Provincial Forum on Adverse Health Events:

Summary of Proceedings

May 26, 2008
The Fairmont Newfoundland

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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
Association of Registered Nurses of Newfoundland and Labrador	Elizabeth Lundrigan
	Lynn Power
	Margaret (Peggi) Earle
Safer Healthcare Now (Atlantic)	Theresa Fillatre
Calgary Health	Dr. Ward Flemons
Canadian Cancer Society	Peter Dawe
Canadian Institute for Health Information	Steve O'Reilly
Canadian Medical Protective Assoc.	Dr. John E. Gray
Canadian Mental Health Association	Geoff Chaulk
Canadian Patient Safety Institute	Dr. Phil Hassen
	Paula Beard

Central Health	Carole Dalton
	Cheryl Peckford
	Denise Duffy-Sheppard
	Jeanne Dillon
	John Kattenbusch
	Julie Nicholas
	Sherry Freake
	Stephanie Power
	Steve Jerrett
CHANNAL	Joan Edwards-Karnazyn
Child Youth Advocate	Darlene Neville
College of Licensed Practical Nurses	Judy Reid
	Paul D. Fisher
College of Physicians and Surgeons of Newfoundland and Labrador	Dr. Cathy Vardy Edward G. Hollett
Commission of Inquiry on Hormone Receptor Testing	Angela Blagdon
	Mandy Woodland
Curtis, Dawe	Peter Browne
Cypress Health Region	Jim Hornell

Eastern Health	Beverley Clarke
	Cathy Burke
	Carol Chafe
	Deborah Collins
	Diane Hart
	Dr. Franklin Kum
	Dr. Gerald Farrell
	Dr. John Guy
	Dr. Ken Henderson
	Dr. Lucinda Whitman
	Evelyn Tilley
	Gail M. Downing
	Heather Predham
	Joan Dawe
	Kevin Hogan
	Lorraine Burrage
	Louise Jones
	Lynn Wade
	Maria Tracey
	Mike Doyle
	Rowena Bryans
	Sharon Lehr
	Shawn Thomas
	Wayne Miller

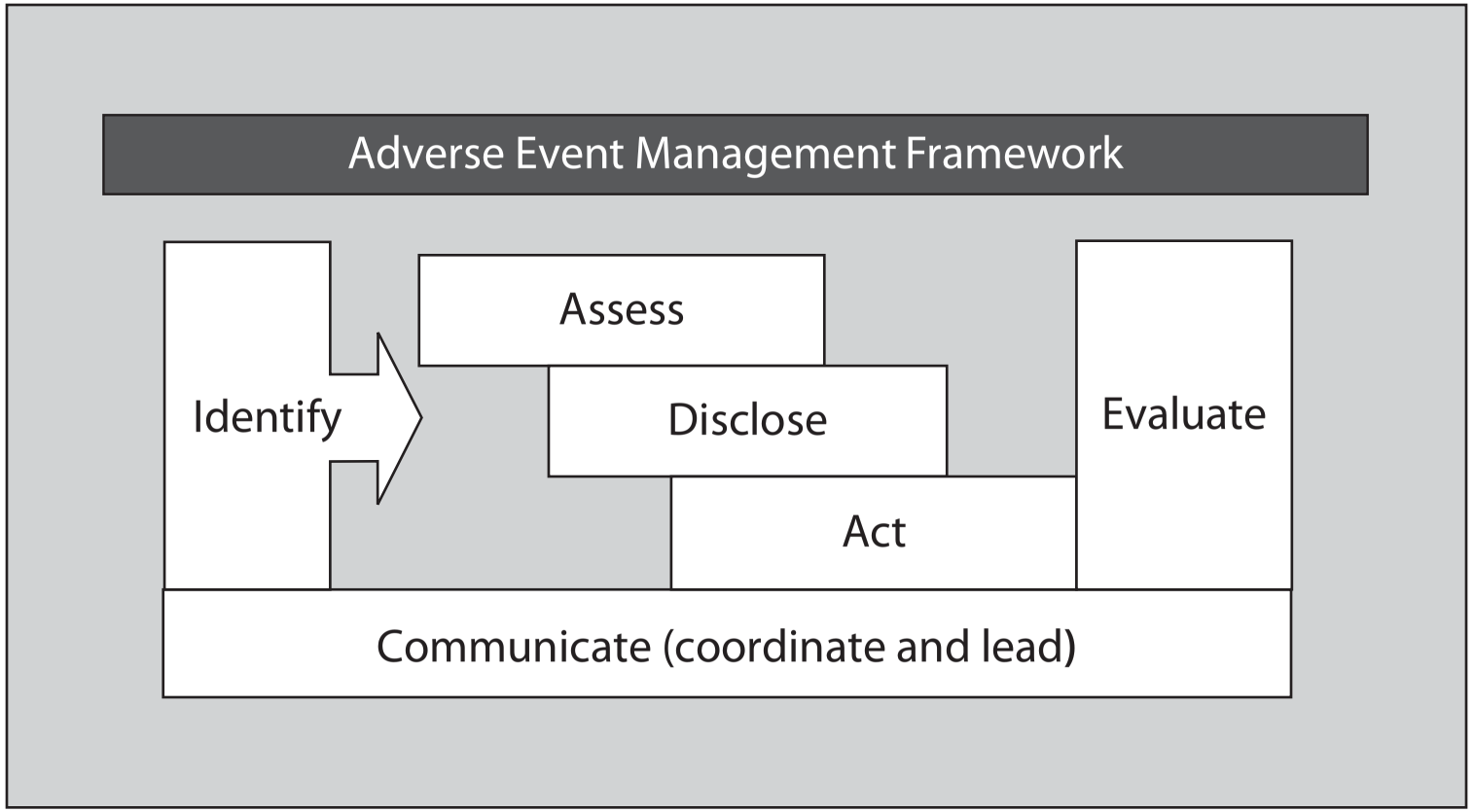
Executive Council, Government of Newfoundland and Labrador	Gary Cake
	Josephine Cheeseman
	Paula Burt
Department of Health and Community Services	Anita Ludlow
	Bev Griffiths
	Glenda Power
	Hon. R. Wiseman
	Ivy Burt
	Jim Strong
	Joy Maddigan
	Kathleen Healey
	Marilyn Collins
	Rosemary Boyd
	Susan Walsh
Health Canada, Atlantic Region	Annette Daly
	Gerald Alexander
	Harold Boudreau
Healthline	Marlene Penney
Independent Living Resource Centre	Stephen Quinn
Labrador-Grenfell Health	Boyd Rowe
	Marjorie Learning
	Norma Forsey
Management Resources	Susan Abell

Medical Council of Canada	Dr. Ian Bowmer
Memorial University of Newfoundland, School of Nursing	Dr. Christine Way
	Dr. Sandra LeFort
Memorial University of Newfoundland	Doreen Neville
Memorial University of Newfoundland , Faculty of Medicine	Dr. Daryl Pullman
	Dr. Barbara Roebothan
	Dr. Catherine Donovan
	Dr. Gerry Mugford
	Dr. James Rourke
	Laurie Twells
	Patrick Fleming
Memorial University of Newfoundland, School of Pharmacy	Dr. Debbie Kelly
Newfoundland and Labrador Association of Laboratory Technologists	Corey Murray
Newfoundland and Labrador Centre for Applied Health Research	Janice Butler
	Theresa Mackenzie
Newfoundland and Labrador Centre for Health Information	Don McDonald
	Kayla Collins
	Mike Barron
	Reza Alaghehbandan
	Tracy Chislett
Newfoundland and Labrador Health Boards Association	Jeannie House
	John Peddle

Newfoundland and Labrador Medical Association	Robert Ritter
Newfoundland and Labrador Provincial Advisory Council on the Status of Women	Elaine Wychreschuk
	Michelle Murdock
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
Newfoundland and Labrador Provincial Advisory Council on the Status of Women	Elaine Wychreschuk
Pharmacists' Association of Newfoundland and Labrador	George W.N. Skinner Don Rowe
Safer Healthcare Now (Atlantic)	Theresa Fillatre
Schizophrenia Society of Newfoundland and Labrador	Christina McGrath
	Florence Budden
Seniors Resource Centre of Newfoundland and Labrador	Rosemary Lester
	Shelly Russell
St. Patrick's Mercy Home	Katherine Turner
Task Force on Adverse Health Events	Robert Thompson Deborah Gregory Loretta Chard-Keane Lorraine Barrett Mabella Whitten Melissa Sullivan
Victorian Order of Nurses	Darlene Billard-Croucher

Western Health	Donna Hicks
	Karen Alexander
	Dr. Ken Jenkins
	Lisa Hoddinott
	Tina Moores
	Susan Gillam
Winnipeg Regional Health Authority	Ryan Sidorchuk

Appendix 4 Adverse Event Management Framework



Task Force on Adverse Health Events,
May 2008

Key Documents in RHAs Related to Adverse Event Management

Newfoundland Labrador

Governance

Legislation	Corporate By-laws
Medical Staff By-laws	Strategic Plan and Accountability

Quality/Risk Frameworks

Risk Management Policy or Framework	
Best Practices Policy/ Committee	CCHSA Accreditation
Quality Assurance – CQI Framework/ Committee	Performance Improvement

Adverse Event and Patient Safety Policies

Compliments and Complaints Policy	Sentinel Event Policy
Occurrence Reporting Policy	Duty to Report Policy
Disclosure of Occurrences Policy	Culture of Safety Policy
Critical Incident Reporting Policy	Patient Safety Framework/ Committee
Disclosure of Adverse Events Policy	

Patient Safety Activities and Initiatives

Infection Control	Risk Management
Safety Walkabouts	Safer Healthcare Now
Other Activities and Initiatives	

Task Force on Adverse Health Events

Background Documents
Volume II: Additional Reports

December 2008