (c) of subsection (4) of the systemic steps, if any, that the hospital is taking or has taken in order to avoid or reduce the risk of further similar critical incidents, and that the content and date of this further disclosure be recorded. Disclosure of Critical Incidents A new regulation comes into effect in July 2008 that amends Regulation 965 under the Public Hospitals Act in order to mandate the disclosure of a critical incident to a patient.	Hospitals will be expected to adopt and implement the regulation, however, they may also retain or develop expanded disclosure policies that exceed (but do not contravene) the requirements of the Act. The amendments place responsibility on hospital administrators to set up a system for ensuring the disclosure of critical incidents; therefore, it will be their task to designate staff duties around reporting, and to establish internal protocols based on what is most appropriate for their particular facility.

Appendix E List of RHAs/ HCO Policies Reviewed

Institute	Province*
Calgary Health Region	Alberta
Alberta Health Quality Council	Alberta
Saskatoon Health Region	Saskatchewan
Winnipeg Regional Health Authority	Manitoba
Sunnybrook Health Sciences Centre	Ontario
McGill University Health Centre	Quebec
Capital Health Halifax	Nova Scotia
Health Canada	Federal Agency

*Policies of the four Regional Health Authorities of Newfoundland and Labrador are reviewed in greater detail in another section of this report.

Appendix F Select RHAs/ HCO Policies

Jurisdiction	Policy Title	Policy
Alberta **Calgary Health Region** **Note**: The policies and procedures are separate documents within the region. The following procedures are available: 1. Immediate & Continuing Management of Serious (Potential) Adverse Events 2. Conducting an Administrative Review 3. Conducting a Safety Analysis 4. Disclosing Harm to Patients 5. Informing Principal Health Partners & Stakeholders – Safety Hazards, Failures, Fixes	Reporting Harm, Close Calls and Hazards Reference Number 1626 Effective Date: 2006/10/18 Next review: 2008/10/18 Definitions ***CLOSE CALL*** means a situation where a patient was nearly harmed, but for one or more reasons, the patient was "saved" from harm. ***HARM*** means an unexpected or normally avoidable outcome that negatively affects a patient's health and/or quality of life, and occurs or has occurred during the course of receiving health care or services from the Region (modified from the Ontario College of Physician and Surgeons, Disclosure of Harm Policy, Feb. 2003). ***Severe harm*** **-** a patient suffers complete loss of limb or organ function or requires intervention to sustain life. ***Moderate harm*** **-** a patient suffers partial loss of limb or organ function. ***Minimal harm*** **-** a patient suffers harm that is less extensive and does not involve loss of limb or organ function. ***No apparent harm*** **–** at the time of the event or reporting of the event, the patient does not appear to suffer any harm, but could do so in the future.	The Region requires its health care providers to report all situations where patients have suffered fatal or severe harm. The Region strongly encourages health care providers to report all situations where patients have suffered moderate or minimal harm or experienced a close call. The Region strongly encourages its health care providers to report all hazards. The Region encourages its patients, families, volunteers and visitors to report all situations where patients have suffered harm or experienced close calls and any hazards that could lead to patient harm. The Region is committed to reviewing all reported hazards and all situations where patients have suffered harm or experienced close calls. This policy applies to all Calgary Health Region health care providers working, training or volunteering in Region facilities or services. Health care providers will complete a Safety Learning Report to report hazards and situations where patients have suffered harm or experienced close calls. The Region has a responsibility to learn from hazards and situations where patients have suffered harm or experienced close calls so that improvements can be made to the safety of patient care.

	Disclosing Harm to Patients Reference Number 1627 Effective Date: 2006/10/18 Next review: 2008/10/18	The Region is committed to open and honest discussions with patients/families when patients have suffered harm. The Region defines this communication process with patients/families as disclosure. The Region is also committed, when it is appropriate, to disclosure when a patient has experienced a close call. In these situations, disclosure is discretionary and based on serving the greatest good for the patient. This policy applies to all Calgary Health Region health care providers working, training or volunteering in Region facilities or services. The disclosure process includes: ▪ Acknowledging harm to the patient/family; ▪ Providing an apology for harm; and ▪ Discussing factual information with the patient/family about how harm occurred and recommendations that have been made to improve the system. During the disclosure process, the Region will provide/facilitate care and support for the patients/families and health care providers involved – including treatment, counseling, debriefing, and other forms of assistance that may be appropriate. In most cases, the health care provider most responsible for the patient's care will disclose to the patient/ family. In some circumstances, as dictated by the severity of the harm, the patient's current health and the health of the health care provider(s) involved, disclosure may also involve a Region administrator and/or a medical leader. The Region recognizes the importance of disclosure in maintaining and rebuilding trust between patients/ families, the Region and its health care providers when patients have suffered harm or experienced close calls. The Region recognizes that the disclosure process must be respectful of the situation, support the needs of patients/families and the health care providers involved, and adhere to appropriate legislation.

	Just and Trusting Culture Reference Number 1628 Effective Date: 2006/10/18 Next review: 2008/10/18	The Region is committed to promoting a just and trusting culture of safety in which its health care providers can readily report harm, close calls and hazards so that the Region can learn and work to improve the safety of patient care. When health care providers have been involved in situations where there has been failure in the provision of care to a patient, the Region commits to: providing appropriate care and support to the patients/families and health care providers involved; evaluating all systemic factors that may have contributed to failure; and following established fair procedures for evaluating the actions and behaviors of health care providers. This policy applies to all Calgary Health Region administrators and medical leaders. Region administrators and medical leaders will use a framework and follow procedures that are just and fair when conducting administrative reviews to evaluate health care providers' actions and behaviors. The framework (See Note 1 in References) includes three types of actions and behaviors and the Region's responses to them: Note 1: Based on the work of Dr. Jan Davies (U of C, Faculty of Medicine, Dept. of Anaesthesia) and the work of James Reason (University of Manchester, UK). ERRORS – when there has been failure in the provision of care to a patient, and the health care provider did not deviate from established policies, procedures, standards or guidelines, then the health care provider will not be disciplined by the Region. NON-COMPLIANCE – when there has been failure in the provision of care to a patient, and the health care provider deviated from established policies, procedures, standards or guidelines, then the Region will commit to evaluate: o the appropriateness of its policies, procedures, standards or guidelines; and of the circumstances that led to the non-compliant action(s), before determining an appropriate course of action. INTENTION TO HARM – when there has been failure in the provision of care to a patient, and the health care provider intended to cause harm, then the Region will seek disciplinary action and criminal investigations may result. (These situations are extremely rare.)

	Informing Principal Health Partners & Stakeholders – Safety Hazards, Failures, Fixes Reference Number 1629 Effective Date: 2006/10/18 Next review: 2008/10/18	The Region is committed to communicating open, honest and timely information to its principal health partners and stakeholders about safety hazards, failures and fixes. The Region defines this process as informing. The Region informs its principal health partners and stakeholders about safety hazards, failures and fixes to: communicate important changes in risks to patients' well-being from known hazards; maintain trust through transparent communication in situations where failures have affected or have the potential to affect confidence in the care and services provided by the Region; foster a culture of sharing information about patient safety which will lead to further system improvements. This policy applies to senior management of the Calgary Health Region. The Region's principal health partners have a right to know about any substantial changes in risks to their well-being from safety hazards that are known to the Region. The Region's stakeholders have a right to know about any safety hazard or failure that has occurred within the Region and could present a risk to their well-being. The Region's stakeholders also have a right to know what recommendations have been made to improve patient care. The Region has a duty to maintain the confidence of its principal health partners in the care and services that it provides.
Alberta **Health Quality Council**	Disclosure of Harm to Patients and Families, Provincial Framework, July 2006.	The framework is a consensus document by the Health Quality Network which is a HQCA collaborative consisting of health authorities, the Ministry, the AMA, College of Pharmacists, the College of Physicians and Surgeons, College and Association of registered nurses, and the federation of regulated health professions. The document states that with this framework Albertans will know that guidelines for disclosure are understood and accepted by all health authorities and professional bodies. The framework is a guideline to enable health authorities and professional bodies to develop and adjust their own specific policies and procedures in a manner which is consistent with the provincial framework. (There does not appear to be any legislative backing for this framework, just a voluntary consensus that it represents good policy.) The framework will be supported on an ongoing basis with disclosure education programs, and dissemination of communication materials for patients, families and health care providers. The document recognizes in several places that disclosure must be accompanied by such things as information on what happened, the causes, and what will be done to ensure the same thing does not happen again. However, it does not address the systems necessary to ensure that good information is available to support those aspects of disclosure. Unless there is a reporting system and an assessment system, there will be only partial information on which to base a disclosure. The quality of the other parts of the system are essential if successful disclosure is to take place.

		When should disclosure occur? Disclosure should occur when a patient experiences harm while receiving health care [Harm is defined as "an unexpected or normally avoidable outcome that negatively affects the patient's health and or quality of life, which occurs or occurred in the course of health care treatment and is not due directly to the patient's illness."]; when an adverse event occurs and there is no apparent harm to the patient but the potential for harm remains; when an adverse event was narrowly avoided prior to harm occurring to the patient (in this circumstance disclosure is discretionary and needs to be determined on a case by case basis by the health care team – as to whether disclosure is in the best interests of the patient – though no criteria are provided). Disclosure should take place as soon as possible, at most within one or two days following the discovery of harm. The framework provides guidance for the kind of setting for meetings (private), who should be present (2-3 people ideally including the direct provider), and suggests that the Health Boards of Alberta, CMPA and other respective insurers "should be informed and consulted as appropriate prior to the disclosure meeting." The framework does not say why the insurer should be consulted. What should be disclosed? At all disclosure meetings "information shared should be factual and agreed upon through a process of consensus by the health care team prior to initiating the disclosure process." (This implies that all members of the team have a veto. This does not appear to support true disclosure if one member of the team does not agree. Some guidance needs to be provided.) Information should be related to the event and not about any individuals – the facts should be related to the patient's diagnostic, treatment and care information (what happened, the sequence of events, diagnostic test results, consequences of the harm, changes to treatment plan and any other relevant factual information). In regard to QACs which are covered by the Evidence Act, the framework says that all facts should be disclosed to a patient and family. Only facts should be shared. "All other information collected during an investigation and Quality Assurance Committee records must remain confidential and protected." Persons who carry out the QA process investigation must not be included on the disclosure team. The lead person on the investigation is responsible for communicating the facts to an "appropriate individual or department within the health authority administration for approval." These individuals will be responsible for determining how the facts will be shared with the patient and family. "Only new facts that would have otherwise been on the patient's chart, as well as actions being taken to try to prevent a similar event from happening again, should be shared." (This process may prevent a full explanation of the causes of an event, especially if the causes reveal information about an individual health care provider or requires assumptions to be made that fall short of facts.) The Alberta framework includes an extensive explanation of the details of disclosure – the meeting, who should disclose, to whom, the type of documentation, the conversation, how to disclose and providing emotional support.

		Multi-jurisdictional disclosure arises when a patient is transferred from one health authority to another, or from a private setting to a public setting. In certain situations the event in an originating setting may not be identified until later. In situations where disagreement occurs, it is anticipated that the organization discovering the harm and the entity where the event occurred will agree how, when and who will disclose to the patient. (This sentence sounds wrong in the Alberta document.) Where immediate disclosure is not crucial, efforts should be made to contact the originating jurisdiction to inform them of the situation and the planned process for disclosure. If possible, representatives from both jurisdictions should be involved. With the adoption of the provincial framework it is anticipated that the disclosure process will be consistent between jurisdictions and disagreements will be rare. If there is still disagreement, the HQC will be available to mediate the resolution of issues in a confidential and anonymous manner. Multi-patient disclosure should not occur in a group setting; steps should be taken to ensure that all patients are contacted prior to a release to the media; patients can be contacted by registered mail or telephone or a face-to-face meeting, and opportunities should always be made for a face-to-face meetings. The Alberta document also includes a glossary, an overview of relevant legislation, and samples of communications materials prepared for distribution to people in the health system.
Saskatchewan **Saskatoon Health Region**	Critical Incident Reporting Date Effective: September 2004 Date Revised: September 2007 Note: The critical incident policy is currently under revision now that the province has gone through a period of three years of legislated reporting.	All critical incidents will be reported through a region-wide reporting process in compliance with Section 58 of the Regional Health Services Act and its corresponding regulations – The Regional Health Services Critical Incident Regulations – and the Accountability Agreement with Regional Health Authorities and Saskatchewan Health. Critical Incident is defined according to the legislation and regulations: ***Critical Incident*** means a serious adverse health event including, but not limited to, the actual or potential loss of life, limb or function related to a health care service provided by, or being provided by, a regional health authority or health care organization (see Appendix A *Saskatchewan Critical Incident Reporting Guideline* for examples of serious reportable events). Critical incidents must be reported immediately to the Director of Risk Management or designate. During the weekend or night shift, the most senior administrator on call is contacted through switchboard or the appropriate on-call process and the administrator will notify the Director of Risk Management and appropriate senior managers – refer to on-call process for your area. The event is entered into the Safety Reporting System (computer-based) or a confidential Safety Report is completed by a staff member, physician, volunteer or student of the service/dept./area who were involved in, witness to or become aware of the critical incident within 24 hours of the critical incident occurring or when the incident is recognized as a critical incident and according to the procedure outlined in Safety Reporting Policy (#7311-50-006). *Time frame is important to overall reporting, however, this should not discourage critical incidents being reported at any time.*

		When the Safety Report form is completed, it must be submitted to Risk Management within 48 hours of the critical incident occurring. Other reporting forms or documentation that may have been completed (ie. a medication error report) must accompany the confidential Safety Report when submitted. When the Safety Reporting System (computer-based) is used, automatic notification to the appropriate individuals will occur. Immediate identification of any medication, medication container, supplies or equipment that may have contributed to the occurrence must occur. Packaging and all components of the equipment should be saved. Quarantine the objects after labelling "DO NOT USE" (immediately contact Clinical Engineering if biomedical equipment is involved). Photographs may be necessary for documentation. Safety Reports are NOT part of the health record. The original report is filed in Risk Management. A factual note of the event and the patient assessment MUST be documented in the patient's/resident's chart. Risk Management will notify appropriate senior management that a critical incident has occurred. Risk Management, according to the legislation, shall notify the Minister of Health of a critical incident within three business days following the incident occurrence or the date the regional health authority becomes aware of the incident. Notification to the Minister of Health by Risk Management shall include de-identified, factual information about the critical incident. SHR shall investigate the critical incident through a nonpunitive, multidisciplinary review (Appendix B – Multidisciplinary Case Review) including: the circumstances leading up to and culminating in the critical incident; any current practice, procedure or factor involved in providing the health service that contributed to the occurrence of the critical incident; actions considered, developed or required as follow-up to the critical incident; and implementation of any recommendations resulting from the critical incident review. Risk Management, according to the legislation, will provide a written report of de-identified factual information, including actions taken, planned and quality improvements the RHA will be implementing as a result of the critical incident review, within 60 days of the RHA becoming aware of the critical incident. Appropriate senior managers within SHR will receive a copy of the written report of deidentified factual information, including actions taken, planned and any quality improvements that will be implemented as a result of the critical incident multidisciplinary case review. Feedback/direction will be provided to appropriate stakeholders to implement quality improvements as required.

Note: The policy is supported by a packet of information for managers, staff and patients/clients regarding disclosure.	Disclosure of Adverse/Unanticipated Events Date Effective: October 2007	The Saskatoon Health Region and affiliates believes that patients/clients/residents and their families are entitled to information about the outcomes of tests, treatment and care. In some cases, poor outcomes are a result of an adverse event (AE). The Saskatoon Health Region and affiliates are committed to respecting the rights of patients/clients/residents and their families to be informed about such events. Disclosure of adverse/unanticipated events[1] to patients/clients/residents and their families is an integral part of Saskatoon Health Region's patient/client/resident safety initiative; it ensures open, honest and constant communication to allow for increased trust and satisfaction between patients/clients/residents and the health care team; a joint responsibility of the Saskatoon Health Region organization and the clinical person(s) involved; a professional responsibility of all care providers[2]. ***Effective communication is at the heart of safe and effective health care*** Discussions with the patient/client/resident or family may be warranted if there is a change in the treatment plan or unanticipated event or outcome of which the patient/client/resident or family may not otherwise be aware. Critical incidents[3] must be reported to Risk Management immediately. Communication of an adverse/unanticipated event must occur when harm has come to the patient/client/ resident. Consultation should occur with care providers and Risk Management in cases of a near miss or harm never reaching the patient/client/resident to determine if discussion with the patient/client/resident or family is warranted. Communication of an adverse/unanticipated event should occur as soon as possible subsequent to a triggering event. Ideally, they should occur within 24-48 hours of the health care team becoming aware of the event. The patient/client/resident or family will be the recipients of the adverse/unanticipated event information. Communication of an adverse/unanticipated event will ideally be provided by a team. The team will likely include the most responsible physician (at the time of the event), a representative for the region (a manager/director for the area) and in some cases, depending on the severity of harm and circumstances, a representative from Risk Management. Lead for the discussions should rest with those who have the most knowledge of the event. All members of the health care team involved should be aware that communication with the patient/client/ resident or family has occurred. Other support resources such as the client representative or social worker (with appropriate permission) may be included in the discussion to assist patients/clients/residents and families by providing support during and subsequent to the discussion. The discussion should take place in a private, quiet location.

		Factual information should be provided professionally, compassionately, truthfully and with the absence of blaming statements. Opinions should not be discussed. Disclosure of the circumstances should not be delayed because all facts are not known. The recipient of the information should be made aware that all facts may not yet be known, and a follow-up discussion should be planned to disclose new facts. An offer of apology or an expression of regret can be offered and is not an admission of guilt. Pertinent health record documentation will be available for the discussion, and patients/clients/residents and families will be provided with information about how to access their health information. The initiator of the discussion must document the content of the meeting in the patient's/client's/resident's health record including date and time of meeting; participants – (including names and relationship to the patient/client/resident), and factual account of the information shared. Meeting notes are to be taken and kept on file by the manager/director involved. The review process that will be conducted should be provided to the patient/client/resident and family. In most cases involving a critical incident, a multidisciplinary review will occur. Quality improvement recommendations from the review can be shared with the patient/client/resident and family if so desired. The occurrence of an AE can have significant emotional and psychological impact on the involved providers' care for the patient/client/resident. Support for the providers involved in an adverse/unanticipated event will be provided/facilitated by the Saskatoon Health Region. Supports such as the Employee Family Assistance Program (EFAP), Risk Management or Social Work can be offered. <u>Multi-jurisdictional disclosure:</u> There may be disclosures that extend beyond jurisdictional borders, such as a patient receives care and harm occurs as a result of the care in the originating jurisdiction, but is not disclosed and/or unknown prior to the transfer to another jurisdiction. Effective communication and cooperation between jurisdictions is key. Ideally, all jurisdictions should be a part of the disclosure. The lead for the system review will typically fall within the responsibility of the jurisdiction in which the event occurred. <u>Multi-person disclosure:</u> There may be disclosures that involve more than one patient/resident/client. Initial contact may include a registered letter, telephone call, or an invitation to an in-person meeting. Appropriate clinicians should be involved and/or advised of the disclosure. [1]Adverse/unanticipated event is defined as an undesired and unplanned occurrence directly associated with the care or services provided to a patient/client in the health care system". The occurrence may result from "commission or omission (e.g., administration of the wrong medication) and can include problems in practice, products, procedures and systems." *CCHSA 2003*

		[2]Policy: Physician Disclosure of Adverse Events and Errors that Occur in the Course of Patient Care. *College of Physicians and Surgeons of Saskatchewan, 2002* and *Professional Codes of Ethics* (Health Care Professionals of Saskatchewan) [3]"Critical Incident" means a serious adverse health event including, but not limited to, the actual or potential loss of life, limb or function related to a health care service provided by, or being provided by, a regional health authority or health care organization. SHR's Critical Incident Reporting Policy 7311-50-008. **Multidisciplinary Case Review: A coordinated approach to managing risk.** Risk Management or the administrator on call will discuss the circumstances with appropriate senior management, including Chief of Staff (if appropriate) and appropriate vice president or other senior management if deemed appropriate. At the direction of senior management, an Ad Hoc Multidisciplinary Review Team may be appointed. The facilitator will be a member of the Department of Risk Management. The membership of the review team will include: The attending physician (if involvement in the event), The department manager(s), director(s), general manager(s) and/ or department head of the department(s) involved, Selected staff who provided care, (e.g. nursing staff, residents, JURSIs) and, other consultants at the discretion of the team. **Mandate of the multidisciplinary review team:** Risk Management or designate will be responsible for gathering all of the relevant information. To meet with 14 days of the occurrence. To review the health record, related documentation surrounding the occurrence, and any relevant policies, procedures and/ or protocols. To interview individuals who may provide additional relevant facts or pertinent background information To summarize their findings in a report to the Senior Management sponsors within 21 days of the occurrence. The report will concisely describe the circumstances that are believed to have led to the actual or potential adverse outcome and the recommended measures to prevent a similar occurrence (if in fact there are any). Documentation is to be concise and focused on the facts of the topic. No copies are distributed of any reports prepared for this process. All documents are clearly marked, "PRIVILEGED AND CONFIDENTIAL – FOR MEDICAL QUALITY IMPROVEMENT PURPOSES." If email is used, messages begin with the note, "Confidential – for Medical Quality Improvement Purposes" and should be discarded as soon as possible. Reporting outside of this internal review process should only be done on the advice of Risk Management and/ or legal counsel for the Region.

Manitoba **Winnipeg Regional Health Authority**	Critical Incident Management and Learning Regional Policy Policy Number 10.50.040 Date: June 2007	Critical Incident is defined as an unintended event that occurs when health services are provided to an individual and result in a consequence to him/her that (a) is serious and undesired, such as death, disability, injury or harm, unplanned admission to hospital or unusual extension of hospital stay, and (b) does not result from the individual's underlying health condition or from risk inherent in providing the health service. "Provisional Critical Incident" is an event that may meet the above criteria but has not yet been designated a CI. legal privilege as described in The Regional Health Authorities Amendment and Manitoba Evidence Amendment Act does not begin until a "Provisional Critical Incident" is designated as a Critical Incident by the facility/program/setting. Therefore, any information collected prior to designating this event is not legally privileged. Any individual, including employees and medical staff, who becomes aware of s CI shall promptly report it in the manner designated by the WRHA Chief Patient Safety Officer in accordance with The Regional Health Authorities Amendment and Manitoba Evidence Act . Any individual, including employees and medical staff, who becomes aware of a CI shall promptly report it in the manner designated by the WRHA Chief Patient Safety Officer, in accordance with The Regional Health Authorities Amendment and Manitoba Evidence Amendment Act. 3.2 With the goal of encouraging a culture of reporting, the WRHA shall support individuals who report a CI in good faith. 3.3 The WRHA shall ensure all CIs are appropriately investigated (including debriefing of appropriate staff, patients and family whenever possible) in order to promote system-wide learning through the appointment of Critical Incident Review Committees (CIRC), as described in The Regional Health Authorities Amendment and Manitoba Evidence Amendment Act, and as detailed in section 4.0 below. 3.4 In the spirit of establishing a just and fair learning culture, the WRHA shall not discipline any staff member involved in events leading to a CI and shall treat the event as a learning opportunity, except as outlined in sections 3.5. 3.5 When a staff member or medical staff has demonstrated disregard for patient safety or has acted in breach of any policies or obligations, WRHA reserves the right to address such instances in an appropriate manner in accordance with applicable policies or processes, collective agreements or medical staff by-laws even when such a staff member or medical staff is involved in a CI. 3.6 The WRHA shall evaluate the implemented recommendations arising from CI reviews. Lessons learned shall be shared with all appropriate individuals and organizations, as detailed in section 4.0 below. 3.7 Disclosure of the CI shall occur in accordance with the WRHA Policy # 10.50.030 – *Disclosure of Critical Incidents* and as described in The Regional Health Authorities Amendment and Manitoba Evidence Amendment Act.

		3.8 No record or information, including an opinion or advice, prepared solely for the use of a CIRC, or collected, compiled or prepared by a CIRC for the sole purpose of carrying out its duties, may be produced in any legal proceeding. 3.9 No witness in a legal proceeding may be asked or permitted to answer any question or make any statement about a CIRC proceeding. Any individual who observes or has knowledge of a Critical Incident (CI) or a Provisional CI shall: 4.1.1 ensure that the patient(s) and personnel are safeguarded, 4.1.2 Identify and secure any pertinent equipment/supplies. Determine if the room or scene needs to be secured, e.g. in the case of a suicide, homicide, suspicious death. 4.1.3 Report the CI/ Provisional CI by calling the WRHA Critical Incident Reporting Line, 24 hours a day, 7 days a week. (*Note: Patient Safety are no longer accepting the paper report form*). Callers who choose to, may report anonymously. *(Note: reported events accepted by the WRHA Critical Incident Reporting Line will be classified as Provisional CIs until designated as a Critical Incident by the involved facility/program/ setting.)* 4.1.4 At the caller's discretion, notify his/her manager/supervisor to provide assistance/support. Employees are encouraged to provide the information to their manager/supervisor, following usual lines of reporting. 4.2 The information collected from the CI Reporting Line at the Provincial Health Contact Centre will be sent to the WRHA Patient Safety CI database application. 4.3 A Provisional CI notification email (containing de-identified information) will automatically be sent from the database application to identified recipients at the involved facility, WRHA Programs, WRHA Patient Safety, and Manitoba Health. *(Note: Information in the notification email is not legally privileged.)* 4.4 During regular working hours (08:00-17:00), a facility/program/setting representative (as identified by the facility/program/setting) shall: 4.4.1 Determine whether or not the reported event meets the defined CI criteria. If assistance is needed with this step, contact the WRHA Patient Safety Team. 4.4.2 If the event is designated as a CI, ensure that: 4.4.2.1 Appropriate disclosure to the patient/family member(s) has occurred. 4.4.2.2 An individual has been designated to provide ongoing contact and support for the patient and family members as appropriate. 4.4.2.3 There is appropriate ongoing support for staff member(s) and physician(s) involved. 4.4.2.4 Any student/trainee contacts his/her supervisor for support. 4.4.2.5 The site insurer is notified when appropriate. 4.4.3 Ensure that a Critical Incident Review Committee (CIRC) is named to investigate the CI (see Appendix). Collaborate as needed with the WRHA Patient Safety Team to determine the level and membership of the CIRC.

		4.4.4 By the end of the next business day, advise the WRHA Patient Safety Team in writing (preferably by email) whether or not the reported event has been designated a Critical Incident. If the event has been designated as a CI, indicate that a CIRC has been established and provide the names and titles of the CIRC members. (*Note: Legal privilege begins once the event has been designated as a CI by the facility/program/setting/WRHA Patient Safety.)* 4.4.5 Within 28 calendar days of the CI, send a status report to the WRHA Patient Safety Team (preferably via email) which is marked "Privileged under Section 9 of the Manitoba Evidence Act" and contains the following information: 4.4.5.1 Date of the CI, any changes in the condition of the patient, indication that a review has been completed or is in progress, review findings and recommendations (if the review has been completed) and the steps taken to inform the patient/family of the unfolding consequences to the patient's health. 4.4.6 Within 88 calendar days of the CI, send a copy of the CIRC's written final report to the WRHA Patient Safety Team (preferably via email). The report must be marked "Privileged under Section 9 of the Manitoba Evidence Act" and contain the findings, recommendations and follow-up action plan. 4.5 During regular working hours (08:00-17:00), the WRHA Patient Safety Team shall: 4.5.1 Verify as needed, in collaboration with the Patient Safety representative from the facility/program/setting (as designated by the facility/program/setting), whether or not a Provisional CI meets the defined CI criteria. 4.5.2 Collaborate as needed with the facility/program/setting to determine the level and membership of the Critical Incident Review Committee (CIRC). 4.5.3 Participate in and/or chair CIRCs as required. 4.5.4 As appropriate, ensure that an appropriate person provides ongoing follow-up and support for the patient/family members. 4.5.5 Ensure that Manitoba Health has received initial notification of the CI. 4.5.6 Within 30 calendar days of the CI, ensure that Manitoba Health receives a copy of the status report that includes: the date and time of the CI, further details, condition of the patient, steps taken to inform the patient/family of the unfolding consequences to the patient's health, confirmation of establishment of a CIRC, indication that a review has been completed or is in progress and review findings and recommendations (if the review has been completed). 4.5.7 Within 90 calendar days of the CI or upon completion of the CI Review, ensure that Manitoba Health receives a copy of the written final report. The report must be marked "Privileged under Section 9 of the Manitoba Evidence Act" and contain the findings, recommendations and follow-up action plan. 4.5.8 Courier the final CIRC Report to the Chief Operating Officer (COO)/Chief Executive Officer (CEO) of the involved facility/setting or, in the case of Community CIs, to the VP of Community Health Services, when CI reviews are led by a member of the WRHA Patient Safety Team.

		4.6 Once the Provisional CI has been reported to the WRHA Critical Incident Reporting line, after hours (between 17:00 and 08:00), or on a weekend or statutory holiday: 4.6.1 A designated representative from the facility/program/setting (as designated by the facility/program/setting) if aware of the Provisional CI, shall notify the WRHA administrator on call by paging her/him. The notification should include the name and contact information of the person reporting, time and date of the Provisional CI, a brief description of the facts, and the patient's condition. 4.6.2 The WRHA administrator on call if aware of the Provisional CI, shall notify Manitoba Health by calling the after-hours cellular phone. The notification should include the name and contact information of the person reporting, time and date of the Provisional CI, a brief description of the facts, and the patient's condition. **CRITICAL INCIDENT REVIEW COMMITTEES** As soon as possible after an event is confirmed as a CI, a CIRC should be appointed by the site or setting where the CI occurred. In order to be a member of a CIRC, an individual must have completed one of the workshops required by the WRHA Patient Safety Team. The WRHA Patient Safety Team maintains a list of such individuals. Certain individuals must be excluded from the CIRC, specifically anyone who: • Has a conflict of interest in the CIRC; e.g., manager of the involved unit; • Was or is directly involved in providing care to the patient; • Has a potential future role in disciplinary matters arising from that CI or the program or site involved; e.g., Manager/Program Director/Medical Director; as outlined in 3.5; • Is the ongoing patient/family support person. The appropriate size and type of CIRC will depend on the CI. There are a number of possibilities: 1) Site based single person CIRC - the most common and efficient type of CIRC; 2) Site based CIRC made up of two or more persons - appropriate if the case is complex or involves more than one program within a site; 3) Regional CIRC made up of one or more persons - appropriate if the case involves more than one facility, more than one program within the region or if the issues are highly "visible"; 4) External CIRC - appropriate if a consultant outside the WRHA is required. In all cases a CIRC will: 1) Reconstruct the sequence of events: • Debrief (hear the story of) involved staff; • Debrief (hear the story of) involved patient and family; • Gather records 2) Meet with persons who are sources of applicable information; 3) Consult with program team regarding recommendations;

		4) Prepare the final report. 5) Ensure that all CIRC documents are marked "Privileged under Section 9 of the Manitoba Evidence Act" and stored in a confidential file in a locked office. As needed a CIRC will: 1) Seek expert opinions; 2) Obtain standards and protocols from external sources; 3) Seek information from non-WRHA sources (e.g., family physician, paramedics, pharmacy, literature, etc.); 4) Convene a meeting of clinical experts to assist the CIRC to formulate recommendations. Special situations for a CIRC: 1) If there are serious concerns about the competence or performance of a provider, a CIRC may and should contact the appropriate Facility Senior Management member or the Site Executive Director/Community Area Director directly. 2) If a CIRC member has a mandatory reporting duty to a licensing body, the CIRC should make the disclosure preferentially through the appropriate Facility Senior Management member or the Site Executive Director/Community Area Director. 3) If there are serious concerns about possible criminal activity, a CIRC may involve police, preferentially by notifying the appropriate Facility Senior Management member or Site Executive Director/Community Area Director. 4) In addition, there may be parallel investigations underway, e.g., police investigations, administrative reviews. The CIRC will send a copy of the final report only to the facility Chief Operating Officer/Chief Executive Officer and the WRHA Patient Safety Officer who will forward a copy of the final report to the Minister of Health (Manitoba Health). The exception is that, upon request, a copy of the final report may also be sent to the office of the Continuing Medical Examiner and, in some cases, the Protection of Persons in Care Office. The WRHA Chief Patient Safety Officer or designate will provide patients/families, facilities, and others with a de-identified abstracted summary of the event, findings and recommendations.

	Disclosure of Information Related to Care and Treatment *Regional Policy* Policy Number 10.50.030 Date: July 2007	**"**Critical Incident**"** (CI) is an unintended event that occurs when health services are provided to an individual and result 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 hospital stay; and b) does not result from the individual's underlying health condition or from a risk inherent in providing the health services. **"**Disclosure**"** is a process that includes sharing pertinent information with the patient and/or substitute decision-maker about the care provided, as well as responding to questions. The process may involve a number of encounters over time as more information is learned about a particular situation. The sharing of pertinent information about care and treatment provided to patients by staff/medical staff will be integrated into the routine processes of providing services. The sharing of information will occur in a timely manner by means of discussions and conversations as well as by providing access to current treatment records, upon request. With respect to events and situations that fulfill the criteria to be considered a **critical incident** (refer to policy 10.50.040) all employees and members of medical staff involved in disclosure discussions which will take place with the patient and/or substitute decision-makers, will include the following: • The facts of what actually happened; • The consequences for the patient and the steps to be taken to address those consequences; • a regret that the event occurred and resulted in harm to the patient; and • the availability of copies of the health record. The sharing of pertinent information will be provided by the most appropriate person(s) after discussion with the supervisor/manager of the clinical area. Questions to be considered will include: • Who has the appropriate knowledge of the event details? • Who is comfortable sharing the information? • Who has developed a trust relationship with the patient/family? Guidelines For Disclosure in the case of Critical Incidents: 1. What events or situations ought to be disclosed? Refer to the definition of critical incident as outlined in the Critical Incident Management and Learning policy (10.50.040). 2. To whom should the disclosure be made? Disclosure should be made directly to the patient and/or his/her substitute decision-maker. If the patient lacks the capacity to understand the information, disclosure should be made available to a person authorized by the regulations to receive information and records on the individual's behalf (see 2.2). 3. When should disclosure take place? The initial disclosure of the Critical Incident should take place as soon as is practicably possible after it has occurred or has been identified.

		4. Who ought to disclose details to clients and/or family? Disclosure may best be accomplished by a team of care providers and requires coordinated planning prior to the disclosure. In most, the attending or most responsible physician(s) should be included in the group making the disclosure. Those involved in disclosure discussion, should be knowledgeable about the details of the event as well as comfortable undertaking such discussions. Advice and assistance will be available through the regional WRHA Patient Safety Team. 5. What ought to be disclosed? This is defined in both the legislation and the Critical Incident Management and Learning policy (10.50.040). In addition to a description of the facts of what actually occurred, the consequences for the individual and the steps that will be taken to address those consequences, it is appropriate to include the following: • An expression of regret that the Critical Incident occurred and caused harm to the client. • An offer to provide copies of the documentation in the health record, as described in the legislation and policy regarding Critical Incidents. These considerations will apply equally to those events that do not meet the criteria to be considered a CI, as well as those events that are considered a CI. In most cases, the most responsible staff members, likely the physician(s) if available, will participate in discussions involving disclosure of critical incidents. Where possible, an offer of a **second opinion**, the involvement of outside assistance, or the transfer of care to another provider or facility.
Ontario **Sunnybrook Health Sciences Centre**	*Accountability for Patient Safety** *Note: This policy is cited in the following article* Etchells, E., Lester R., Morgan, B., & Johnson B. (2005). "Striking a Balance: Who is Accountable for Patient Safety?" *Health Care Quarterly*, 8(Special Issue), 146-150.	It is a strategic goal of Sunnybrook Health Sciences Centre to be the safest hospital in Canada. To create a culture that will support the goal, Sunnybrook has adopted, the following principles about patient safety that will guide Sunnybrook employees, physicians, students, volunteers and agents of the hospital [theses categories of individuals will be referred to collectively as "staff" through this policy]: 1. The organization and each individual staff member share the accountability for ensuring the safest possible patient care and service. 2. Staff reports of errors, near misses and adverse events are a critical component of patient safety and must be reported diligently and without fear of reprisal by all staff. 3. The majority of errors, near misses and adverse events involve competent and caring staff interacting with complex systems. Sunnybrook responds to reports of errors, near misses, and adverse events by carefully examining and improving the systems of care. 4. Sunnybrook needs and values the participation of staff and professionals in the investigation of the system of care, and in creating and testing improvements. 5. Sunnybrook has a responsibility to address the actions of individuals when their actions fail to meet professional, patient care and/or services standards. These situations include intentional acts meant to harm or deceive; physical or mental impairment of staff; substance abuse by staff; staff incompetence. If it becomes clear that a staff member cannot practice in a reliably safe manner, in spite of education and counseling, this situation will be treated as a staff competency issue in accordance with professional standards and Human Resource principles.

Ontario **Sunnybrook Health Sciences Centre**	*Disclosure of Adverse Medical Events and Unanticipated Outcomes of Care*	It is Sunnybrook & women's policy, in keeping with our mission, vision, values and philosophy of care, to ensure that patients and/or their substitute decision-maker, and/or their family are properly informed about their health care. This includes an obligation on the part of all physicians and health care practitioners to inform patients about significant adverse medical events and unanticipated negative outcomes of care that may affect their well-being. **DEFINITIONS:** **Adverse Medical Events (significant):** Adverse medical events are negative patient outcomes that can occur as the result of health care treatment and not due to the patient's illness. They are often unanticipated and unexpected outcomes of health care that do, or have the potential to, negatively impact a patient's health and quality of life. They include complications and side effects of treatment as well as errors in the performance of medical duties. Adverse medical events are not necessarily markers of substandard care. **Non-Significant Events:** Non-significant medical events are minor incidents that do not have a negative impact on patient outcomes, now or in the foreseeable future. No extra procedures affecting the patient are required to prevent negative patient outcomes. These events are not significant from the patient's perspective and disclosure to the patient and /or substitute decision-maker or family is discretionary. **Disclosure Process** Disclosure of significant adverse medical events is required as part of the general professional duty to inform patients about events that have affected or may affect their health in the future. It is the timely and open response to such difficult incidents by trusted and responsible medical personnel that can prevent dissatisfaction with care and improve the quality of care provided to patients in the future. Health care practitioners are encouraged to seek out the available hospital resources to help them inform patients about an adverse medical event. [See Appendix I: Frequently Asked Questions (FAQ's), which offers guidelines for disclosure and resources to enable practitioners to be open with patients about difficult incidents] **APPENDIX I** **Frequently Asked Questions (FAQs)** About Disclosing Adverse Medical Events & Unanticipated Outcomes of Care 1. What events ought to be disclosed? * Incidents causing patients harm or, in some cases, having the potential to do so, or * Incidents requiring additional non-trivial interventions to prevent Harm. **Examples:** This might include events such as an unexpected admission to intensive care due to a drug reaction, a prolonged hospital stay on account of complications arising from treatment, or an intraoperative event, such as rupturing an organ or major blood vessel, that requires unexpected and significant interventions to correct.

		2. To whom should disclosure be made? * Disclosure of the event should be made to the patient, or in certain circumstances, the patient's substitute decision-maker and/or family. * ii. If the patient is deemed incapable of understanding a discussion of this nature, then in accordance with the Health Care Consent Act (1996), the patient's substitute decision-maker should be informed. When should disclosure take place? * Disclosure of the event should take place as soon as practically possible after it has occurred or has been identified. * Disclosure to the patient should occur when the patient's condition is stable and/or the patient is able to comprehend the information. Disclosure to the patient's substitute decision-maker may occur prior to this and will depend on the severity of the event. 4. Who ought to disclose events to patients? * If the event is most associated with physician staff, the patient's attending physician, whether or not this physician was involved in the event, would usually initiate the discussion with the patient. There may be situations where another staff physician would take the lead, for example where the event occurred in one of the diagnostic units. * If the event is most associated with non-physician staff/employees of the hospital, such as nursing or other health care professionals, the manager or director of the area would usually initiate the disclosure in consultation with the Director of Quality and Risk Management or delegate. The patient's attending physician will always be informed of the event and will be given the option of being part of the discussion with the patient. 5. Are there events where disclosure is not required? * Disclosure of non-significant events (ones that do not harm a patient), should be a matter for clinical judgement by the skilled practitioner. Such incidents do not require disclosure to the patient because they do not affect the patient's well-being. Disclosure is a matter of "proportionality": the greater the harm or risk of harm caused by an event, the greater is the duty of the health practitioner to disclose this event to the patient and/or to the patient's substitute decision-maker. **Examples:** A minor delay in giving a patient a medication may be an unwanted event ,but if there was no harm to the patient as a result, disclosure would not be required. The disclosure of certain intraoperative events, such as bleeding or hypotension that are promptly treated with no consequence to the patient, would also be discretionary.

		6. What mechanism will be in place to help with disclosure? * During business hours, staff involved in an event who are employees of the hospital will immediately contact the Director of Quality and Risk Management or delegate to review an adverse event. The role of Quality and Risk Management is to facilitate the staff's discussion about the event and to help plan the conversation with the patient or substitute. * After hours the on-site Manager or Administrator-on-Call is contacted immediately. * The Director of Quality and Risk Management or delegate is available upon request to support physicians in the disclosure of adverse events. 7. What are the beneficial consequences of disclosure? * Patients will receive prompt and thorough interventions for any harm suffered or anticipated. * Patients and/or their families will have their concerns and fears openly addressed and respected. * Patients will receive important information about their care in a timely manner. * Errors and adverse events, while unwanted, are opportunities for practitioners and institutions to learn how to improve the quality of care and patient safety. 8. What is the difference between an error and an adverse event? * Errors and adverse events overlap but are also different. * Adverse events and errors are alike in that they are unwanted and often unanticipated events or processes of care. They occur to even the most careful practitioner and are not markers of negligent care. * Some adverse events are unexpected, such as an allergic reaction to a first-time treatment with penicillin. * An error is sometimes considered to be a "preventable adverse event," such as prescribing penicillin to a patient with a history of penicillin allergy. It is unlikely, however, that all errors are "preventable." * What may seem like an "error" after the fact may simply be due to differences in professional judgement. Professional judgement tolerates a wide variety of approaches to patient situations. Less than optimal patient outcomes and even adverse outcomes may be due to legitimate differences in approach rather than any "error" per se. * Adverse events are "adverse" because they cause, or threaten some harm to patients. Not all errors are harmful to patients if caught in time, such as a pharmacist, who, noting the patient has a penicillin allergy, alerts the prescribing doctor. Such "harmless" errors are "near misses" that should not require disclosure to the patient. 9. What actions are recommended for staff to take when a significant event occurs or is identified? These actions apply to those most immediately responsible for the care of the patient. * The event should be documented in the patient's chart in an objective, factual and narrative way. This should be done as soon as possible after the event has occurred or has been recognized. * Staff who are employees of the hospital will involve their manager and the Director of Quality and Risk Management or delegate immediately. Quality and Risk Management is available upon request to support physicians with disclosure on request. * Disclosure of the event to the patient, substitute decision-maker, and / or family should take place in a timely way. The adverse outcome may be obvious; what may require special attention is disclosure of the circumstances leading up to / surrounding the event. [See #2, "When Should d Dsclosure Take Place?"; #6, "What Mechanism Will Be in Place to Help with Disclosure?"; #7, "What are the Beneficial Consequences of Disclosure?"]

		* Discuss the event with members of the patient's care team and, where appropriate, the manager or department/division head. 10. What Hospital actions will be taken when a significant event occurs or is identified? * The hospital encourages reporting of adverse events and errors and will support staff in this initiative. Patient safety is the primary concern of the organization, not disciplining the individuals involved in events. The hospital will focus on correcting the factors that allow events to occur and work with staff affected to prevent the recurrence of such events. * Secondary records made about the event, e.g., incident reports, interview notes, will be factual and objective. They will be stored in a secure area and will be destroyed in keeping with Retention Guidelines. Summary reports used for quality improvement or to meet the requirements of Sunnybrook's Accountability System. Secondary records will not contain information that would identify the patient or staff. 11. What are the recommendations for disclosure? * The attending physician or manager (see #4 above) should meet with the patient / substitute decision maker as promptly as other duties permit and as appropriate given the patient's clinical condition. The assumption is that most patients / families would want to know what has happened. However, patients have the right to decline disclosure. If in doubt, ask before you tell. Waivers of information should be recorded in the patient's chart. * Disclosure is a process. Practitioners should avoid speculation, focus on what is known about the event at the time of the discussion, and answer questions from the patient or substitute decision-maker to the best of their ability. Unanswered questions ought to be noted, and prompt and thorough responses sought. * Avoid attributing blame to specific individuals or simple explanations as to "cause". Most serious events have multiple contributing factors that may not always be apparent at the time of the first meeting with the patient/family. * A timely and empathic expression of sorrow or regret and condolences may well be appropriate and should not be construed or taken to be an admission of liability or fault. ("This must be very difficult for you. I wish things had turned out differently.") Doing so soon after an adverse outcome can help promote confidence in hospital staff and prevent unnecessary feelings of distrust.

Quebec **McGill University Health Centre**	*MUHC Policy on Sentinel Events*	The MUHC is committed to taking positive steps to reduce and prevent errors in order to improve patient care. If a sentinel event has occurred, the MUHC is committed to understanding the processes, attitudes and behavior that underlie the event, and making changes in the systems and processes, as well as attitudes and behavior, to reduce the probability of their reoccurrence. This policy is based on the belief that, in order to improve performance, organizations need to conduct credible investigations of sentinel events. The objective is not to assign blame but to improve patient care by understanding the processes that led to a mishap. **Sentinel Event** A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or risk thereof. Serious injury specifically includes loss of limb or function. The phrase, "or risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and response. **Policy** When a member of the MUHC community becomes aware that a potential sentinel event has occurred at the MUHC, he/she must notify the appropriate individuals within the organization. The facts will be reviewed to determine whether the event should be treated as a sentinel event. Once it is deemed to have been a sentinel event, an investigation will be undertaken to understand the causes that underlie the event and to make changes in the organization's systems and processes as well as attitudes and behaviors to reduce the probability of such an event in the future. The investigation is designed to identify the contributing factors, and the response includes actions to reduce the likelihood of recurrence. Criteria for selecting sentinel events is based on the CCHSA event types (surgical events or invasive procedures, device or product events, patient protection events, environmental events, care management events and criminal events). The MUHC Policy and Procedure User's Guide gives very specific timelines and required actions. This user's guide can be accessed at http://www.msss.gouv.qc.ca/ministere/vigilance/download.php?id=72541,73,2

Nova Scotia **Capital District Health Authority (Halifax)**	*Patient Safety Reporting –Event Category and Types*	The Capital Health Patient Safety Reporting System uses an event category and type listing as a guideline for the reporting of an adverse event across the region. There are 11 categories as listed below. Examples are provided for each category. 1. Diagnostic procedure – results reporting issue, missing specimen, specimen collection issue and so on. 2. Medication related – medicine incidents related to professional practice, drug products, procedures and systems. May include prescribing, order communication, product labeling/ packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use. 3. Medication Administration-related –adverse drug reaction, extra dose, incorrect (wrong) patient, incorrect (wrong) rate, and so on. 4. Medication Order-related –illegible order, incorrect order, incorrect (wrong) patient chart, known allergy, and so on. 5. Medication Dispensing-related – expired drug, incorrect (wrong) drug dispensed, incorrect patient, and so on. 6. Patient/Client Behavior – accidental injury, left against medical advice, refusal of treatment, self-inflicted injury, suicide, sexual assault, and so on. 7. Patient Identification and Documentation –misfiled reports/records, missing record, patient armband/identification, and so on. 8. Patient-related equipment –equipment failure, equipment misuse, inappropriate for the task, and so on. 9. Privacy issues – conversations overheard, records unsecured, released patient information/ hospital documents without consent, release of patient information/hospital documents to the wrong party, and so on. 10. Falls. A **fall** is defined as a sudden, uncontrolled, unintentional, downward displacement of the body to the ground or other object, excluding falls resulting from violent blows, other purposeful actions, strokes, fainting, and/ or seizures. A **near-fall** is a sudden loss of balance that does not result in a fall or other injury. This can include a person who slips, stumbles, or trips but is able to regain control prior to falling. An **unwitnessed fall** occurs when a patient is found on the floor and neither the patient nor anyone else knows how he or she got there. http://www.patientsafety.gov/Topics/fallstoolkit/notebook/index.html. 11. Therapeutic Procedures – blood type issue, delay in patient management, infection control issue, patient identification issue, procedure delayed, procedure cancelled, surgical count issue, retaining foreign body, and so on.

	Patient Safety Impact Classification	Capital Health utilizes a Patient Safety Impact Classification System consisting of eight levels of harm as described below. ***Level 1* - No Harm / Detectable Harm** There was no injury or no harmful effect to the patient and no potential risk identified. **NEAR MISS** ***Level 2* – Minimal Temporary Harm** Requires little or no intervention. ***Level 3* – Minimal Permanent Harm** Requires initial but not prolonged intervention. ***Level 4* – Moderate Temporary Harm** r Requires initial but not prolonged hospitalization. ***Level 5* – Moderate Permanent Harm** Requires intensive but not prolonged hospitalization. ***Level 6* – Severe Temporary Harm** Requires intervention necessary to sustain life but may also require prolonged hospitalization. ***Level 7* – Severe Permanent Harm** Requires intervention necessary to sustain life and prolonged hospitalization, long-term care or hospice. ***Level 8* – Death** Drastic outcome as a result of an event.
		Guide to Disclosure: **Clinician-Patient Interviews** 1. Choose appropriate physical setting. 2. Involve the care team. 3. Listen & deal with emotions. 4. Factual explanation. 5. Communicate a strategy. Closure and follow-up. Definition of adverse event: an unexpected and undesired incident directly associated with the care provided to the patient, or the environment in which care was provided, which does, or can be reasonably expected to, harm the patient (negatively affect the patient's physical and/or psychological health and/or quality of life).

Nova Scotia Health (provincial policy)	*Disclosure of Adverse Events Policy*	All designated organizations providing health care in Nova Scotia that receive public funds, are required to have a process in place to promptly inform clients of pertinent facts associated with adverse events. This process requires maintaining a written policy that outlines the associated responsibilities, procedures and support. The provincial policy on health care disclosure of adverse events aims to assist organizations to provide an environment where clients receive the information they need to understand what happened and to make informed decisions about their care and create an environment where clients, care providers and managers all feel supported when adverse events occur. This policy applies to the Nova Scotia Department of Health (DoH) and to Nova Scotia organizations receiving public funds to provide health care, such as district health authorities, the IWK Health Centre, and N.S. DoH contractors providing emergency health services. **Adverse Event–** an unexpected and undesired incident directly associated with the care or services provided to the client or the environment in which the care is provided. **Near Miss** - an event or circumstance which has not affected the client nor caused harm but the potential for harm exists. This near miss "almost happened" but may not have reached the client due to chance, corrective action, and/or timely intervention. The policy outlines the conditions that require disclosure. At minimum, the facts of the event and its impact on the client and on the care must be disclosed when an adverse event occurs during the process of providing health care and results in client injury, death or negatively impacts health (real or perceived). A sample organizational ethics decision-making framework for disclosure of significant adverse events is provided as a guideline for the health regions.

Health Canada	*Canadian Adverse Drug Reaction Monitoring Program* *Guidelines for the Voluntary Reporting of Suspected Adverse Reactions to Health Professionals and Consumers*	Adverse reactions (ARs) to Canadian marketed health products, including prescription, non-prescription, biologic (including fractionated blood products, as well as therapeutic and diagnostic vaccines), natural health and radiopharmaceutical products are collected by the Canada Vigilance Program. An adverse reaction (AR) is a harmful and unintended response to a health product. This includes **any** undesirable patient effect suspected to be associated with health product use. Unintended effect, health product abuse, overdose, interaction (including drug-drug, and drug-food interactions) and unusual lack of therapeutic efficacy are all considered to be reportable ARs. To report a suspected AR for health products –[pharmaceuticals, biologics (including fractionated blood products, as well as therapeutic and diagnostic vaccines), natural health products or radiopharmaceuticals] marketed in Canada, – health professionals or consumers (preferably in conjunction with their health professional, so that information about medical history can be included in order to make the reports more complete and scientifically valid) should complete a copy of the Canada Vigilance Reporting Form Report of Suspected Adverse Reaction Due to Health Products Marketed in Canada (HC/SC 4016): This form may be obtained from the Internet at: http://www.hc-sc.gc.ca/dhp-mps/medeff/reportdeclaration/ar-ei_form_e.html, from your Canada Vigilance Regional Office, and is also available in the appendices of the *Compendium of Pharmaceuticals and Specialities.* To report an Adverse Event Following an Immunization (AEFI) for a vaccine used in the prevention of infectious diseases, the same criteria as stated in these guidelines are used. Health professionals should complete a copy of an Adverse Event Following Immunization Reporting Form. This form is available on the internet at http://www.phac-aspc.gc.ca/im/aefi-form_e.html or in the appendices of the CPS. Forms also exist as customized provincial/territorial adverse event forms which can be obtained either from local public health departments or from the provincial/territorial health authorities. Any information related to the identity of the patient and/or the reporter of the AR will be protected as per the Privacy Act.

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Provincial Forum on Adverse Health Events:

Summary of Proceedings

May 26, 2008
The Fairmont Newfoundland

Prepared by: Loretta Chard-Kean

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Introduction:

The Task Force on Adverse Health Events was announced by Government in May 2007. The Terms of Reference are:

- *to examine and evaluate how the health system identifies, evaluates, responds and communicates in regard to adverse events within the health system;*
- *to examine best practices in other jurisdictions;*
- *to propose a mandate, structure and budget for the establishment of a health quality council in Newfoundland and Labrador, and to make such recommendations as may be appropriate.*

Planning for the Provincial Forum on Adverse Health Events began in late March 2008 and included consultations with Task Force staff and members of the Health System Liaison Committee, senior health system officials responsible for quality, and safety and risk management personnel. An agenda to guide the work of the Task Force was developed to reflect the key elements of an adverse health event framework.

A Preliminary Notice of the Forum (see Appendix 1) was developed and distributed to targeted stakeholders via email and advertised on the Task Force on Adverse Health Events website on May 2, 2008. A Forum Agenda (see Appendix 2) featuring a variety of provincial and national experts in the management of adverse health events was distributed to participants as they registered.

The Provincial Forum on Adverse Health Events was held on May 26, 2008, at the Fairmont Newfoundland.

One hundred and thirty-nine (139) individuals registered for the event. In the final analysis, 130 representatives from Regional Health Authorities (RHAs), professional and regulatory bodies, learning organizations, patient advocacy groups, unions, related health organizations and various provincial government departments attended the Forum proceedings. (See Appendix 3 for list of participants.)

Forum Proceedings

This document reflects a summary of the Forum proceedings. All presentations are accessible on the Task Force website at www.gov.nl.ca/ahe.

Phil Hassen, CEO of the Canadian Patient Safety Institute (CPSI), served as Forum chair. In his opening remarks, Mr. Hassen welcomed participants to the Forum and reminded them of the tremendous opportunity to engage in the important work of patient safety and to help advance work on behalf of patients and caregivers across Canada.

Mr. Hassen provided an overview of CPSI and its work. He indicated that the definition of an adverse event adopted by CPSI is "*an unexpected event in health care delivery that results in harm to the patient and is related to the care, and or services, provided to the patient rather than the patient's underlying medical condition.*"

He noted that the word "patient" also means other clients served, and we should not underestimate the enormous issues that underlie other areas of the health care system. Key points included the following:

- CPSI is working with all provinces and health care providers to improve the system.
- Mr. Hassen made an analogy with the airline industry. Twenty-five years ago it had huge issues with safe travel and has since reduced deaths by 80%; the anesthesia field has also achieved remarkable results: the death rate 30 years ago was 1 in 1,500 and is now 1 in 300,000.
- Canadians receive the safest health care in the world.
- One in ten adults contracts an infection in hospital; one in ten patients receive the wrong medication or wrong dosage; more deaths are reported because of adverse events in hospital than deaths from breast cancer, motor vehicle accidents and HIV combined.
- A Post Discharge study stated that 19%, or 76 patients, had an adverse event and 66% were drug-related.
- In the home care setting 78% of patients taking five or more drugs are at risk for medication error.
- In long-term care, a six-month prospective surveillance per 1,000 days of care showed that of the 859 patients studied, 11.8 acquired infections.

Honorable Ross Wiseman, Minister of Health and Community Services

Minister Wiseman welcomed participants and speakers and noted the context for discussion and the kinds of recommendations that will emanate from discussions. He noted:

- The magnitude and impact of recent adverse events in NL were so profound, most notably the issues around hormone receptor testing, that Government took measures to ensure that this type of occurrence never happens again.
- A Commission of Inquiry for hormone receptor testing was established, and some $2.3 million invested in data management and quality assurance measures within regional health authorities to ensure quality testing in provincial laboratories.
- Government recently announced one of the most comprehensive packages in the country for pathologists, recognizing that a strong workforce of oncologists and pathologists is critical to ensuring a state-of-the-art cancer care program in NL.
- The establishment of a Task Force on Adverse Health Events, to examine how the health system identifies, evaluates, responds and communicates adverse event.
- That the Forum is a vital element in bringing together experts in adverse health management, along with health professionals, leaders of the health system and front-line caregivers to help develop a set of recommendations for consideration.
- A call for submissions from the public and other health-related organizations to gain as comprehensive a perspective as possible related to adverse events.
- That through the work of the Task Force and the Commission of Inquiry, Government hopes to strengthen the health care system so it is prepared to respond to the unfortunate events that occur as a result of adverse health events.
- Resulting reforms from these initiatives will ensure that the health and well-being of patients are the central consideration.
- While the hope is that an adverse event never arises again, preventing such reoccurrences is the goal, as is "doing best by people of the province by ensuring that the system is prepared to respond to any eventuality."
- That taking these significant steps in building our responsiveness will help restore a greater confidence in the health care system.
- The reality is that there are thousands of excellent professionals providing quality care to our residents every single day; Government recognizes this, and the goal is to have the people of the province recognize this as well.

Minister Wiseman thanked participants for their commitment in participating in the process of sharing best practices and learning from each other so that the people of NL receive quality care. He noted that he looks forward to receiving the Task Force Report.

Adverse Event Management Framework: Robert Thompson

Robert Thompson, Chair of the Task Force on Adverse Health Events, acknowledged the leadership shown by those in the health and community services system in NL who, because they are seized with the importance of patient safety and are motivated to improve how adverse events are managed share a common cause.

He provided an overview of the mandate of the Task Force on Adverse Health Events and noted:

- It was formed in May 2007 as a separate process from the Commission of Inquiry on Hormone Receptor Testing, although it grew out of the same general public concern about the retrospective reviews of laboratory tests and diagnostic images.
- The Commission of Inquiry has a mandate under the Public Inquiries Act to examine a specific, yet complex and very important adverse event, ER/PR testing.
- The recommendations arising from the Inquiry will provide beneficial guidance that can be generalized to adverse events beyond ER/PR testing.
- To ensure a broad range of adverse events are reviewed, the provincial government created the Task Force on Adverse Health Events, which has a policy mandate, not an investigative mandate, to make recommendations to ensure that the health and community services system is well equipped to manage a wide variety of circumstances.
- One of the premises of the Task Force mandate is that, to some extent, adverse events will always happen, because no matter how technology, systems or skill sets are improved, health and community services are human services and periodically things will go wrong.
- Patients and the public understand this point, but they find it difficult to accept if the system does not respond in a quick and effective manner when things go wrong. By building upon the policies already in place for managing adverse events, we can together create another foundation for public confidence.

Mr. Thompson noted that the mandate separates the adverse event management process into its component parts and asks the Task Force to assess and examine each piece separately.

The elements of the Task Force work plan were highlighted and included:

- a review of policies and practices across Canada and a more detailed review of the policies and practices in Newfoundland and Labrador;
- interviews with experts in Canada, and internationally;
- case studies of adverse events in NL and elsewhere;
- a provincial forum on adverse health event management;
- written submissions;
- direct meetings with agencies and groups who wished to have more focused and detailed discussion; and
- the establishment of a health system liaison committee.

Additional parameters being considered by the Task Force include an appropriate definition of an adverse event and the need to focus on community-based services in particular, including such areas as public health, home care, long-term care, and child, youth and family services. Some adaptation may be necessary to ensure the concepts work appropriately in the community and across the full continuum of services.

It was noted that the Task Force is interested in the full continuum from single patient/ client events to large multi-patient events. It is also interested in the issues of coordinating across jurisdictions and between health care organizations.

Mr. Thompson provided an explanation of the Adverse Health Event Management Framework (see Appendix 4). He noted that it was developed as a way to break down the process into distinct parts for analytical purposes. The six parts are overlapping and integrated and include:

- *identification;*
- *assessment;*
- *disclosure;*
- *action;*
- *communication, coordination and leadership*; and
- *evaluation.*

He invited suggestions on how the Task Force could add to, or modify the framework to ensure that it captures all of the parts of the management process. He also highlighted another chart depicting patient safety/quality initiatives policies used by regional health authorities (Appendix 5).

Mr. Thompson reviewed the agenda and encouraged individuals to actively participate in the workshops. He noted the objective was to canvass, and capture all the relevant issues from different perspectives.

Finally, Mr. Thompson stated that he hoped the Forum would stimulate the thinking of all the groups represented and motivate a written brief for the Task Force by June 13, 2008.

Keynote Address: Embracing a Culture of Quality and Safety

Dr. Ward Flemons, Vice-President Quality and Safety and Health Information in the Calgary Health Region, provided an excellent keynote address on embracing a culture of safety and learning. He indicated that it was his firm belief that operational approaches based on a model or a framework should form the base of work in this area, if it's going to stand the test of time.

He noted that the body of work by James Reason, Professor Emeritus, University of Manchester, UK, has helped shape policies and practices at Calgary Health Region in terms of managing adverse health events.

The Royal College of Physicians and Surgeons Task Force Report, he noted, was really one of the things that spawned the creation of the Canadian Patient Safety Institute (CPSI). It also highlighted the power of stories in getting people to think and to react at a different level, rather than just showing the statistics, which are sometimes easy to gloss over.

He told the story of Betsy Layman, the mother of three young children and the health reporter of the *Boston Globe*, who was undergoing experimental chemotherapy for breast cancer in a Boston hospital. Because of a misinterpreted order she received a four-fold overdose and died of a cardiac arrest. Another patient had suffered exactly the same adverse health event, and although the person didn't die, they remained in the intensive care unit for many weeks with terrible cardiac failure. Dr. Flemons noted that a systematic failure in the patient care had actually occurred. A data clerk discovered the error and reported it. In 1995, the Dana Farber Cancer Institute made a very difficult decision to go public. The Chief Operating Officer, Jim Conway, led the organization through this extremely public and tragic event in 1995 in Boston which ultimately took the organization to a completely different place; it is now one of the safest places to receive treatment.

Dr. Flemons also highlighted a 2004 sentinel event in the Calgary Health Region where two dialysis patients died in an intensive care unit in Calgary as a result of being dialyzed with a solution of potassium chloride rather than sodium chloride. Stories are important, according to Dr. Flemons, and should not be forgotten.

Dr. Flemons noted:

- adverse events were really brought to light in 1999 with the release of the Institute of Medicine Report, *To Err is Human*;
- the early 1980s' studies highlighted how often patients are harmed as a result of receiving care within institutions;
- the Canadian Adverse Event Study, 2003, brought patient safety and adverse health events to the consciousness of people within health care;

- models are important in helping understand why bad things happen (not just in health care, but in just about any industry) because they allow for the design of safer systems;
- in terms of adverse event(s) management it is important those organizations start from a foundation or a framework; manage patients and families, after the fact; don't forget that health care providers, who are the second victims, be looked after as much as patients, so as not to lose them from the institution; and figure out how to manage stakeholders in health care.

Dr. Flemons discussed the theories of James Reason, a leading thinker in organizational safety, and as well as the "Swiss cheese model of accident causation." He provided an overview of Reason's two models of accident causation: the systems model and the person model. The person model provides an explanation of why bad things happen at the individual or the person level in the context of where they're working. An error-filled paragraph was used to illustrate the amazing cognitive ability humans possess in processing information. It's a power not often recognized. A second quote was used to illustrate that these same types of cognitive skills also sometimes let people down, for example, when critical information is missed.

He provided statistics relating to general error rates, especially in high stress areas like health care. These rates need to be taken into account when an organization is assessing why bad things happen. Is it because of bad people? Or is it because of the way our brains are hardwired?

Dr. Flemons also noted that one of James Reason's cautions is to avoid the myth that bad people make bad mistakes.

He highlighted newspaper clippings to demonstrate the reaction of some of the print media in Calgary, following the 2004 potassium chloride tragedy. Naming, shaming and blaming is the reaction of the person model.

Dr. Flemons provided an overview of Reason's "Swiss cheese model" to illustrate why errors happen. A video clip featuring Dr. Reason discussing the system model, in contrast and distinction to the person model, was played for participants.

Dr. Flemons summarized by showing a slide depicting a pyramid of unsafe acts with people at the sharp end. A big contributor to these unsafe acts is errors. Human beings and errors are part of the system and part of what goes wrong, but they're not the only thing. There is also a context for why errors occur called the "local workplace factors."

According to Dr. Flemons, when organizations are thinking about "causes" they need to think about things, and when investigating is underway there is also the need to look past the individuals who perform unsafe acts. But there is also something which Reason calls "violations."

Calgary Health Region changed this term to non-compliance. He noted that Region has also availed of the expertise of Jan Davies, an anesthetist at the University of Calgary, who has worked in the field of patient safety for years, has worked closely with Jim Reason and obtained his approval to start talking about non-compliance rather than violations. Violations or non-compliances are really where there is a standard operating procedure, a guideline, a written procedure for how to do something and somebody doesn't follow it. It's not an error. It's an intentional act because they didn't do what they should have done. He pointed out that sometimes there is a good reason for that.

Dr. Flemons also noted that there is the very, very infrequent willful intent to harm called "sabotage," where somebody is actually intent on hurting people. What Reason actually encourages us to think about, noted Dr. Flemons, is that errors happen all the time. He added that punishing people for making errors doesn't make the system safer, even though "heads have to roll in a matter of public confidence."

Dr. Flemons outlined some of the issues surrounding the 2004 potassium chloride tragedy in Calgary to illustrate how events can be investigated, tracked and managed. He noted the possible contributing factors surrounding the adverse event, including the role of the staff closest to the event, the system of checks in place and the manufacturing, packaging and labeling. All were pieces of Swiss cheese, noted Dr. Flemons. All the holes lined up that day, and as a result two patients died.

Dr. Flemons' added, Reason would say that these staff were actually set up to make this error. The people who designed this system were operating on the basis of efficiency, and not thinking about how bad things might happen.

Dr. Flemons noted that the Reason principles of the system model stress that safety really needs to be engineered into the system. He noted that making safer systems is not about redesigning people or getting rid of people, it's about redesigning systems. As Don Berwick said, "Every system is perfectly designed to achieve the results it gets; it is about design and taking the time for design." In health care, Dr. Flemons noted, we're often too busy to really stand back and design from the ground up with safety as the central tenet.

Creating a Culture of Safety

Dr. Flemons stated that his interest in the safety culture of the Calgary Health Region peaked after the potassium tragedy. He indicated:

- The organization subsequently received help from an external review team led by Rob Robson of Winnipeg.
- Dr. Robson demanded that he not be limited to reviewing just pharmacy practices but should have access to the entire gamut of the Calgary Health Region and part of that involved reviewing the culture of safety.
- Other leaders, such as Lou Gesner, a retired CEO of IBM, and organizations such as the National Quality Forum, promote the idea of creating a culture of safety.

- He also referenced James Reasons' second book, *Managing Maintenance Error, 2003*, in which he describes what an organizational safety culture includes. A learning culture is driven by a reporting culture. A culture that, when it sees something that is wrong or could be wrong, is willing to stand up and alert the organization.

Dr. Flemons noted that if there is to be a learning organization, there must be a reporting culture, and this is not possible unless there is a *just* culture. People who work for the organization have to feel they're safe, that they can stand up and point out mistakes, point out their own/others errors, point out unsafe systems, and not be taken to task for it. He indicated that when Calgary Health Region thought about this they really saw a "just reporting and learning culture" driving what they call "safety management."

He outlined the thinking and events that led to Calgary developing a "just culture policy."

He discussed the organization's insight regarding disclosure to patients, and recognized that they did not do it well. He also talked about the influence which subsequently came from the participation of the daughter of one of the patients who had died.

According to Dr. Flemons the organization subsequently set out to create a disclosure policy, and then a just and trusting culture policy. Following discussions the organization defined

- **disclosure** as "that conversation an organization holds with patients and families when something goes wrong";
- **reporting** as "that conversation that employees and physicians of Calgary Health Region, including physicians who don't work in the region, have with the Calgary Health when they see something not right";
- **informing** as "that conversation that the organization has with every other principal stakeholder and key partner that they have when things go wrong."

Dr. Flemons shared a diagram to highlight what patients experience, or are exposed to, including hazards, close calls and adverse events. He also stated that when adverse events/ close calls are recognized by a health care provider, reporting to the Calgary Health Region is expected. That information, he added, is used in combination with the providers, to disclose back to patients when they have had adverse events and close calls. The organization also needs to give feedback to providers about that reporting. The diagram also illustrated how the informing aspect interfaces with other groups. All of this discussion/sharing is founded on a just and trusting culture.

Dr. Flemons commented very briefly on the meaning of a just and trusting culture and the two types of evaluations that occur when things go wrong:

- A system evaluation or a safety analysis where the focus is on systems versus individuals, and it involves a structured, analytical approach and a root cause analysis. Here, he noted, the process, not the tool is important.
- An individual contribution to adverse events is also important, but it should be separate from the safety analysis. In Calgary, it is called an administrative review, and is done by a different person who has administrative authority. Roles, responsibilities and competencies of people are looked at, but from the right perspective.
- The concept of hindsight bias and "actual" versus "close calls" and how they are dealt with was discussed. A just and trusting culture says that it shouldn't matter what the outcome is. Calgary Health developed a policy around this that actually states that if a health care worker makes an error, discipline will not result.
- A just and trusting culture promotes accountability, and where there is willful intent to harm, there is "no tolerance."
- The tough stuff centers on non-compliance because sometimes there is a good reason for people to be non-compliant with the policies and procedures of the organization. Sometimes there isn't a good reason. What the policy basically says is that the organization will fairly evaluate people who didn't follow standard operating procedures/guidelines.

Reporting Policy

Dr. Flemons noted that the Calgary Health Region's reporting policy on adverse events recognizes that Adverse Events are really only the tip of the iceberg and that:

- "Close calls" are really where the focus of attention should be, if for no other reason than that they're more common than adverse events. They're free lessons.
- It is necessary to tap into people's understanding of how close calls can translate into harm for patients and act before it actually does.
- The World Health Organization has developed draft guidelines on what makes a good reporting system. It's really based on the best of the business, both in health care and also the airline industry; it stresses learning systems.
- In Calgary, the organization tried to encourage employees to report safety hazards, not incidents. This is not a tattling system rather a need "to fix the system."
- The organization now has a safety/ learning/ reporting system, not an incident reporting system, which was launched in March, 2008. It is a confidential web-based system which promotes reporting.

Disclosure

According to Dr. Flemons, disclosure is about stepping up and admitting that things do and have gone wrong in health care. Calgary Health Regions' disclosure policy acknowledges all harm. The definition of harm is akin to what the Canadian Patient Safety Institute has defined as an adverse event: when it's related to the health care received, not related to underlying disease. He noted:

- the organization will apologize for all harm, but the level of harm will dictate how the organization discloses, who discloses, and how complicated that disclosure looks. Discretion is used for close calls;
- apology legislation doesn't exist in Alberta yet;
- factual information is actually disclosed;
- because there is more than one victim, support is offered for health partners, patients and their families as well as for staff, physicians and health professionals.

Managing Adverse Events

Dr. Flemons acknowledged that adverse events will happen, and the only thing worse than an adverse event happening is dropping the ball a second time by not managing it well. He advised that the focus is really on harm, the adverse event itself and its immediate and continuing management. This comes down to what model one is based on, the Person or the System Model, which would dictate the management strategy employed.

An algorithm set up in Calgary to train senior health care providers and senior management about how they should deal with adverse events was discussed. The acronym RESPOND has been adopted to identify some steps that need to be taken immediately after it appears as if the patient has been harmed. This will be discussed further below.

Dr. Flemons noted that it is important for an organization to have the Person Model versus System Model figured out, and alluded to newspapers and journals that do not. If the "person model thinking" is supported, these organizations will disclose medical error, because people make errors.

If a "System Model" is supported in terms of how the system failed, they would disclose harm, not medical errors. Dr. Flemons surmised that we can't seem to get this across to the academics who write about patient safety.

Informing

Informing sends a strong message about transparency and opens up the possibility of healing. This is important in health care as everyone knows the system isn't perfect.

Individuals can't heal, Dr. Flemons noted, if one can't admit the fallibility of the system. He discussed the role of key leaders within Calgary Health and the excellent leadership demonstrated during the potassium tragedy. Public discussion also occurred around the time when Calgary was hosting the Halifax 5 Canadian Health Care Safety Symposium. A public forum was organized and stories told of patients who had suffered unanticipated outcomes in the Calgary Health Region. The public, the media and all health care providers were invited. International safety experts, who were part of the Symposium, also attended, and video clips of patients telling their stories were featured. He highlighted a specific clip featuring the CEO, who in Dr. Flemons' opinion demonstrated remarkable courage in telling the stories.

Setting a culture of safety, noted Dr. Flemons, has to come from the very top. People in the organization are always looking at what their leaders are saying, and if they're not saying anything, patient safety probably isn't a huge focus for the organization. A patient-and-family safety council was subsequently formed, and it includes a family member of one of the patients who died. She has been very active.

Healing also occurred when the family member and the Pharmacy Director, where the potassium tragedy occurred, met some two years later to talk and seek reconciliation for what had happened to her mom. It was quite therapeutic for both.

The Calgary Region Patient/Family Safety Council is an active group who sometimes pushes the region really hard. Each and every one of them has a tragic story to tell. And they're led, he noted, by an extremely capable facilitator, Sharon Neddleton. She's the support for the Calgary Health Region who keeps this group going. They've been exceptionally important for the whole safety movement in Calgary.

Conclusion

Dr. Flemons advised that, for him, a patient safety culture is based on trust and transparency. He likened this to a three-legged stool where, in order to keep patient safety stable, three supports are required: the organization, the patients/clients and the providers/staff. Disclosure firms up this tripartite relationship. A just and trusting culture supports that relationship vision. Reporting hazards and safety events will happen more frequently when there is a just and trusting culture. On the "platform of informing," there is also need to have the trust, respect and confidence, through transparency, of the people served. Whenever an adverse health event happens, an organization runs the risk of losing confidence. People's confidence is mostly shaken when they think that the organization isn't being open, and there is a perception of hiding.

Dr. Flemons noted that informing happens to providers, to other health care organizations, and sometimes to regulatory agencies. He indicated that all of these things need to be improved.

A number of comments /questions arose from participants:

Q: With respect to reporting, is it done anonymously?

A: Dr. Flemons advised that the report is not anonymous, but it is confidential. He noted that the report is filed with clinical safety leaders. They immediately scrub any information that is identifiable, including the patient's name and the reporter's name. Only the patient's anonymous story is told.
Calgary Region's understanding of their safety reporting system is that (the report) would be deemed a piece of information of a quality assurance activity that would be protected

against any legal attempt to get to the background report. You absolutely have to assure people of that.

Q: What is the patient's role in creating that culture of safety?

A: Dr. Flemons commented that Calgary Health Region has just started a campaign called Safer Together, where they talk to patients through both video and print about their role in making the system safer. He expressed that the very heart of this is putting patients in the centre of the care team, rather than adopting a rather paternalistic attitude and telling patients what the organization is going to do with them. Inviting patients to be part of that process would go all the way from extending an invitation to join daily rounds, in an in-patient setting, to making sure that they understand how they can protect themselves, such as asking practitioners to wash their hands, checking their medications, knowing their medications etc.

Q: An audience member asked Dr. Flemons to further discuss aspects of the administrative review when looking at health care workers.

A: Dr. Flemons advised that this is a 1,000 mile journey and that Calgary Health Region has only taken a few steps down this road. He noted that the organization is trying to encourage an administrative review be conducted by somebody with administrative authority, a front-line worker and by those involved in the health event itself. The idea would be to train this team in how to evaluate people fairly by looking at their actions and behaviors at the time they made decisions, rather than judging them after the fact. The safety analysis is done by a small group who has no administrative authority over the individuals that are actually part of that adverse event. He noted the team would assess the communications systems, the equipment, how people are interacting and any systemic problems the breakdowns from a system level. .

Panel Presentation: Perspectives on an Adverse Event Management Framework

The Forum chair introduced the four panelists participating in this session: Paula Beard, Director of Operations with CPSI; Dr. Daryl Pullman, Professor of Medical Ethics at Memorial University of Newfoundland; Dr. Ward Flemons; and Susan Abell, Management Resource Consultant, who has extensive experience in community-based organizations.

Assessing Adverse Health Events: Measurement Tools – Paula Beard

Ms. Beard provided an overview of a root cause analysis that took place in response to an adverse medication event, which led to a death at the Cancer Agency in Alberta. The Agency released their report publicly. During the course of the investigation it was discovered that the same or similar incident could happen in other health organizations. The systems failures that were identified in this event exist in other cancer treatment centers. In fact, similar events have happened before, although causal information and learning from previous events are either difficult to find or are unavailable.

She noted that event analysis is being done in Newfoundland and Labrador, the Calgary Health Region, as well as British Columbia. Saskatchewan has at least 16 reports that are widely available. An important job for her, she added, was to start to coordinate that information and make it available from one end of this country to the other.

A variety of tools can be used by organizations to determine the causes of adverse events and to prevent similar ones from happening. Ms. Beard acknowledged that there are several different methods of identifying information about events – some of those fall within the organization and some outside, as is occurring in NL.

Four specific tools were identified as useful in starting to identify learnings from an organization own reported events:

- trigger tools, probably most widely made available by the IHI in the US;
- event analysis;
- peer review; and
- failure modes and effects analysis (FMEA).

From an external perspective, Ms. Beard also noted the use of public inquiries/coronial reports, reviews, inquiries and regulatory reviews. Organizations' Claims Registries, she pointed out, are often rich in information.

Trigger tools are essentially signals for detecting probable adverse events, and they're fairly simple to use and identify. They're utilized for retrospective reviews, but they have also been used in real-time events. These tools can actually be used in concert with event analysis.

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Event Analysis is very much criteria-based, and provides a simple solution, although it is not easy to perform. It is intended to determine what happened, why it happened, and what could be done to reduce the likelihood of a recurrence. An organization has to gather the information and obtain an understanding of what happened. Additional information may be gathered through interviews; policy reviews; identifying photos of the event, or walking through where the event took place. A literature review is done to find out where this has happened previously and how it was dealt with. An understanding and a final timeline is also attached. The analysis starts by working through contributing statements to determine the root causes, formulate causal statements and develop actions. The participation of the organization's leadership is absolutely required for credibility.

Ms. Beard noted that there are four levels of analysis developed by CPSI, including root cause analysis that can be applied to close calls and actual harm events.

(i) A one-page structured template is usually used to study low harm events, and it contains all of the items, including collaboration with staff and physicians and identifying contributing factors.

(ii) The next level, in terms of intensity, is the time and resources required to do a basic **root cause analysis**. It involves a full analysis by a small ad hoc group, and includes staff and physicians local to the event.

(iii) A comprehensive root cause analysis would require more resources, and likely include external, independent experts and consultants, and is usually conducted for severe harm, death and critical events.

(iv) The type of report that's produced when a major event, such as happened in the Calgary Health Region, is based on a full investigation and process by an independent agency. High volume, high impact events, such as falls or attempted suicides, where some of the work being done is through aggregate analysis, may also be completed.

On a quarterly basis, noted Ms. Beard, an organization would conduct an assessment, find out where weaknesses exist, and provide follow-up to make the system more robust.

Peer Review is probably one of the oldest forms of review. Generally it's a function of the medical advisory committee. It addresses issues of diagnosis and treatment choices and most often involves a single discipline, but some of the new and emerging models are actually interdisciplinary.

Failure Mode and Effects Analysis (FMEA) is a prospective attempt to predict error modes (the likelihood of a particular process failure) and is combined with an estimate of the relative impact of the error to produce criticality and deaths. An example might be looking at the medication system to identify weaknesses, without an event being present, to determine the probability of errors, and how critical such potential failure(s) are to the process. Steps in the process are ranked so that in the final analysis an organization can determine which areas should be addressed on a priority basis.

In summary, Ms. Beard noted that root cause analysis, FMEA, trigger tools and other tools all come together. She noted that each one can work separately or be combined to provide a more comprehensive analysis. Each analysis can be time consuming but can provide a meaningful way for organizations to address potential adverse health events without being overwhelmed.

Disclosing Adverse Health Events: Ethical Considerations – Dr. Daryl Pullman

Dr. Pullman noted that in discussing the disclosure of adverse health events and ethical considerations, a discussion of values was important. Values are complex, and often come into conflict with each other. There are broad social values that are set by social policy, institutional values that are tied to institutional goals and personal values that affect our goals in life. When organizations talk about disclosing adverse health events, there is the need to think about the values at a number of different levels and where conflicts may arise.

He noted that from his perspective as a clinical ethicist, many of the issues that arise are communication-related/failure to communicate issues. Analyses are needed because there are complex issues at every level. To communicate that complex message is very difficult, and how we manage it in terms of disclosing determines whether or not it will break down at the end.

The media, however, wants to have a simple message, a story. They don't want to have a lot of statistics; they want a story about a patient who had something go wrong. Who's responsible, and whose heads should roll?

Dr. Pullman indicated that the moral maxim, "knowledge entails responsibility" often comes into play. He presented some slides to illustrate his point. If one has information/knowledge that is of material importance to the physical and/or emotional well-being of another individual, one has a duty to act upon that information. At times, one might think that duty to warn, or duty of care, is related to the distance from the event. Questions such as how close do you have to get to investigate, and how much more information do you need to know, and who is responsible for informing a person that an accident may occur, are likely to arise. In other words, in terms of disclosure, who's responsible for what is important.

He noted that generally four principles are used as the principles of biomedical/health care ethics, and include:

- autonomy – an individual's right to have control over their own life, self-rule – respect for the individual's right to the ability to control their own lives;
- beneficence – the duty to do good;
- non-maleficence – do no harm; and
- justice – fairness.

Often an ethics analysis includes a quick run-through of those four principles. Dr. Pullman noted that, seen as a kind of ethics first-aid, they're very useful principles that can help to identify some issues. Generally, however, ethics is deeper, and more complicated than just running through these four areas.

In terms of disclosure or reporting, Dr. Pullman referred to a moral geography in terms of mapping out where we are in the ethics landscape. A series of questions was posed for consideration when considering an adverse event: what to disclose; to whom to disclose; when to disclose; and how to disclose. He noted that it's not always the same person, group, or body that is responsible for gathering the information and for deciding whether enough information is known.

He presented some of the ethical tensions which come into play – the right to know, for example, versus the duty to protect. Who has the right to know and who are we trying to protect? And duty to protect doesn't just mean that we're trying to cover something up. We may have other responsibilities as well, and the tension between autonomy and beneficence can come into play.

He noted that philosophers often talk about the fundamental tension between the "right versus the good" parts of a broad spectrum. He illustrated this via a slide. What weight should be given to individual privacy rights? Does the public have a right to know? He noted that this work comes into play when we start talking about managing disclosure, because at different levels we have what we call micro and macro considerations:

- At the **macro** level, government sets general health policy, in an anonymized way and at a very broad level, to disclose certain kinds of information, such as a public health issue;
- At the **meso** level, where the institutional perspective is considered; and
- At the **micro** level, where a specific clinical situation is at play, the context of disclosure is somewhat different, because now an individual story is being told.

Dr. Pullman advised that tensions will exist because of the different perceptions of the right and the good. Key questions to be considered when gathering information and data were presented. He discussed the rule of justified paternalism that places sick, vulnerable patient's way down on the autonomy scale. But our goal in health care is to treat people and get them way up on the autonomy scale. The same applies in giving information. Intent in disclosing information should be based on wanting to move people back up the autonomy scale.

Many of the struggles organizations have when they do assessments and begin to understand systemic problems, and are trying to take steps to fix them, are around what needs to be immediately disclosed to the public and in what way. He provided the bottom line principle – transparency is always the best policy. What to disclose, when and whom to disclose, and how to disclose must be assessed carefully and deliberately, in order to ensure the enhancement of patient and public autonomy rather than the undermining of it.

Acting on Adverse Health Events: Dr. Ward Flemons

Building upon the information presented as part of his keynote address, Dr. Flemons presented additional information concerning the immediate and continuing management of adverse health events. He referred to his organization's RESPOND acronym as the basis for discussion.

R means resuscitating the patient – it's what health care professionals do and are trained to do. People usually don't have to be reminded to do that, but it never hurts to just be alerted.

E is to ensure the environment is safe. If one patient is in danger it could mean that there is something else or other people are at risk in the immediate vicinity. Determining whether the providers are still able to provide care should be also taken into account.

S means secure the equipment. It is often challenging for health organizations when things go wrong and there is a piece of equipment involved (and, as people are dealing with the immediate events, the equipment goes one way and the patient goes the other way). Isolating the equipment to find out what role it had is important. It may also mean that the equipment is dysfunctional and shouldn't be used on other patients.

P represents protecting other patients and providers. The example of the potassium tragedy, where approximately 30 bags of dialysis circulated throughout the region, was noted as an example where people, outside the immediate vicinity could have been harmed.

O focuses on the idea of offering initial support, both to the family and to the providers.

N is the idea of notifying, which involves letting people in the chain of command know that something has happened. Relying on reporting systems is not recommended here. Doctors have a hard time understanding this concept because they are not used to the idea of a chain of command.

D represents disclosure as an early conversation, an acknowledgement that something has happened, and about all you can do at that point is to promise to look into it. One of the lessons learned from their Patient Safety Council is: don't speculate.

One of the important questions here is, Who does this initial assessment? Who is responsible for getting this timeline of information and looking at it and saying, So now what? Do we handle this as a serious adverse event? Do we start mounting a safety analysis? Do we start talking to the family as if this is an adverse event? Who makes that decision? In Dr. Flemons' opinion, it should be someone far up the administrative chain (but below the CEO), perhaps the vice-president.

In terms of advocating, Dr. Flemons mentioned that his organization hears from patients and families all the time that "we've let them down in terms of supporting them, that we

don't offer them the psychological support they need." Offering financial assistance to bring a family member to where the event happened, he suggested, is a good idea.

Communication, noted Dr. Flemons, centers on the idea that disclosure involves reporting and informing, as well as evaluation. He added that his organization has not gotten far with respect to administrative reviews. They are relying on Jan Davies to adapt some of James Reason's work around the concept of culpability and holding people culpable for what they did, as opposed to the idea that they are as much of a victim as the patients.

In terms of the practicalities of managing adverse events, patients, according to Dr. Flemons, experience two types of disappointments: the disappointing outcome that they experience as being a part of the adverse event, and the disappointing way that people act or the health care system responds to them after the fact. They often feel isolated; nobody talks to them because people are afraid of what to say. Research clearly shows, however, that patients are willing to forgive the first mistake, but not very willing to forgive the second. He recommended that this is where organizations really need to pick up actions and behaviors around managing adverse events, and not letting those communication channels break down even further after an adverse event happens.

Dr. Flemons also noted Calgary Health Region now has a counseling and grief support program for patients, as well as the financial support for "out of pocket expenses" which, he added, goes a long way in telling patients and families that you are thinking about what they need.

In terms of a disclosure team, Dr. Flemons recommended that organizations give consideration to the provider that was part of the adverse event being involved, versus a CEO. In addition, because there will be a need to answer clinical questions, clinicians need to be at the table. Financial questions may also have to be answered, so a team is needed. He also noted that the disclosure conversation with patients is not one event but a process, and may involve a number of meetings.

Two roles are critical in managing adverse events:

- a senior administrator role: one person who is accountable right from the outset; and
- a patient liaison person who is assigned to the patient. This assures the patient that they have an entry point into this complicated, complex organization, and that this person will act as their conduit.

Dr. Flemons provided an overview of an algorithm to demonstrate how all of these elements/roles in managing an adverse event come together for that disclosure meeting with the patient and family.

With respect to conversations with patients, Dr. Flemons noted:

- The **first** conversation acknowledges only that something went wrong;

- The **second** conversation focuses on indicating what the organization understands to date, and telling what is known "now." This avoids the perception that information is being hidden.
- Following completion of the safety analysis, there is a need to figure out how that information is passed on to patients. That's usually the **third** discussion. What takes even longer is learning what recommendations from that safety analysis the organization is actually prepared to commit to. That doesn't happen right away, so you usually end up having another conversation saying, "Here is what the organization is going to do to try to keep this from happening to somebody else." What patients really want to hear is, What are you going to do to make it safer for people who come after me?

Dr. Flemons indicated that the lesson they have learned is that senior administrators and medical leaders must control the game, and they must understand that. A safety committee infrastructure is necessary so that lessons learned can be shared.

He noted that it is really hard linking recommendations to stories, however, without the stories events are pretty shallow and most people won't pay attention to them over the long term.

In terms of the Evidence Act legislation, Dr. Flemons indicated that it's different in every province, and depending on how you interpret it and who you talk to, it will dictate whether you can share, or think you can share, the evidence with patients and families outside of protected quality assurance.

There is a need to develop permanent communication and education strategies, so that once lessons are learned they can be shared throughout the organization.

Informing, noted Dr. Flemons, is having that conversation with your broader public stakeholders that may not be strictly necessary. Calgary Health has three reasons for having such a policy:

- everyone within the region has a right to know when there has been a substantial chance of risk to their own personal health and well-being;
- maintaining confidence and transparency; this is probably more important when it comes to an adverse event;
- the necessity of letting other people learn from your adverse event.

He noted that getting negative media attention is a given, and it's hard to withstand that. It's extremely demoralizing to everyone in the organization. Also expect related stories to get into the media.

While demoralizing, informing helps normalize the system discussion around individual and system failures. For the first time you start talking about the idea that you're not perfect. We can't learn if we don't talk, and we're probably not going to learn if we don't share.

Informing also gives permission for others to share. There is nothing like another health care leader standing up and talking about adverse health events to send the subtle signal, or perhaps not so subtle signal, to the rest of the organization that it's okay to talk. It's okay to talk to the rest of your patients, and it's okay to talk to your colleagues. We've set a different culture in Calgary Health Region, noted Dr. Flemons. "It's really important for healing. If we don't talk, we don't heal."

Community Perspectives on an Adverse Event Management Framework: Susan Abell

Ms. Abell began by telling participants that how she prepared for the forum (without slides), in some way signifies, or is a symbol, of, the community services sector.

Community services, she noted, like health care, are the ones being provided right this moment to the people of this province and across the country. But it is the people on the streets, and in the daycares and in homes and in group homes and foster-care settings and a great variety of places who want and need the service. One can only think of all the variables that will come to play noted Ms. Abell. She indicated that when she saw the image of the "Swiss cheese model" she felt that one could put a lot more holes in those barriers when you think of the environment were services are being offered and delivered.

Community services, Ms. Abell noted, are often not operating within a structure, not within the walls of a building or an institution. In the community it is when, not if, adverse events happen." Often they are open to a lot more scrutiny and public opinion, because they happen very much in the community. Certainly in social services/human services, a great variety of opinion and expectation always abounds, so the handling of adverse events is one that is obviously a part of everyday life, and is very difficult to manage without structures and models.

Community is also the system, the organization, the service itself; it's the allied professionals and, of course, it's the public at large in the communities that we're working in. Often the media, she noted, finds these types of services as "good grist for the mill" in terms of human interest stories; they also see themselves as very much needing to be at the forefront of pushing issues such as child abuse or other ineffective services; that perhaps they need more attention to bring them to the level of the community.

Ms. Abell spoke of some of her experiences in community-based organizations in Ontario. She asked participants to think of transposing even a small amount of what they heard this morning into the community, whether it's the child welfare system, daycare providers, or the youth justice system. You must have an alert system where you cam document and report the event. Investigations will depend on the level of the event, how adverse it is and its impact. It isn't enough, she noted, just to say we're good people doing good work. The

benefit has to come from reporting it back, and looking at the themes and issues coming out.

And when you see, for instance, numbers of children threatening suicide, who are living in group homes, and staff responding inappropriately, it doesn't take long to realize that training is needed. They aren't just "one-offs" because these incidents happen in one part of the province and then in another.

Ms. Abell noted that she's been involved in death reviews. Systems for these exist within health care settings, but also for children or young people, known to community services, who have either suffered great harm or even died. Models are there, but from her current experience, it's necessary to consistently bring people together to examine the circumstances – a multi-disciplinary approach. We need a better understanding in order to consistently determine what's happening and then bring these recommendations back to the people who have been involved in delivering the services.

An emerging issue is safe sleeping for infants. This does not only involve where they're sleeping. Children should not be left in playpens and waterbeds; neither should they sleep with parents who are intoxicated. The environment in which children sleep is a very important issue.

Ms. Abell noted that she was pleased recently to see one of the large Children's Aid Societies handing out pamphlets to families and going over these issues. It may sound small, she noted, but that's how improvements in the community system are made.

Reporting and reviews, she noted, must be at arms-length. She also noted that one of the most demoralizing things for staff, after the shock of the initial event (when it's a significant one), is to have someone come and do a review. And, of course, in regular reporting and reporting back, how many times do we hear people say, "Well, it was an issue but I never heard what happened or what we're doing about it?"

She related a story of someone in another organization who had to work through a very difficult inquest. The leadership team had learned, and knew that to keep everybody on the page and doing their job, every night before the team ended their work, they had to make a point of communicating. They did this by issuing a communiqué that everybody had available to them the next day.

She asked participants to think about good communications, especially where services are delivered in a community that may not only be diverse, but distant.

She related the story of a little boy of about nine or ten who drowned in front of three staff. He had just been placed in a group home, and had a lot of behaviour difficulties. His family had a number of issues – daily living issues, as well as issues managing him. The staff decided to take the children –there were four or five of them – swimming on a hot summer afternoon. The three staff were sitting down with the children not far away, within

eyesight, and this little boy drowned in front of them. When the situation was looked at, besides the family, obviously the institution, the organization, and the people who had placed this little boy there, were just overcome. It became very personal. Later when the organization could stand back, what became obvious was that the staff were good people. They wanted to do a good job. For a system or an organization it can be difficult to look at an adverse event and think well, we don't want to blame. We can't have an atmosphere that continually blames people. But when you stand back and look at a system, there are pretty big holes in that "Swiss cheese."

The only way we're going to move forward, noted Ms. Abell, is to import some of what we've heard here directly into our community services, our community partners, and put it in their context. That will strengthen our system. Good management is always needed through adverse events and makes us stronger. Continue to keep supporting your integrated regional health and community services model because you have an opportunity to sit together and make sure that everybody is at the table and can benefit from programs like these. The commitment to make those weak points stronger on behalf of children, families, and everyone living in your communities is important.

Comment: An audience member commented that she was challenged by a situation recently about the personal care of a man who had a stroke. The daughter's view was that her mother didn't need to receive a disclosure. The daughter thought that there were situations where it was actually more damaging, than helpful, for disclosure to happen. The participant said that "disclosure done poorly is absolutely worse than no disclosure, where you can say "It's better not to do it."

Phil Hassen noted that 98% of the time, disclosure is the way to go. He noted that there has to be some context, but it is often the context that overwhelms the reality of what a person would want to know. He indicated that he has not met a patient who has been harmed and who wouldn't have wanted to know. He also noted that he too had been challenged (on whether disclosure was necessary), but he would stay that course because "We've harmed so much on the other side and lost the trust of our patients because of that."

Q: What about the role of legislation, and the duty to report in all this?

Paula Beard responded that there are some natural tensions that exist between reporting, learning and protecting. She felt that depending on where you live, the legislation protects certain aspects. What we've seen, she noted, is a new trend or propensity to forego legislative protections in order to overcome this barrier to sharing. She further noted, however, that that brings with it some significant risk of creating a scenario where you have health care providers who don't want to be part of the conversation due to risks of liability.

Ward Flemons: It's a lot more helpful over the long term to create an environment where people are encouraged to report, because it's the right thing to do and people can see it can make a difference.

Phil Hassen: With respect to legislation, reporting is voluntary. It's your decision, an ethical decision, because no one else may know about it. So, in the end, you have to decide. Notwithstanding, the culture has to make it prevail.

Comment: An audience member commented on a recent case where someone died while incarcerated and who she indicated, "had been denied medication."

The Chair was not familiar with the case, but acknowledged many parts of our system need fixing.

The Forum Chair, Phil Hassen, showed a short video clip to illustrate that participants don't need to look outside themselves for leadership. He reminded participants that they are the leaders who will take this to the next generation.

Luncheon Speaker: A Personal Perspective

Ryan Sidorchuk, Patient Voice Facilitation and Safety Officer with the Winnipeg Regional Health Authority, shared his powerful and moving story concerning the loss of his young daughter Paige, to a "misdiagnosis."

The diagnosis was provided by an oncologist in another province while Paige and her Mom were on vacation. The diagnosis was Wilms' tumour, a form of kidney cancer most favourable to treatment. Ryan noted that the confirmation of it was quite important, not just within the health care team, but certainly for the family because it was the most treatable. The diagnosis would hopefully lead to Paige's recovery.

A subsequent pathology report, in Winnipeg, obtained as a result of a needle biopsy, also reported Wilm's tumour but added "can't be sure." In retrospect, Mr. Sidorchuk noted, "that probably would have been a good opportunity to do another biopsy; that would be the simple answer, although not necessarily the most easy", as with waiting lists it may have meant that another child would have had to wait.

Chemotherapy was commenced, as opposed to a full resection of the tumour and her kidney because, "According to the surgeon the tumour was too large to safely remove at that time. So the idea was to shrink the tumour with chemotherapy and remove it a little bit later." Mr. Sidorchuk noted that the plan seemed reasonable, despite it being a little bit at odds for the North American protocol for Wilm's, but supportive of the European approach.

Initially, treatment appeared good, however, around mid-September Paige's health really started to go downhill, and "About four days worth of pages and phone calls finally got us into Cancer Care to have her seen by a doctor." Her appetite and thirst markedly decreased, and a CT scan showed that, in fact the tumor had not shrunk at all, but it had in fact, grown. Her breathing started to become labored as well and it was decided that, on an emergent basis, Paige would go into surgery and have the tumour removed.

About a week after the tumour was removed the family found out that it wasn't Wilms at all, it was a tumour called the Rhabdoid tumor of the kidney, which is the deadliest form of pediatric kidney cancer. The one-year survival rate is just 30%, and it's a terrible, terrible disease like any cancer, Ryan stated.

Ryan noted that the surgeons were unable to "get it all." It was quite extensively wrapped around the retroperitoneal cavity and spinal cord etc. and "They couldn't sew her abdomen, so they packed it and netted it and she spent the last month of her life in ICU with an open abdomen and, basically to help control her pain, in a medically induced coma."

On October 30 the breathing tubes were removed and Paige passed away. It was finally at that time that Ryan and his wife were able to hold Paige again. He noted that "It had been over a month while she was in that bed in ICU that we could not hold her. We could only

touch her hands, and indeed her hands needed to be restrained from this nervous twitch that she had developed". It was a very, very difficult time, he noted.

About seven months later, Ryan noted, he initiated a conversation with Dr. Rob Robson, Chief Patient Safety Officer in the Winnipeg Regional Health Authority and talked to him a little bit about what had happened during Paige's care. He noted that Dr. Robson seemed to think that he was coming at it from a fairly positive point of view. He noted that he wasn't looking, at any point, for any one individual's head on a platter. He stated that he knows this is sometimes the response of patients and families, and has seen it himself in patients and families that he has worked with. He reminded participants that there is a real injury to what we understand as fair when something like this happens, and it takes a long time for people to work through that and, indeed, many never do.

He noted that a good friend of his, John Lewis, who also lost his daughter, Claire, to some preventable adverse events that happened during her care, puts it really plainly: "If we weren't out here doing this, like today, and like John does quite regularly across the country, we'd be in the looney bin, in a mental institution." and he indicated that he meant no disrespect by saying that. "If you're not part of the solution, then you're probably part of the problem, and I wanted to try to be part of the solution." he noted.

Ryan noted that he has since been working with the Winnipeg Regional Health Authority and organizations like the World Health Organization and said that he's enjoyed a terrific relationship with the Canadian Patient Safety Institute for several years now. They've been instrumental in getting an organization called Patients for Patient Safety Canada, up and going. He indicated that he hoped his conversation will create a seed in everyone when looking for an organization to partner with on initiatives that require patients and families to be involved in an improvement team. They would welcome the opportunity to sit at the table with you and be a part of that solution.

He noted that we talk a lot about measurement in patient safety and "that which is measured gets managed." It makes sense in business. Certainly it makes sense in a lot of different aspects in health care, but sometimes, he noted, it can lead us astray. He stated for example that participants had probably all heard quite clearly the idea of a culture of safety or a culture of reporting. Those types of notions are inherently difficult to measure, whereas, health care-associated infections are quite easy to measure. So you may see at times a disproportionate amount of funds geared towards antibiotic resistant organisms, for example, instead of creating systems and methods for us to all communicate better and to all work together, instead of at times feeling like we're at odds with one another.

He related that one of the most frustrating aspects of Paige's care was the numerous experimental treatments that were brought to the oncology team and, one after another, were dismissed as impractical or not possible. He also indicated that since Paige passed away he has seen journal articles that have shown quite a bit of success with a few of those different treatments for Rhabdoid tumour of the kidney and many other types of cancer

that have been typically resistant to many of the chemotherapies currently used today. He noted:

- He felt like one of the team, until things went wrong;
- When the family needed help the most, the doors started to become closed. That's something very interesting and very tragic about patient safety events around the world;
- "We're starting to move in a different direction now, and I applaud that and welcome it with open arms. But traditionally when patients have been harmed, the wall of silence goes up and information becomes sparse, becomes filtered, becomes non-existent sometimes";
- With the CPSI's promotion of disclosure guidelines we're starting to see that change. He noted that Calgary Health Region has been a leader in this initiative, and actually helped Winnipeg Health Authority identify Dr. Dan O'Connell as a good person to come and teach the organization how to properly disclose information to patients and families;
- These are some of the most difficult conversations that you will ever have in your life as a provider or as a patient or family member. It's bad news of the worst kind;
- Participants need to be aware of their own emotions and skills when it comes to dealing with these types of issues with patients and families, as it's a complex type of thing.

Ryan noted that there are still times when he feels a tremendous amount of anger and rage over what happened to Paige. A lot of times, men, in particular, will internalize the event and tend to view it as their mistake. As her father, he felt he should have been able to protect Paige. He noted that it's really only been during the past year that he's been able to fully forgive himself for what happened to her.

He provided a couple of reflections on safety, a nebulous concept from his perspective. It's very hard, he noted, to pinpoint what the issue is, especially for negative evidence, and he wondered how we prove that we're getting somewhere that can only be shown by a "lack" of something happening.

Ryan spoke of the World Alliance for Patient Safety Now, which was launched probably in response to the Institute of Medicine's 1999 report, "To Err is Human," and a number of other incident studies that were coming out. Individuals involved in the Canadian Adverse Event Study, he noted, have been integral to the advancement of the World Alliance for Patient Safety's initiatives. He stated that this was one of the six original work strands and to ensure the perspective and viewpoint of patients, families, and health care consumers from all corners of the globe, it is infused in the efforts of all work strands, of the world alliance, and carried out through full partners and initiatives.

Ryan noted that he had the privilege of being part of the research group (from Argentina, Harvard and Europe) that looked at the gaps in knowledge that currently exist in patient

safety literature. When asked to identify the one goal he would like to see implemented for patient safety he noted that he chose clean, safe and effective desalinated water, because so much is undrinkable around the world.

He noted that Patients for Patient Safety Canada met November in Winnipeg with the help of CPSI and some folks from the Calgary Health Region, such as Sharon Neddleton. They discussed how they were going to get this initiative "on the lips of every health care organization in the country," and noted that they are starting to get there. An election for a board of directors for the organization was held, and Ryan indicated that he was pleased to be one of the twelve individuals elected.

They were the first group to establish a strategy. The vision is to make every patient safe; the mission is to champion the patient voice in order to advance the safety of health care. The organization has four goals, which include:

- to promote the CPSI Canadian Disclosure Guidelines;
- to engage with researchers to influence the research agenda inclusive of the patient experience;
- to establish an inventory of leading best practices that have led to patient safety and advocate for further adoption;
- To be continual learners in education about patient safety.

Ryan noted that some of the challenges included the fear felt by health care providers. What will the patient say? He noted that he heard an interesting comment: "…that we would meet with patients more regularly if they just wouldn't use the F word so much." Sometimes patients have a right to be angry, he stated. How patients use that anger is sometimes destructive, not only to building partnerships, but also to themselves.

From his own perspective, he indicated that he's tried to adopt a stance of non-anger and forgiveness, because he recognized, in part due to his academic background in conflict resolution, that a person who benefits the greatest from forgiveness is the forgiver. He made the decision that he wasn't going to let this consume him for the rest of his life, although it consumes a tremendous amount of his time, but in a way that he feels both positive and hopeful about.

Workshops (One to Five)

Five concurrent workshops featuring a presenter, facilitator and recorder were held on the following topics: Using Health Information Systems for the Management of Adverse Events: Assessment of Adverse Health Events; Issues in Disclosing Adverse Health Events; Operational Response to an Adverse Health Event: Short and Long Term; and Leadership, Coordination and Communication of Adverse Health Events.

Workshop One: Using Health Information Systems for the Management of Adverse Health Events

The session was led by was Mike Barron, CEO, Newfoundland and Labrador Center for Health Information.

Mr. Barron provided an overview of high-level justification for the use of information systems to manage adverse health events and improve patient safety. He presented statistics to justify the need and noted that for every one thousand (1000)

- hospital admissions in Canada, 75 people will suffer an adverse event ;
- patients with ambulatory encounter, 20 will suffer a serious adverse drug event;
- patients discharged from hospital, 90 will suffer a serious adverse event with the drugs received upon discharge
- laboratory tests performed, up to 150 will be unnecessary (range 50-150);
- Emergency Department visits, 320 patients had an information gap identified, resulting in an average increased stay of 1.2 hours;
- women at risk for cervical cancer, 300-400 are not screened;
- Canadians recommended for influenza protection, 370-430 are not vaccinated.

Mr. Barron noted that a key assumption is that "The availability of comprehensive, accurate, relevant and timely information at the point of care can reduce adverse health events and improve patient safety." He also noted that a key success factor involves the adoption of electronic health records by health professionals.

He also provided a historical overview of the Provincial Health Information System in NL and stated that implementation began in the early to mid 1980s with Meditech in the acute-care hospital system. NLCHI was established in 1996; in 1998 the first integrated community health system (CRMS) was introduced, as was the first Diagnostic Imaging/ PACS system; 1999 saw the first region-wide electronic patient record; in 2001 the provincial client registry became "live". In 2002 NL was chosen as national CR/UPI lead by Canada Health Infoway; 2003 saw the Pharmacy requirements completed; during 2004 planning occurred for Pharmacy, DI/PACS, Telehealth and iEHR, with Infoway supporting these projects in 2005.

Mr. Barron noted the differentiating factors between EHR (electronic health record) versus EMR (electronic medical record) versus EPR (electronic patient record). In terms of the NL Provincial Electronic Health Record, Mr. Barron used a schematic to demonstrate the multitude of interfaces involved, such as hospitals, public health surveillance, community pharmacies, laboratories, registries, cancer care, long-term care etc.

The **Regional Occurrence System Enhanced (ROSE**) is an Eastern Health Initiative, partially funded by Infoway. The occurrence reporting (OCR) process "facilitates the identification, monitoring and analysis of adverse events and incidents that take place during health care treatment and /or within health care long term care facilities." It also tracks complaints about the service. Mr. Barron noted that the OCR is the key health care tool used in pursuit of greater clinical safety and satisfaction.

The ROSE Project, noted Mr. Barron, will entail the development, implementation and evaluation of an electronic occurrence reporting system across the Eastern Health (EH) continuum of patient/client/resident care. Every employee and physician will have easy access in the workplace to report occurrences electronically using the EH information network. According to Mr. Barron, the OCR will be safe, simple, and will provide end-users with timely feedback of useful information, essential to reducing adverse health events, and improving clinical safety and quality of care provided. Supportive of the EH EHR initiative, the OCR will be integrated as part of the clinicians' computer desktop.

The **Public Health Surveillance System** (Panorama), a Department of Health and Community Services led initiative, comprises part of the National Software License (Canada Health Info way). The key stakeholders include Regional Health Authorities and relevant health professionals. It assists in managing pandemics (SARS) and other issues related to public health (inoculation, tracking, provincial disease screening, etc.).

The **Regional Health Authority EPR Consolidations** were also discussed. Mr. Barron noted that this:

- creates a comprehensive client record on a regional level basis;
- provides information that allows for more efficient use of resources (reduces unnecessary testing); and
- provides opportunity for standards setting.

In discussing the NL EHR roadmap, Mr. Barron provided another illustration to depict the timelines and projects underway from 2008 to 2011. He outlined the benefits associated with comprehensively evaluating the various systems prior to their implementation. The NL approach includes fully engaging end-users with the identification, design and implementation of systems; aligning initiatives (to the extent possible) in order to take advantage of opportunities for standardization and other leveraging; and collaboration and communication. Mr. Barron cited that a number of success factors in the collaborative processes stem from:

- NL's greatest asset is its highly engaged stakeholders;
- many years spent planning and building consensus (Benefits Driven Business Case, 1998);
- open and continuous communications; and
- autonomous organizations working together for the common good – the Virtual Health Enterprise.

Mr. Barron also outlined current environmental opportunities including:

- all systems design should take into account the potential to meet AHE management and communication requirements;
- create a culture of patient safety and information quality (standards) and imbed it in information systems projects; and
- ensure robust change management occurs that encourages health providers to adopt available technologies (health transformation).

Some of the discussion/key messages arising from Workshop One participants included:

- There is support for provincial implementation of an electronic occurrence reporting system;
- most policies for reporting are already mandatory, however, there is no way to enforce them (honour system used);
- it is better to get buy-in for the importance of reporting than make it mandatory;
- reporting must be expected equally across all groups (staff and physicians);
- important to have a just and trusting culture;
- need to start showing support for the health care providers who do the reporting;
- important to capture near misses/close calls;
- the technology is the tool, the processes are all about people;
- important to provide feedback to the people who are reporting – not just let the report fall into the big black hole;
- need to identify the implications of relevant legislation for quality improvement, research and planning; need to identify the responsibility for entering the data; and
- need to find ways to use technology to make education about patient safety more accessible to staff.

Workshop Two: Assessing Adverse Health Events

Paula Beard, Director of Operations, CPSI, led Workshop Two: Assessing Adverse Health Events. Ms. Beard focused her presentation on three key objectives: (i) discussion of levels of assessment /severity scales; (ii) assessing the causes and contributing factors of adverse events; and (iii) discussion of legislative protections, the impact of full disclosure

for patients, and sharing lessons learned. She began by noting that the Canadian Root Cause Analysis Framework Document was available at www.patientsafetyinstitute.ca.

In determining the appropriate level of review, Ms. Beard noted that organizations should consider developing definitions of reviewable events and recommend the level of corresponding event analysis based on a set criteria. In determining eligibility **for Root Cause Analysis (RCA**) a key question should be posed. Was the event thought to be the result of:

- a criminal act;
- a purposefully unsafe act;
- an act related to substance abuse by provider/staff; or events involving suspected patient abuse of any kind (i.e., situations outside the scope of the risk management /quality improvement program)?
- If yes, Ms. Beard noted that applicable administrative processes/policies should be referenced.

To determine eligibility for RCA, Ms. Beard referred to the National Patient Safety Agency (NPSA) Incident Decision Tree. This decision tree is based on James Reason's culpability model and helps managers and senior clinicians decide what initial action to take with staff who are involved in a patient safety incident. It is intended to promote a consistent and fair approach in dealing with people. She provided an overview of a Stratification System used by the Department of Veterans Affairs, called a Safety Assessment Code (SAC) Matrix, to assist in determining the level of severity/probability of the incident on a scale of 1 to 3, where 1 was rated minor and 3 catastrophic.

In terms of understanding unanticipated outcomes, Ms. Beard discussed a tool/process called **Event Analysis**. She described how this works and noted that a number of steps are involved, including a fact sheet; brainstorming; the development of a cause and effect diagram to identify root causes; and determining root causes from contributory factors. A number of illustrations and examples were presented to provide participants with an understanding of how each tool is utilized in establishing the nature and scope of the adverse event.

Ms. Beard also discussed emerging **legislation** related to Patient Safety in Canada. She provided an overview of the 2002 Quebec Mandatory Disclosure to Patients Legislation; the Saskatchewan, 2004, requirements for reporting and review of Critical Incidents; the British Columbia, Saskatchewan and Manitoba 2006-08 legislation that allows for an apology without admission of liability in a legal proceeding; and the Ontario, 2004, legislation that protects the confidentiality/privilege which is associated with Quality Reviews (including Root Cause Analysis).

Quality Assurance Protections in the context of legislative provisions were also highlighted, and it was noted that:

- all jurisdictions in Canada now have legislation related to the protection of quality assurance/improvement activities; and
- these provisions vary slightly from province to province.

Some of the issues noted for discussion included the variability of legislation from province to province; the age and language contained within legislation (i.e., "hospital" and "quality assurance"); restrictions prohibiting the sharing of valuable lessons learned; protection from admission in a legal proceeding defined within legislation; and the variability of protections including which proceedings the QA protection applies to – civil, regulatory, criminal, coroner or public inquiry.

Ms. Beard also highlighted some emerging trends with respect to Quality Assurance protection, including risks and benefits. Related to **risks** it was noted that:

- staff and physicians may become reluctant to participate in reviews.
- Who can decide to forgo the protection, and what is the effect on staff, physician and patient privacy rights?

In terms of **benefits** Ms. Beard noted that:

- organizations are seen to be transparent in their review process; and
- other organizations can learn from the circumstances and recommendations described in published reports.

A question was presented for discussion regarding the communication of results. Is there a generic way to communicate the information learned from the event analysis to those who could also benefit from the information, for example, patients and family members? Within the organization? Outside the organization?

Following audience discussion, a number of key issues/themes emerged:

- With respect to the CPSI definition, it was suggested that "close calls" should be mentioned. Possible wording could be, "which results in unintended harm or potential harm."
- Some best practices that participants felt should be considered, include multidisciplinary teams to pool expertise for investigation; develop and adopt a definition of reviewable events (based on the Veteran Affairs Model); sharing experiences while encouraging people to talk about the processes that led to the adverse event; brainstorming using categories (time /item/info source) to plot how the event happened and identify what should be changed; the importance of utilizing all tools available; in the absence of technology employ a "do-not-use list" for written orders/prescriptions etc. (for example, the "trailing o " as in 1 rather than 1.0, which can be mistaken for 10 in some handwritten circumstances); adopt a policy for an independent check of orders; use root cause analysis to identify the root cause of the adverse event so that crucial, versus superficial changes are

made; involve physicians and the Medical Advisory Committee early and often in the assessment process, even if they express liability concerns.

- Participants felt that the guiding principles (such as the World Health Organization Patient Safety Taxonomy) are best for legislation, rather than rigid frameworks. CPSI will be asking provincial governments to consider adopting apology legislation to separate apologies from liability assessment; it was suggested that no-fault legislation should be considered (New Zealand); confidentiality should be protected where appropriate – appropriateness should be defined in legislation, regulations or policies.
- Communicate often and fully with patients, without speculating, on what is known about the adverse event. Apologize to patients. Apology is seen as essential and the "right" thing to do. The benefits of full communication are that the organization is seen to be transparent and therefore trustworthy. In addition others can learn from the event. Where there is reluctance there will always be risk.
- There was unanimous agreement that the culture has not changed at all from the "shame and blame" culture; paradigm shifts are needed.
- The Department of Health and Community Services/Health Quality Council's role should include leadership in standardizing policies, coordinating responses, ensuring consistency across the province, maintaining central database for learning purposes and generally managing the cultural shift.
- Education is continually needed in order to understand both the patient safety process and the necessity to report adverse health events.

Workshop Three: To Disclose or Not to Disclose: Ethical Considerations

A presentation was conducted by Dr. Daryl Pullman, Ph.D., Professor of Medical Ethics, Memorial University of NL.

Dr. Pullman commenced his presentation with a hypothetical case involving a patient who contracts MRSA in hospital and is later discharged to a personal care home in the community. Who needs to know the MRSA status? In order to set the context for discussion around disclosure he cited several definitions of an adverse event from the Canadian Patient Safety Dictionary (2003).

Dr. Pullman outlined the preliminary steps involved in the basic approach to patient disclosure, including:

- Providing prompt attention to the situation to eliminate or reduce immediate and potential risks.
- Initiating an Occurrence Report.
- Notifying appropriate manager(s) to seek assistance with reporting and follow-up on the error or event (e.g., Management of Program/Department or Quality and System Improvement Department).
- A student or physician-in-training must inform his/her supervisor immediately upon becoming aware of an adverse event.
- In preparing for the disclosure, the clinical team, in consultation with the Program Leadership Team and/or Executive Management, will determine the most appropriate person(s) to disclose information to the patient and/or the substitute decision maker.
- When disclosing information pertaining to the event, consideration should be given to having at least one other person from the Program or Department present at the meeting, as well as a representative of the Quality and System Improvement Department.
- In terms of timing, arrangements should be made as soon as possible to meet with the patient and/or substitute decision maker.
- In making the disclosure, the person should (a) concentrate on what happened and the possible consequences while avoiding too much detail and technical language; (b) remain factual; refrain from providing opinions on the care and/or service of others; (c) take the lead in disclosure; don't wait for the patient to ask; invite questions now and later; (d) outline a plan of care to rectify the harm and prevent recurrence for this patient and others; (e) offer to obtain second opinions where appropriate; (f) offer the option of a family meeting; (g) document the need for a follow-up meeting and who should attend; (i) be prepared for strong emotions and offer personal support and support from others; (j) accept responsibility for outcomes, but avoid attributions of blame; and (k) apologies are appropriate, probably sooner than later.

- If the patient and/or substitute decision maker refuses to participate in a disclosure discussion, this refusal must be documented in the patient's health record. The opportunity to discuss the event at a later time should be communicated.
-

In discussing Ethics Consultation with respect to disclosure, Dr. Pullman quoted the CPSI Disclosure Guidelines (2008): "When uncertain about whether harm has occurred, it is recommended that disclosure take place; however, further consultation may be required before proceeding. Consider consulting with an ethics committee or another similar body of experts for advice about the clinical risk of future harm and the need to disclose."

Dr. Pullman used three specific cases (a radiology error, a multi-patient adverse event involving unsterilized laboratory equipment, and a medication error involving an infant (with no apparent untoward effects) to engage participants in discussion concerning disclosure.

Key points emerging from the audience discussion included:

- With respect to the CPSI definition of adverse event(s), potential adverse events/ near misses are not captured, nor is the severity; the patient's involvement in the reporting process (should be more clearly defined); how should disclosure with near misses be managed?; it is important to consider the natural course of illness; consider the physical and emotional impact as well as capturing the "community" issues/actions /care aspects; does the definition meet the needs along the continuum of care, such as long-term care.
- Careful consideration should be given to both who should be present for the disclosure process, and the support for family.
- Can policy produce a culture that is totally responsive?
- Patients want to hear an apology and what happened to lead to the event.
- Timeframe and disclosure should depend upon the nature of the event; guidelines are needed for this as part of disclosure policy.
- Education for staff related to disclosure policy and implementation is important.
- Some comments arising from the discussion of the case situations included:
    - the importance of reporting/making contact with appropriate regulatory bodies when staff become involved in adverse events;
    - more education is needed for staff throughout the RHAs;
    - there is a fear of reporting because of possible repercussions by patients;
    - processes need to be further developed so that people know what is going to happen when adverse health events are reported; and
    - there is a need to think outside the "medical model."

Workshop Four: Operational Response to an Adverse Health Event: Short and Long Term

A presentation was conducted by Dr. Ward Flemons, Calgary Health Region

In his discussion of managing serious adverse health events, Dr. Flemons presented a flow chart to illustrate the immediate and continuing management of the situation. He noted that the immediate management phase includes focusing on what exactly happened – the basic facts. The "initial timeline" is important and is requested by an accountable, administrative lead; the source of information is the patient chart, and it is completed by a trained chart reviewer. Dr. Flemons noted that in the Calgary Region the RESPOND acronym is used to guide the immediate steps: R=Respond; E=Ensure the environment is safe; S=Secure equipment; P=Protect the other patients; O=Offer initial support; N= Notify; D= Disclosure (Acknowledgement). Following this, a clinical safety evaluation within a specified timeline comprises part of the initial assessment.

The Continuing Management Phase, or the longer term, involves three specific elements:

(i) **Advocate** - assigning a patient advocate; providing ongoing support for the patient and family and for the health care providers. Information/communication is important at this stage, as is emotional/psychological support. Financial support for out-of-pocket expenses only, offered in a timely and proactive manner is also important. Compensation is difficult because of the legal complexities involving the organization's lawyers, the insurer/insurer's lawyers and CMPA/CNPA.

(ii) **Communicate** - disclose to the patient and family; safety learning report and the informing process. The disclosure team should include an Admin (Medical) Lead; the Attending Physician; a Non-Physician and a Patient Advocate. This team must be able to convey concern and regret; answer clinical questions; answer administrative questions, and answer financial questions. There are four phases to the disclosure process, including acknowledgement, the initial contact, follow-up and the final phase.

Dr. Flemons noted that the informing phase is important in that: (i) everyone in the region has a right to know when there has been a substantial change in risk to their health/well-being; (ii) maintaining confidence in principal health partners when there has been a substantial system failure (transparency –trust) is important, and (iii) learning about situations when things go wrong (stakeholders) is also important. He highlighted newspaper clippings to illustrate informing the public, as well as a statement from the Chair of the Calgary Health Region following their 2004 Potassium Chloride Tragedy, indicating that "It is vital we learn from these mistakes."

Dr. Flemons also provided insight into why informing is frowned upon: (i) negative media reaction; (ii) related stories get into the media; (iii) it may bring into question all the care that is provided in the Region; and (iv) there is a huge drain on morale for the third victims (health care providers).

(iii) **Evaluate** – a safety analysis and administrative review is important in determining the cause of the adverse event.

Key comments/questions from participants regarding Workshop Four included:

- Leadership is imperative to change.
- Stories and lessons learned from adverse health events can be a catalyst for change.
- A "slush budget" for safety infrastructure and just-in-time action is needed.
- The accountability role for managing adverse health events should be vested in the Executive Team, probably at the vice-president level.
- Separating and maintaining the integrity of patient safety versus professional practice reviews, particularly at smaller sites, requires CMPA advice.
- How airtight is the definition/protocol for quality assurance reviews under the Evidence Act?
- Patient/family awareness of medical concerns or the complaints process should be known.
- There is a need for patient safety education for medical and other health disciplines. Reference was made to the CPSI Patient Safety Competencies document.
- The integrated health system refers to all parts of the care continuum – how do we link reporting/communicating to primary care physicians? (HQCA has the ability to cover primary care physicians through protective insurance, if desired.)
- Face-to-face disclosure is preferred as opposed to written communications; however, it depends on the nature/context of harm etc.
- Is the term "disclosure" appropriate?
- Balancing and protecting individual identities in smaller communities is challenging. The key message is to maintain public confidence that the system is addressing concerns (generic messaging).
- There are limited adverse event experiences shared nationally – this is important to learning; feedback on safety reports is important in reinforcing new culture/ behaviors.
- In Calgary "grey" events are harder to manage than "black and white" events.
- In terms of the CPSI definition of an adverse event, participants noted that the definition of harm "should be close by"; it should be broadened to include the community and consider omission versus commission; near misses should also be considered.

Workshop Five: Leadership, Coordination and Communication

The workshop was led by Jim Hornell, CEO, Cypress Health Region, SK.

Mr. Hornell began his presentation with a series of quotes to illustrate thinking around leadership. He noted that the first responsibility of a leader is to define reality and that "We lead first by being human; we do not lead by being corporate, professional or institutional." He also noted that the culture for reporting and disclosing does not come easy.

Mr. Hornell discussed the role of coordination when an adverse health event happens and noted that "It is not what the plan is…it's what the plan does." He presented an overview of a protocol used in a disinfection/sterilization (D/S) failure cited in *Infection Control & Hospital Epidemiology* 2007, 28:146-155 as a useful coordination tool. He also provided an overview of a sterilization adverse event which occurred within the Cypress Health Region and stressed that in **coordinating** an event:

- The CEO takes the lead and sets the tone.
- Communication support is critical.
- Clinical/technical expertise (who is prepared and knows their limitations) is key.
- Site management must be considered.
- Keeping the Board as well as physicians (local and regional) and staff informed is important.
- Engaging municipal leadership, government, and other health agencies in the process is also important.

In terms of **Communication,** Mr. Hornell stressed the importance of engaging, empathizing, educating and enlisting key stakeholders as important principles that should be considered. In dealing with adverse events, he offered his thoughts on communication principles and lessons learned, including:

- The need to be proactive and balanced with respect to timing (patients first).
- Communicate early and often (feed the media); measure the time for media information requirements.
- Remember the internal audience; visit and support site personnel early.
- Designate a single spokesperson (also consider the clinical/technical and organizational expertise needed).
- Establish a separate investigation team; quick turnaround is necessary;
- Use scripts for client contacts; personal contact /phone call by a doctor before a letter is important.
- Provide progress updates, don't wait to be asked.
- Consult lawyer/ministry.
- Use technology.
- If bad news is to come, you announce it as soon as possible; get all the bad, or potentially bad, information out at once.

- The longer emergency/crisis situation exist there is less confidence in the organization.
- Get to know the media – build trust over time; watch/listen to open lines.
- Talk about the adverse event; watch for opportunities for change – don't assume all see urgent.
- Sell transparency and rebuild trust.

Some of the discussion/key points derived from this workshop included:

- Knowing when to disclose is important for an organization.
- Sharing the lessons learned with other organizations should occur.
- Some non-compliance with directives given after the event requires strong leadership on the team.
- Good management of disclosure discussions is also required.
- There is need for ongoing education concerning patient safety for both organizations and the public; a strategy on engaging the public in changing cultures is needed.
- There is also a need to engage the media in discussions/forums of this nature.

Adverse Event Management – Lessons from Canada's Blood System

Dr. Heather Hume of the Canadian Blood Services provided an insightful and relevant presentation concerning some of the lessons learned concerning Canada's blood system, following the organizational transformation that occurred after Justice Horace Krever submitted his 1997 report. She indicated that, for those in transfusion medicine, the Krever Report is now regarded in some way as one of their guiding Bibles. She noted that she selected only some of the important lessons from the three volumes to share with participants.

Dr. Hume reminded participants what was in the media about the blood system, and recalled such words as "tainted blood victims", -"cause of death," "systematic, bureaucratic bungling" and that, indeed, the blood system was characterized by such terms in 1993. Quite appropriately, in her view, the Federal Government determined that there was a need for an inquiry. In 1995, an interim report, with 43 recommendations, was released that addressed many hospital and clinical activities, such as the need for informed consent.

The final report was released in November of 1997 and contained 50 recommendations. The first recommendation was about compensation. The second recommendation laid out what Justice Krever thought should be the basic principles of the Canadian blood system. There were also a number of very practical recommendations addressing the blood operator, the regulator and the need for regulations.

In 1998, two new blood operators came into being –Canadian Blood Services and Hema-Quebec. Canadian Blood Services serves all the provinces and territories in Canada, except for Quebec, which is served by Hema-Quebec. Apart from Quebec, this is a national organization funded by each province, with an independent board of directors, appointed by the provincial ministries of health.

Dr. Hume highlighted three quotes from Justice Krever, as well as examples of how the organization tries to live by them. The first quote, she noted, arises from the very first sentence in the report's foreword. "In the pages that follow, an account is given of a public health disaster that was unprecedented in Canada, and, if we have learned from it, one that will never occur again." She advised that when something bad has happened, people want an explanation, compassion, perhaps compensation, but they want to know that it was not all for nothing.

Something, Dr. Hume noted, that has become quite important in the field of transfusion medicine is called the precautionary principle: "When there was reasonable evidence that serious infectious diseases could be transmitted by blood, the principal actors in the blood system in Canada refrained from taking essential preventative measures until causation could be proved with scientific certainty, and again the result was a national public health

disaster." So, she stated, Krever was encouraging the system not to always absolutely require scientific certainty in order to begin to act.

She noted that Krever also talked about balancing the risks and the importance of partial measures: "But the balancing of risks and benefits – taking action should be not only on the likelihood of the risk materializing but also on the severity of the effect. If there are no measures that will entirely prevent the harm, measures that only partially prevent transmission should be undertaken." So, again, she noted, this is something that they are trying to put into effect.

Recommendation six and others were highlighted: "That the blood supply system be operated in an open and accessible manner. The current lack of confidence in the blood system results, in no small measure, from the absence of public participation in the decision-making process that until now has characterized the system." What a challenge Justice Krever put to us, she noted. Another quote was, "That the following standing committees be created to facilitate the work of the national blood service – we need to have information from a whole variety of people, stakeholders and others, national, international, professional, public" And again, "All committees should have as members, representatives from consumer groups and the public. [so that] there will be an effective exchange of information between the national blood service and all hospitals." She stressed that the theme coming through this was communication.

Much of the Report, noted Dr. Hume, is the need to audit, a national system and funding, and the way it should be operated. A number of recommendations made reference to communication such as, "That on learning of the potential risks associated with blood components or blood products, the national blood service cause recipients to be informed," here we see more communication. And finally, "That there is an active post market surveillance of blood components and blood products."

Dr. Hume discussed recommendation 28 with respect to look-back and trace-back. She noted look-back is "the process of identifying and initiating testing of recipients who receive blood components from a donor, who on subsequent testing is confirmed positive for transfusion of a transmissible infectious agent."

A different activity is trace-back, the process of "investigating donors who contributed blood components for transfusion to a patient who developed a blood transmissible disease." So trace-back starts with a patient, look-back with a donor.

She outlined some of the difficulties in conducting look-backs at the beginning noting that they weren't begun in a timely manner. Justice Krever, she said, devoted a whole chapter to this. She explained that if a person is HIV positive from a blood transfusion but they're not informed of that, their sexual partner and child may also become positive. For a multitude of reasons, such as poor record keeping, noted Dr. Hume, these delays happened. These have now been addressed, and policies and standard operating procedures are in place. Resources to do this kind of thing are needed.

Dr. Hume noted that the most recent summary of CBS look-back activities shows the magnitude of the public health care tragedy. For HIV and HCV only, it was found that 717 donors were HIV positive from the time testing started. The organization figured that from those donations, there were probably 1,559 recipients affected. Of this number they found 251 positive, 373 negative, 935 who either were already deceased, probably for the most part from their underlying disease, and many were never found.

In terms of HCV, over 10,000 donors and over 26,000 components were affected. Dr. Hume noted that approximately 6,000 people were found to be positive. The number of recipients not found/status unknown was over 18,000. Of these 18,000 probably as many as 80% died; however, the number is not definitive as some patients were lost to follow-up, partially because of the poor records.

In 2002 another virus, the West Nile Virus, made its way into the blood system somewhat unexpectedly. Staff consulted the Krever Report to see if they could deal with this one more efficiently. Because the basic structure had changed, there was greater confidence; however, particular attention was given to things that were not inherent in the structure. To apply the precautionary principle (to implement partial measures and to ensure an adequate exchange of information) a number of factors were considered.

Dr. Hume provided some context for the HIV and West Nile Virus. HIV or AIDS first started to be recognized around 1981, but throughout the course of 1982 it became obvious that it could be transmitted by blood. In 1983 the virus was isolated, so manufacturers could start thinking about a test, and testing was begun in Canada in 1985. In the United States, testing began in March of ’85, and that was one of the highlights Krever looked at in his report.

Dr. Hume noted that an associated challenge for the organization was the fact that there was no test for the West Nile Virus that was in the blood supply. But she noted, that from barely recognizing the situation in September of 2002 and having no test, the manufacturers got together, and by July 2003, a test had been devised. So what was different between these two viruses? As opposed to the West Nile Virus, HIV was unknown when it appeared. West Nile had been known in Africa and Europe for a long time. The whole technology for blood donor screening had advanced remarkably in those few years, and this was very important for the CBS as the operator. They also had access to independent funding. A contingency fund that had been made available at the implementation of the new blood services, both for Hema-Quebec and CBS, was able to be used.

There were, however, still some challenges: communication among health care players had really been quite limited at the time of HIV. It was much improved by the time they began to deal with West Nile Virus, but liaisons with public health were not as good as they should have been, and possibly through the West Nile Virus challenge, they forged very strong relationships. Consequently, there was a good outcome.

Dr. Hume noted that CBS certainly didn't think about the precautionary principle at the time HIV came into the blood system, but it was absolutely one of their guiding principles in addressing West Nile. Public and stakeholder expectations were not so high in 1984, although she noted that it is probably an understatement to say they were very high in 2002. By that time they were certainly under the public scrutiny.

The precautionary principle, then, was put into effect. A number of partial precautionary steps were taken, particularly back in 2002 when the organization realized they had frozen product circulating that was probably carrying the virus and no test had been performed.

CBS was extremely conscious of communications. Krever had been quite critical about the lack of communications, so CBS tried to have good communication with hospital customers. Regular conference calls were held that were open to scrutiny with partners. They also worked closely with their American colleagues. There was intense media scrutiny (106 media interviews in November and December alone led by Dr. Graham Sher and Dr. Hume). [Dr. Hume noted that they did feel that CBS could justify that what they were able to justify their actions adequately through the media.] She has since thought that this was probably a good standard. Overall, she stated that CBS felt the media coverage was a fairly positive experience for them.

Another example was cited emphasizing that the blood system should operate in an open and accessible manner and that there should be public participation in the decision-making process. A patient representative, Dr. Hume noted, is now a member of the Transfusion Committee at Sainte-Justine Hospital. CBS is also considering speaking with patients individually and in small committees. She noted however, that while involving the public in decision making at the Canadian Blood Services level is a challenge, it is being attempted through committees, including a professional hospital advisory committee, a national advisory committee, a scientific and research advisory committee, as well as their national and regional liaison advisory committees which are committees, with stakeholder groups.

Dr. Hume noted that the national liaison committee is a recent example of public participation in decision making. She noted that their deferral policy and the donor selection process that prohibits men who have had sex with men, even once since 1977, from giving blood, has been criticized as discriminatory.

Tests are also performed an manufacturing practices, which is a very essential part of safety. The MSM deferral policy was implemented in the mid-1980s. This was obviously a very different time: either there was no test or they were just beginning to use the test; the test was also not so sensitive. CBS felt it was time to review this policy in light of their overriding principles: (i) that the basis for donor deferral rests on the assessment and information of the various types of risk associated with donated blood; and (ii) that any change to existing policies on donor deferral must result in improved or equivalent safety by comparison to what now exists (required by regulators). She noted that it can be rather difficult to prove that something is of equivalent safety.

Dr. Hume described the process of addressing this sensitive policy. The organization reviewed the literature, assessed surveillance data, reviewed best practices around the world and sought an independent risk assessment regarding the possibility of removing the question. Stakeholder consultations were also held with the national liaison committee and high-interest groups at either end of the spectrum such as the gay and lesbian communities and the blood recipient community. They were brought together to talk about this with an independent facilitator. Board members were present, a medical presentation was made, and the independent risk assessment was presented. The question asked was "What would you or your organization like CBS to take into consideration when reviewing the MSM policy?" While the group had an opportunity to see the final report, it was always clear that the Board had the final decision. Finally a decision was made not to change the question. This meant however, that further research was needed to try and understand a number of factors that CBS felt might need changing.

Dr. Hume noted that the benefits of that exercise brought new points of view to the CBS Board: it increased acceptance of the decision; there was no public outcry; and no media reports were generated. And there was a positive recognition of this in the process. She indicated that while there were a lot of people who were not pleased with the decision, particularly in the gay and lesbian community, they acknowledged and respected the process and had some understanding of how CBS got to where it did. And it certainly increased mutual understanding. Mostly importantly, even the people who disagreed with the decision said they would work with CBS again in this context.

Recommendation # 40, that there be an active program of post-market surveillance of blood components and blood products, was also discussed by Dr. Hume. As CBS were not leaders in this, it was really taken on by the Public Health Agency of Canada, and Dr. Hume acknowledged that the slides were given to her by the Public Health Agency of Canada.

She highlighted two programs: (i) TTISS- Transfusion Transmission Infection Surveillance System, a voluntary surveillance system for capturing moderate and severe transfusion transmission reactions. She noted that CBS and the Public Health Agency of Canada collaborate and agree on definitions and reporting elements. Not all reactions need to be reported to CBS, so only a subset that goes to TTISS will go to CBS and Hema-Quebec. Reconciliation is collaborative.

Dr. Hume noted that in most provinces when an adverse event is identified and reported to a hospital blood bank, it will go to a provincial blood office. Then, on a regular (biyearly) basis, it is reported to TTISS. She noted that the 2006 report is just about to come out. In 2004-2005,about 70% of RBC red blood cell units transfused in the country were reported through this system (the aim is 100%), and that has increased since 2005. Newfoundland is at 70% or higher. The report contains only moderate or serious adverse events related to blood component transfusions, including RBC, platelets, plasma or plasma derivatives, and manufactured products such as albumin and IVIG. In 2005 for example, there were a total of 411 that are further subdivided.

This reporting makes CBS aware of the types of adverse reactions and determines which are the most important and should be followed up. As a result, CBS has paid particular attention over the past two years to bacterial contamination and TRALI transfusion related to acute lung injury.

Dr. Hume also noted that the Public Health Agency of Canada has now embarked on an important and complementary activity related to CBS called TESS, Transfusion Errors Surveillance System. This is a pilot project carried out in four provinces involving 11 small, medium and large hospitals. It's a nonpunitive, anonymous reporting system related to hospital-based transfusions. The aim is that this will become a national system, integrated with TTISS. The results over two years show there were almost 21,000 errors reported in those 11 hospitals: 6.8%, or 1,427, with the potential for patient harm, and 42 where there was patient harm. And, of course, that is primarily what CBS wants to work on and prevent in the future. There is a real cost to this. But in just two years (in 11 hospitals) the number of components that had to be destroyed because of some sort of error amounted to $668,000. CBS serves some 750 institutions, so it's really quite striking the amount of money involved. We therefore, should be putting some money into preventing these errors.

Dr. Hume concluded her presentation with the quote 'Men do not learn very much from the lessons of history; it is the most important lesson of history." The challenge for us, she noted, is to try and reverse that and continue to learn from our lessons and strive to do better.

Forum Synthesis

Dr. Ian Bowmer, Executive Director of the Medical Council of Canada, began by echoing the view that participants had made an obvious commitment to the quality safety issue – and the Province – in terms of addressing it in a very eloquent and amazing way over the day. He noted the comments of Forum Chair, Phil Hassen, indicating we are all on a journey. It reminded him, he added, of readings he'd done about First Nations people who don't consider that they are lost on a journey, but that they do not have enough knowledge about a particular part of the country. In his view this reflected very nicely the kinds of issues discussed throughout the Forum in we've all been acquiring more and more knowledge.

Dr. Bowmer admires the work of James Reason. He recalled a statement from his book, which noted that high reliability organizations, that have less than their fair share of accidents, recognize that human variability is a force to harness in averting errors. He also noted that these organizations work hard to focus that variability and are constantly preoccupied with the possibility of failure. He reflected that, as a physician, failure is not viewed very well. He added that he's come to realize over the past several decades that whether it's about death and dying, or adverse events, "We sometimes bury our heads in the sand."

To illustrate this point Dr. Bowmer referenced the hesitancy of a 1,000-bed facility in Chicago to allow theological students to talk with dying patients. Despite the fact that the organization was recording some 30 to 50 patient deaths daily, the response was that "no one was dying." This attitude has changed significantly over time, and Dr. Bowmer acknowledged that, thanks to CPSI and other like-minded organizations, we are on our way to improving how we deal with adverse events. He added that he very much liked the motto of CPSI that it wants to become "The safest health care system in the world." He also noted that he liked the call from Task Force Chair, Robert Thompson, for diverse perspectives and to identify best practices, as well as the comments by Minister Wiseman that government is willing to invest in the management of adverse health events.

Dr. Bowmer noted that the other point that came up repeatedly throughout the morning is that we're moving into an era of patient-centered care. He added that the message heard clearly from Ryan Sidorchuk related to patients desire to be partners in the reform of our institutions. He reflected upon his work in the HIV field and acknowledged that the patients/clients can be "an incredible, powerful force in moving us along in that direction."

In referencing Ryan Sidorchuk's presentation, Dr. Bowmer noted that he was interested to hear him say "that the doors start to close when things go wrong and the barriers go up and information gets filtered,:" He noted the clear message "that that's not really the way of the future." He reminded participants that if we want timely response incorporation of the learnings from adverse events, and movement towards patient-centered care, it should occur across the continuum of care, not just institutionally. The opportunity to use the

framework that has been published by the Task Force is an opportunity to set the agenda in this direction.

Dr. Bowmer noted that:

- The keynote address eloquently set out the challenges in moving forward to a culture of safety and learning. They arose largely from a tragedy that created transformative change in the organization, and it's another tragedy in this province that hopefully is going to create the same transformative changes.
- The idea of Reason's person and system model and the great clips of Dr. Reason's speaking, as well as the dramatic demonstration on how our minds can overcome conflicting input and make sense out of nonsense, assisted greatly in understanding how adverse events can occur.
- Jerome Groopman's book on how physicians think is another eloquent explanation of how when something doesn't fit into a pattern of recognition, we ignore it rather than embrace it, the book also gives emergency room examples and many different physician care examples of how we actually get fooled by our cognitive abilities.
- Dr. Flemons' discussion about the culture of safety and learning was interesting, and the idea of an environment that is trusting and just is the goal expressed in workshops.
- During the workshops participants expressed the view that maybe "disclosure" was the wrong word; in Dr. Flemons' presentation the word "conversation" was used: conversation with the family, conversation with the patient, conversations with the system, and conversations with everybody else.
- Two approaches were reviewed in looking at adverse events management: a system safety analysis, which looked at issues in the system, and an administrative review, which looked at individual performances.
- "Close calls" rather than just adverse events should also be reported from the perspective of safety hazards.
- A confidential reporting system is necessary but it's not anonymous. People have to stand by what they say, but as it goes into the system "identifying information" related to the reporter and patient is scrubbed.
- Confidentiality within small communities/groups is a challenge, even when identifying information is scrubbed.
- There is a role for either collaborative work across regions or outsourcing some of the activities within smaller communities.
- The acronym RESPOND used by Calgary Health region is something that we will all remember.
- The use and the identification of the role of the Patient Family Safety Council is a powerful component of the process, and a visible demonstration of how the patient can actually be involved in the safety policy within an institution.

In summarizing key messages from the Panel Presentation**,** Dr. Bowmer noted that:

- Identification of measurement tools was stressed by Paula Beard, CPSI, who indicated that an organization really needs a toolbox with multiple sets of tools to look at a variety of events ranging from a peer review to event identification, whether they're trigger points or legislation or mandatory reporting. All of those tools should be used to really facilitate the process.

- For disclosure, the idea of a patient safety team is appealing, and should include a senior administrative leader who takes responsibility and is accountable, as well as physician for clinical backup. A patient advocate was also discussed. For positive results and to support the culture, there is need for proper training.

- Disclosing also normalizes open discussion and recognizes that you can't learn unless you disclose. It also gives permission (especially when senior management is involved) for others to disclose. Most importantly, it opens the pathway to healing.

- Some important ethical considerations about the tensions between the desire to protect the patient, which is a natural response to enable autonomy for the patient, and some potential dilemmas was presented by Daryl Pullman. More health care professionals need to be engaged in these discussions, because the immediate response is to try and protect our patients. But, sometimes by protecting them, we actually don't give them enough information. Sometimes the information is not presented in a way so they can actually absorb it.

- Creating balance between autonomy, on one scale, and paternalism on the other, is actually a useful image/graph, as it works in terms of the individual patient, groups and families of patients, and for the public. If we want people to be more autonomous, then we have to actually be willing to open up and share. The ultimate goal of the disclosure of information then, is really to move the patient and the public up on that autonomy scale.

- Susan Abell challenged participants to start formally applying institutional safety principles and approaches to the community. We need to talk to people in the community. She also identified something that was expressed frequently in the workshops: that there is a real need for training and modeling of some of the activities. She noted that if we really want to incorporate learning in this area, we have to open up more educational activities; multidisciplinary approaches are critical and should be considered as part of the environment.

Dr. Bowmer took a few minutes to focus feedback from workshop participants around the CPSI definition of adverse events. He noted that there were a lot of comments and questions and maybe a touch of criticism around the definition. A couple of important issues that arose included:

- It doesn't clearly state if the so-called "close calls" or "safety hazards" are incorporated; this was seen as important when talking with the public about adverse events.

- It was too institutionally oriented, even though there is small print included about community. But this should be in bigger print. If we want to talk about the continuum of health care in today's world, we have to move out of the institution and get involved across the continuum of care. Biological, social, psychological harm, or discomfort should be considered and added into the definition.

- It talks about the care and services delivered, but in some groups thought that the omission of care or the omission of services might be just as problematic. It may be actually explained in terms of harm in the definition, but on the surface this isn't obvious.

- Adding products, as well as care and services, is important since it was mentioned that certain products can do harm.

In summarizing the workshop discussions**,** Dr. Bowmer thanked the reporters and facilitators and noted that there was a lot of dynamic discussion within the groups, including the following:

- **Legislation:** One group mentioned that mandatory reporting wasn't useful because it couldn't be enforced, and that it was better to have voluntary reporting. Another group saw it as one critical component of this toolbox so that the system knew, and individuals knew, that they actually could report appropriately and that it gave the appropriate protection to the reporters. Overall legislation was viewed as being beneficial in order to protect people and that it should clearly demonstrate that it applies to all staff and physicians, and that everybody is equal.
- **Apology:** The other interesting point was that a very strong apology is "a must." The ability to apologize was seen by this group of people at least, as absolutely critical. If legislation was necessary in order to be able to apologize without the feeling that you are admitting guilt for further litigation, then we should have legislation in that area.
- **No-fault insurance legislation**: The other idea that people thought should be considered is the idea of no-fault insurance legislation. Again, it's just one part of disclosure, but it fits in with reporting, event analysis, and person and peer review.
- **Culture of Blame:** Dr. Bowmer indicated that there was a concern that in our province there is a strong culture of blame. He noted that it was made very clear that this needs to be put on the table, because the sense among health care workers and leadership alike is that we're going to have a lot of difficulty creating the culture we desire – i.e., moving from a culture of blame to an open and trusting culture.
- **Definitions:** One of the things that were quite clear is that we really need common definitions. Even across our own regions they are different. The groups felt that

there is a role here for CPSI and Health Canada in facilitating comparative data from all the jurisdictions.

- **Best Practices**: Identifying best practices across jurisdictions and across regions is important, should be shared, and there should be a formal way to share. This conference was wonderful because we heard about test practices from at least two jurisdictions outside of Newfoundland, but we don't have that kind of information flowing on a regular basis.
- **Resources**: There was unanimous agreement from the groups that we need significant investment by government in order to bring about a safety culture. There is clear need for an electronic health record and an information system that will actually help with assessments. The sooner we get that, the faster we will actually be able to do the work.
- **Leadership**: There was a feeling that a role exists for the Department of Health and Community Services and a Health Quality Council in terms of provincial policies, coordination, creating consistency across the different boards and ensuring that shared definitions are utilized in all the regions; At the Regional Health Authority level, it was felt by some of the groups that the role for the board of trustees has not been clarified; there is a sense that a lot of the quality assurance activity going on in institutions, is below board level. A quote used to illustrate this point was "They don't know what's happening under the surface." It was also noted that sometimes in authorities the quality assurance role and the operations role were blurred – that the same person in the organization may have responsibility for both.

  The issue of integration across all sectors of the RHAs should be part of the leadership role. There is need to identify the responsibility, roles, and accountability for the person or people who input/enter the quality and safety data. Who does that and who is responsible?

- **Education:** The need for education around adverse events throughout the health care system – whether it's physicians, licensed practical nurses, managers, or emergency room staff – exists at every level. Topics such as the meaning of what is meant by adverse events, a new culture of reporting, and how does it affect an individual practitioner or a member of the organization, should be addressed.

A challenge was thrown to the educational/training facilities to start looking at the competencies of individuals coming into the system. What part of the curriculum of our various schools addresses this area and what is included? Should the topic be an entry requirement for all health care workers?

In terms of educational activity involving disclosure practices, team of training was seen as critical. Training in chart review, reporting, and developing benchmarks with colleagues across the country, as well as the development of educational resources for giving appropriate feedback so that behaviours start to change, require resources.

Engagement of the public and media: In terms of quality and safety, Dr. Bowmer discussed the issue of meaningful public and media engagement in a positive way. He noted that we certainly see media act in a negative way across all jurisdictions. Is there a way to engage the public and the media on our behalf to actually start moving this along? He noted that one of the most powerful groups is the patient family safety committee, who actually believe that they are making a difference and see a difference. Their stories are powerful and compelling for the media.

We must also be able to share disclosure practice and best practices across jurisdictions and regions, and we need a mechanism to do that.

Finally, Dr. Bowmer queried that, since he is a physician, he is often asked how we engage physicians in this process. It was suggested in the groups that once physicians are involved, they're actually very engaged. Engaging the physicians, at any level, can help start the process. If it's in the middle of something, get them involved, and then have them brought up to speed. If there are individuals who want to be involved in the beginning, then welcome their involvement. But have them engaged in as many places as possible in the system.

Dr. Bowmer expressed his thanks and gratitude for allowing him to come back to Newfoundland for a visit and to participate in the day.

Phil Hassen, Forum Chair, thanked Dr. Bowmer for his outstanding synthesis report and invited comments from the floor.

Comment: "If we don't start getting upstream and doing our safety assessments in the absence of an event, then I think we're going to lose a tremendous amount, both within and outside the system".

Comment: 'I don't know if there will be another opportunity, but I do feel that it would have been very helpful to have media here in conversation with us."

Ryan Sidorchuk: "When we talked about the difference between mandatory and voluntary reporting, I suggested that I thought voluntary reporting was the way to go, with just one caveat – that patients and families are offered the opportunity to call into those reporting lines."

In his summary comments Phil Hassen noted:

- That of the billions of dollars allocated for the quantity of health care, it is time that quality was addressed. He added that participants' voices should be there with it, that quality and safety are as important as quantity.
- That the CPSI will soon forward a letter asking all provinces to introduce apology legislation. Three provinces have it; we believe all provinces should have it.

- The feedback with respect to the CPSI definition of "adverse event" was appreciated.
- That the CPSI has a working group on the role of trustees; this will begin study of the second generation of what it is that trustees need to do. It's a Canadian derivative of the work of IHI and is being led by Moira Davies of Saskatoon and Jim Nininger, who is the former CEO of the Conference Board of Canada.
- The CPSI is working with the Royal College of Physicians and Surgeons to develop a competency framework for educational organizations that will be released in the fall. A patient safety officer course will commence in September and CPSI is working on staffing so that a train-the-trainer approach is available.

Mr. Hassen acknowledged that from his perspective it has been a remarkable day. He noted that Robert has a tremendously complex task, of which this Forum is the framing of a step forward on a journey, and that he would do whatever he and the CPSI could do to help. Robert Thompson thanked Mr. Hassen for his offer of assistance and indicated he would follow up. He also thanked:

- Audience members for their participation and time; he noted the Task Force will be back to many stakeholders for more ideas and input.
- All the speakers throughout today, starting with Ward Flemons who did a triple play, and especially for the wonderful keynote address.
- The panel members and Ryan Sidorchuk for his excellent and moving presentation, and to all the workshop presenters, facilitators and recorders who brought together such lively discussion.
- Heather Hume for such a relevant presentation on Canadian Blood Services;
- Ian Bowmer for his great wrapup.
- The people in our office who helped make this day possible.

In terms of where to go from here, Mr. Thompson noted that the next deadline for the Task Force is June 13, 2006, for the written briefs. He encouraged participants to take away what was learned, and what participants gave, and give it to us again as input in the form of a submission. He advised that the Task Force is available for direct meetings and indicated that time would be made available to hear the perspectives of various groups. The Health System Liaison Committee will continue to be active. In terms of completing the work of the Task Force, Mr. Thompson noted that it will likely be at the end of the summer, more or less on time. He expressed deep thanks to Phil Hassen "for coming all the way here to serve as our leader today, and to take us through not only what has met, but surpassed, all of our expectations."

Appendix 1 Preliminary Notice of Forum

Newfoundland Labrador

NOTICE OF PROVINCIAL FORUM ON ADVERSE HEALTH EVENTS

Join a host of local and national speakers for this one day interactive Forum hosted by
The Task Force on Adverse Health Events

May 26, 2008
The Fairmont Newfoundland
St. John's, NL

The Task Force on Adverse Health Events was established to examine how the health system identifies, evaluates, responds and communicates in regard to adverse health events within the health and community services system.

Featured speakers include:

Hon. Ross Wiseman, Minister of Health and Community Services
Paula Beard, Canadian Patient Safety Institute (CPSI)
Ward Flemons, Calgary Health Region
Ryan Sidorchuk, Winnipeg Regional Health Authority
Daryl Pullman, Memorial University of Newfoundland
Mike Barron, Newfoundland & Labrador Centre for Health Information
and other experts and professionals

To register call 709-729-4349 or e-mail lbarrett@gov.nl.ca

www.gov.nl.ca/ahe

Appendix 2 Forum Agenda

Provincial Forum on Adverse Health Event Management
The Fairmont Newfoundland
St. John's, NL
May 26, 2008

A G E N D A

08:15 – 08:45	**Registration**
08:45 – 09:30	**Opening Remarks - Salon "B"**
	Phil Hassen Chief Executive Officer, Canadian Patient Safety Institute (CPSI) Forum Chair
	Hon. Ross Wiseman Minister of Health & Community Services
	Robert Thompson Chair, Task Force on Adverse Health Events
09:30 – 10:30	**Keynote Address**
	Embracing a Culture of Safety and Learning
	Dr. Ward Flemons Vice President of Quality and Safety, Calgary Health Region
10:30 – 10:45	**NUTRITION BREAK**
10:45 – 11:45	**Panel Presentation: Perspectives on an Adverse Event Management Framework**
	Assessing Adverse Health Events: Measurement Tools
	Paula Beard Director of Operations, Canadian Patient Safety Institute (CPSI)
	Disclosing Adverse Health Events: Ethical Considerations

Dr. Daryl Pullman
Professor of Medical Ethics
Memorial University of Newfoundland

Acting on the Management of Adverse Health Events

Dr. Ward Flemons
Vice President of Quality and Safety

Adverse Health Events: Observations from a Community Perspective

Susan Abell
Consultant, *Management Resources*, Port Hope, ON

11:45 – 12:15 **Participants Questions/Comments**

12:15 – 13:30 **LUNCHEON (provided) - Salon "A"**

Adverse Health Events: A Personal Experience

Ryan Sidorchuk (Luncheon Speaker)
Leader, Patient Voice Facilitation, and Safety Officer, Winnipeg Regional Health Authority

13:30 – 1500 **Towards Implementing an Adverse Event Management Framework in Newfoundland and Labrador**

WORKSHOP 1 – Salon "B"

Using Information Systems for the Management of Adverse Events

Presenter: Mike Barron, Chief Executive Officer, Newfoundland and Labrador Centre for Health Information

Facilitator: Dr. Doreen Neville, Associate Vice President, Academic, Memorial University of Newfoundland

WORKSHOP 2 – Salon "C"

Assessment of Adverse Health Events

Presenter: Paula Beard, Director of Operations, Canadian Patient Safety Institute

Facilitator: Jeannie House, Management Analyst, Newfoundland and Labrador Health Boards Association

WORKSHOP 3 – Salon "D"

Issues in Disclosing Adverse Health Events

Presenter: Dr. Daryl Pullman, Professor of Medical Ethics, Memorial University of Newfoundland

Facilitator: Lisa Hoddinott, Vice President Quality Management and Research, Western Health

WORKSHOP 4 – Garrison Room

Operational Response to an Adverse Health Event: Short and Long Term

Presenter: Dr. Ward Flemons, VP of Quality and Safety, Calgary Health Region

Facilitator: Carole Dalton, Chief Operating Officer, Central Health

WORKSHOP 5 – Signal Room

Leadership, Coordination and Communication of Adverse Health Events

Presenter: Jim Hornell, Chief Executive Officer, *Cypress Regional Health Authority, SK*

Facilitator: Marjorie Learning, Vice President and Chief Operating Officer, Acute and Long Term Care, Labrador-Grenfell Health

15:00 – 15:15	**NUTRITION BREAK**
15:15 – 16:00	**Canadian Blood Services** *Adverse Event Management - Lessons from Canada's Blood System* Dr. Heather A. Hume, MD, FRCPC, Executive Medical Director, Transfusion Medicine
16:00 – 16:30	**Workshop Synthesis** Dr. Ian Bowmer, Executive Director, Medical Council of Canada
16:30 – 16:45	**Conclusion**

Appendix 3 List of Participants

Forum on Adverse Health Management
Registration List

Organization	Name
Association of Allied Health Professionals	Sharon King
	Patti O' Keefe
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Newfoundland and Labrador Medical Association	Robert Ritter
Newfoundland and Labrador Provincial Advisory Council on the Status of Women	Elaine Wychreschuk
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Newfoundland and Labrador Public Health Association	Fay Matthews
Newfoundland and Labrador Association for Health Care Risk Management	Glenys Walsh
Newfoundland and Labrador College of Physiotherapists	Deb Noseworthy
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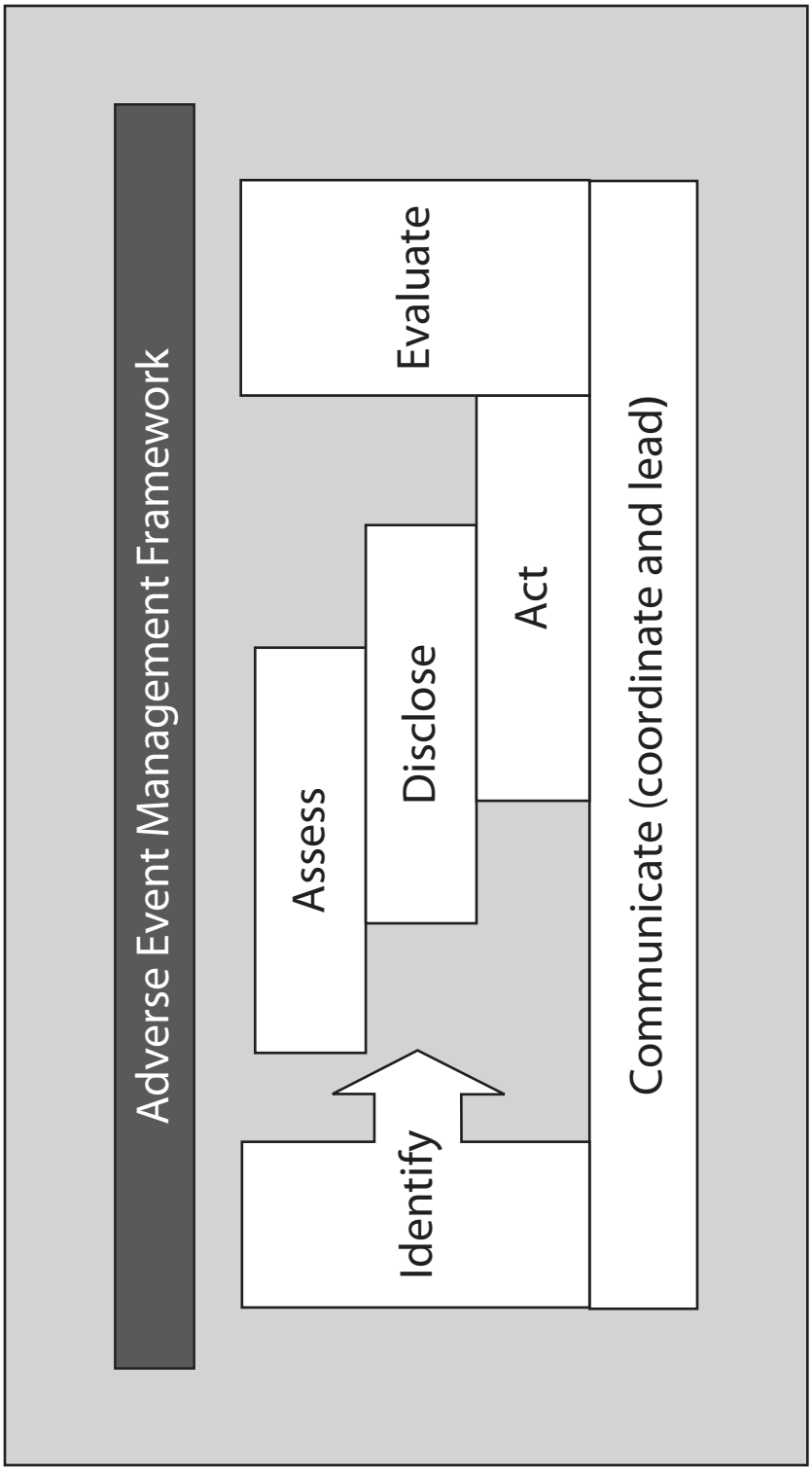
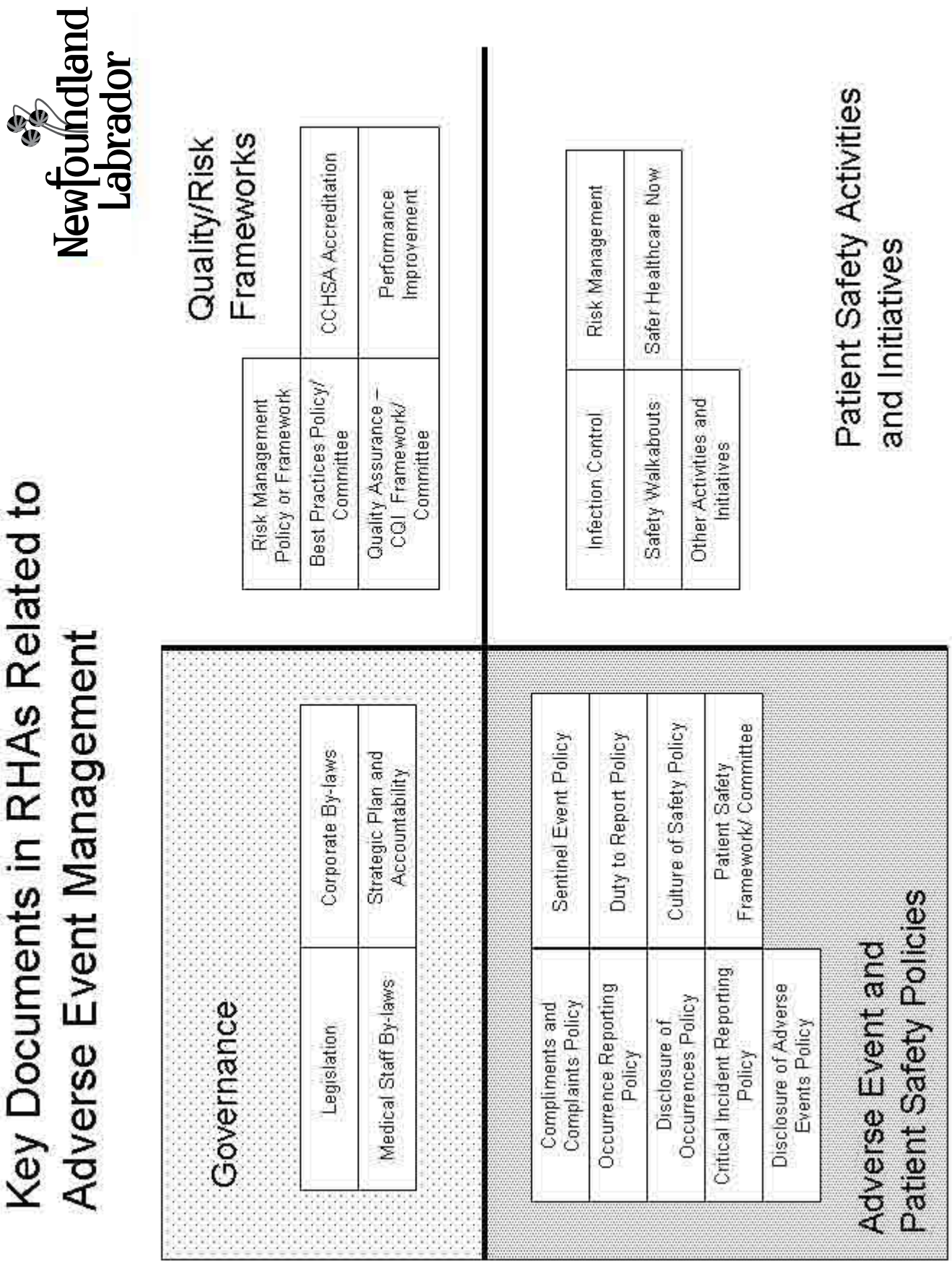
Appendix 4 Adverse Event Management Framework



Task Force on Adverse Health Events,
May 2008

Appendix 5 Governance Documents Related to Adverse Event Management



Task Force on Adverse Health Events

Background Documents
Volume II: Additional Reports

December 2008