



The Patient Safety
Education ProgramTM
CANADA

Module 7b: Patients as Partners:
Engaging Patients and Families in
the Disclosure Process

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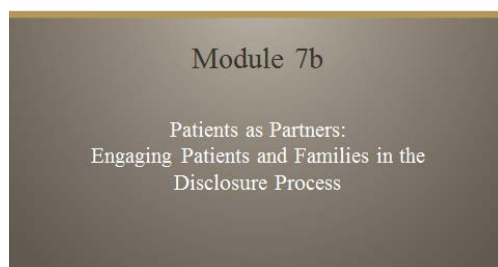
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Abstract

Slide 1



Despite being acknowledged as a public health priority in many countries for several years, there is widespread concern about the lack of progress on patient safety. Leaders cite the failure to engage patients in patient safety work as one factor in delaying progress. Patients/families often see things that busy healthcare workers do not. When healthcare organizations fail to integrate patients/families involvement in managing systemic risk, they lose access to important knowledge that cannot be gained from any other source.

Until recently, the only pathway for discussion of medical risk with patients and families was the informed consent process, which is often inadequate. Despite the long-standing ethical obligation to disclose a patient safety incident when it occurred, legal counsel or risk management actively discouraged open communication about a patient safety incident that might increase liability exposure. One of the hallmarks of the patient safety movement is re-commitment to disclosure of patient safety incidents as a mandatory requirement of authentic engagement of patients. The practice of disclosure positions patients and families as partners with a common interest in healing, implementing lessons learned and preventing future harm. Opportunities for patient partnership are growing as attention to the importance of disclosure and apology grows.

In addition, newly formed or refocused patient organizations and networks are shifting the emphasis from being primarily concerned with victim support or victims' rights to more prospective prevention activities. These organizations are working to orient patients to the realities of systems-based risk and create conduits for feedback to providers and policymakers. For instance, the Institute for Safe Medication Practices Canada (ISMP Canada), Canada's consumer-focused organization is part of the Canadian Medication Incident Reporting and Prevention System (CMIRPS), a Canadian initiative to prevent harmful medication incidents. Its website and phone systems offer venues for practitioners and consumers to report medication incidents and to get information about using medication safely.

This module provides an overview of patient/family engagement activities that naturally divides into two dimensions: (a) learning and healing opportunities after a patient safety incident has occurred, and (b) engagement of patients in preventing harm.

Keywords

Harmful incident, advisory council, apology, communication, complaints, cultural norms, disclosure, education, patient safety incident, fear, informed decisions, liability, mediation, patient and family, patient-centered, patient engagement, patient rights, partnership, partnership councils, proactive, rapid response team, reporting, questions, Ask. Listen. Talk campaign stories, victims.

Teaching methods

Didactic, video film, appreciative inquiry interviews, small group discussion, and story telling

Objectives

Slide 2

Knowledge requirements

- Patient/family needs following a harmful incident
- The usefulness of patient concerns or reports
- The role of patients in patient safety
- How organizations engage patients
- Apology Legislation and how it may affect disclosure

Slide 3

Performance requirements

- Describe the basic steps in a disclosure process
- Explore the usefulness of patient concerns or reports in patient safety work
- Explore the unique value of patient or family participation in analysis of patient safety incidents
- Describe the importance of patient/family input into development of patient programs
- Explore the importance of supporting patients/families

The objective of this module is to understand the critical importance of patient engagement in the disclosure process and the challenges in achieving it.

Knowledge elements

The knowledge elements include an understanding of:

- what patients/families want after a harmful incident occurs;
- the usefulness of patient concerns or reports in patient safety work;
- the ways in which patients/families are contributing to patient safety work;
- the ways in which innovative organizations are achieving patient engagement; and
- Apology Legislation and how it may affect disclosure.

Performance elements

The performance elements include engaging in exercises to:

- describe the basic steps in a disclosure process;
- explore the usefulness of patient concerns or reports in patient safety work;
- explore the unique value of patient or family participation in the analysis of patient safety incidents;
- describe the importance of patient/family input into development of patient engagement or patient education programs; and
- explore the importance of supporting patients/families who engage in patient safety work.

Clinical case on trigger tape

Slide 4

Trigger tape



Linda Kenney entered the hospital for ankle replacement surgery. Soon after her anesthesiologist, Dr. van Pelt, administered a nerve block, Mrs. Kenney suffered cardiac arrest. Mrs. Kenney's interview gives the patient point of view of an adverse event and, together with Dr. van Pelt's interview, provides a model of productive partnership between providers and patients.

Why is everybody talking about patient engagement?

Slide 5

Why patient engagement?

- Patient-centered care one of six IOM aims
- Growing role of the patient
- The hope that engagement can reduce harmful incidents

In its landmark *Crossing the Quality Chasm* report, the Institute of Medicine (IOM) outlined a vision for a healthcare system in the 21st Century that included being patient centered as one six fundamental aims. So too, have Health Quality Councils and other health organizations across Canada accepted this as a fundamental aim. Notwithstanding this emphasis on patient-centeredness or the importance paid rhetorically to “including the patient as partner,” patients have been the least represented stakeholder perspective in healthcare safety and quality improvement movements. Because patients and their families are not as organized as other stakeholder groups, their interests and needs, their responses to the safety improvement recommendations, as well as recommendations for future action have not been well captured or well integrated into research activities, policy development, patient safety educational curricula, patient education or patient safety incident reporting systems. Recently, patient safety leaders have observed a lack of progress in reaching the patient safety incident reduction goals. It may be due, at least in part, to our failure to effectively engage patients/families as partners in ensuring the safety of care.

Is there evidence that patient engagement is effective?

Slide 6

Is it effective?

- Unclear evidence for reduction of harmful incident
- Strong patient interest in being involved
- Involved patients may achieve better outcomes

At this time, there is no clear evidence that engaging patients and families as partners in care actually reduces patient safety incidents or systems failures, and human factors

experts have weighed in, expressing caution about assigning responsibilities to the patient or family without a clearer understanding of what their role is in preventing harm. However, a study by Waterman et al. indicated a strong willingness, 91% among hospitalized patients, to be involved in patient safety incident prevention activities, with their comfort doing specific tasks varying depending on the task as well as on their comfort in talking about the patient safety incident prevention. For example, 85% were comfortable asking about a medication's purpose, but 46% were very uncomfortable about asking healthcare workers whether they had washed their hands.

Findings like these point to the importance of patient education about risk and patient safety incident prevention, as well as the importance of engaging patients as members of the care team. We are really at the beginning of that journey, hampered by healthcare's own lack of understanding about how to talk publicly about patient safety incidents and risk without being alarmist or undermining public confidence in the effectiveness of healthcare.

The preceding PSEP – Canada Module 7a: Patients as Partners: Engaging Patients and Families describes comprehensively the concept of patient and family centered care, its importance, how to achieve it, as well as the barriers organizations may encounter on the journey to patient and family centered care. Disclosure to patients and families after a patient safety incident will be one of the most challenging and important conversations to take place between the patient/family and providers/organizations. The concepts of patient and family centered care combined with the recommendations contained in this module from patients and families who have gone through the disclosure process will assist providers/organizations to achieve an effective, satisfying disclosure process.

Entwistle et al. found in a 2005 study that most education materials asking patients or families to engage in safety were developed without significant research about what patients wanted to know and asked patients to perform tasks (e.g. asking questions) for which they had little support. It is essential that when patients and families do ask questions or are actively involved in care that the care team be prepared to welcome the participation and respond respectfully. Staff must be educated to understand why patient engagement is so important to patient safety and satisfaction. As discussed in the PSEP – Canada Module 7a: Patients as Partners: Engaging Patients and Families proponents of patient engagement point to an extensive body of findings showing that patients achieve better treatment outcomes when they are actively involved in the self-management of their own care. This has been shown over a wide range of health and disease conditions, including management of asthma, diabetes, blood thinning medications, and HIV, just to name a few. The inference is that the combination of effective communication about risk and the patient or lay caregiver's important role in managing it as part of the care team makes a measurable difference. It is reasonable to infer that these findings be extrapolated to patient safety.

If existing research is clear on anything, it is that among patients who have experienced healthcare systems failure, there is a strong personal desire to prevent another patient

from experiencing the same or similar injury. Several studies consistently show that the desire to prevent future harm is often more important than the desire to receive financial compensation for the harm caused. Honest disclosure of the facts about what happened, acknowledgement of responsibility, where applicable, and an apology is strongly desired by patients or the surviving loved ones of patients who have died.

This curriculum takes the position that the disclosure of material facts after a patient safety incident is fundamental to patient-centered care, for the simple reason that patients have told us it is. Patients expect to be informed about harm they have experienced, whatever the reason for it, and this information needs to be delivered in a caring manner. Accordingly, it is a cornerstone of effective patient engagement. Without confidence that healthcare providers will communicate honestly with patients, there can be no sustainable trusting partnership between patients and providers.

Movement towards patient engagement

Slide 7

Engagement movement

- First patient contributions were stories
 - illustrated gaps in safety
 - highly motivational
- Learn about system failure through stories
- An international movement
 - Australian Council for Safety & Quality
 - World Health Organization
 - Consumers Advancing Patient Safety (US)

Patients as motivators

Initially, approaches to patient engagement consisted primarily in providing forums for patients who had experienced medical system failure, either as patient or lay caregiver, to a family member or friend, to tell their stories. This was beautifully accomplished in Susan B McIver's book, *Medical Nightmares-The Human Face of Errors*, which used patient experiences to viscerally illustrate the human toll of systems failure and bridged eloquently to the need for improved learning systems, education, public reporting and other policy initiatives. Susan B McIver and Robin Wyndham collaborated on a follow up to "Medical Nightmares" in –*After the Error-Speaking out About Patient Safety to Save Lives* (2013) where the focus is on how the active engagement of patients and families following a patient safety incident have helped to lay the foundation of current patient safety programs and how they continue to raise awareness, identify problems and provide solutions.

The importance of involving patients is expressed in the opening page of the Patients for Patient Safety Canada website (www.patientsforpatientsafety.ca):

“We see improvement projects that lack authentic patient input to be incomplete in important ways, and that the success of such projects hinge on a holistic and inclusive diversity of perspective and experience, from bedside staff providing care every day to the patients and families receiving that care. There is no greater stakeholder in the effort to improve the safety of care than patients and families.” The real life stories and personal tragedies of patients and families succeed in reaching into the deepest realms of the patient safety movement.

Patients’ experience as learning sources

The Canadian Patient Safety Institute (CPSI) acknowledges the value of patient stories and experience as more than just a motivational tool but also as a unique source of knowledge. The commitment of CPSI to tap this largely unknown source was to provide project support to a national group of patients and family members who, as part of the World Health Organization (WHO) World Alliance for Patient Safety, are members of a global network that have been harmed by healthcare and are ready to work in partnership with healthcare organizations to improve patient safety. This group, Patients for Patient Safety Canada works closely as a resource for CPSI when the patient/family perspective is desired. Patients and families have been presenters at major health conferences and, and are actively sought to be expert advisors on many national and international Working Groups, symposiums and roundtables and were full partners at the table in the revision of The Canadian Disclosure Guidelines(2011) and the Canadian Incident Analysis Framework (2013).

In October 2009, the report, “For Patients’ Sake” the Patient First Review Commissioner’s Report to the Saskatchewan Minister of Health was released to the public. This report was founded on the voices and perspectives of healthcare patients and their families, providers and system leaders. This report was unique in its focus on the care and caring experience. Patients were given the first and last voice in the research that cumulated in the report released by Commissioner, Tony Dagnone. Approximately, 4000 Saskatchewan residents had shared perspectives, ideas and opinions.

In the words of Commissioner Dagnone: “Patients ask that health care workers and their respective leadership see beyond their declared interests so that the interest of patients takes precedence at every care interaction, every future contract negotiation and every policy debate. I call upon health system leaders and health care providers to adopt and practice the values that support a truly patient-and patient- and-family centered health system.”

Two organizations that acknowledged early on the value of patient stories as more than a motivational tool, but also as a unique source of knowledge, are the Australian Council for Safety and Quality in Health Care and the World Health Organization (WHO). Established in 2000, the Australian Council made an early commitment to “harness the experiences of patients and their caregivers to drive improvements” and through this commitment produced a number of important tools, including Better Practice Guidelines

on Complaints Management for Health Care Services and the (Australian) National Patient Safety Education Framework. To quote from the former:

Consumers (including patients and caregivers) have a unique expertise in relation to their own health and their own perspective on how care is actually provided. Consumer complaints are therefore a unique source of information for health care services on how and why adverse events occur and how to prevent them.

Australia's National Patient Safety Educational Framework followed the same path in putting "patients, clients and caregivers at the centre of healthcare learning and service delivery." Each learning topic in the framework incorporated an illustrative patient narrative, to underscore that:

A health care team is made up of more than the health care workers and professionals; the team also includes the patient and their caregivers. Patients and caregivers play a key role in ensuring safe health care by: helping with the diagnosis; deciding about appropriate treatments; choosing an experienced and safe provider; ensuring that treatments are appropriately administered; as well as identifying adverse events and taking appropriate action.

Currently the health care system underutilizes the expertise patients can bring to the health care partnership. In addition to knowledge about their symptoms, preferences and attitudes to risk, they are a second pair of eyes if something unexpected happens.

The current curriculum adopts this approach as well, and is strongly influenced by the Australian framework.

WHO established Patients for Patient Safety (PFPS) in 2006, one of six original action areas that comprise WHO's World Alliance for Patient Safety. Quoting from the PFPS Statement of case,

Patients have much more to offer than visceral reminders to healthcare workers, administrators and policymakers that we are victims of tragic medical errors. Important as that perspective is, a victim orientation does not position us well as partners working with healthcare providers to prevent harm. Indeed, the perception that patients and their families are helpless or antagonistic victims has served to distance us from playing meaningful roles in the development and implementation of patient safety work in the past and generated fear among some clinicians who would have otherwise engaged with us. Patients and their families have needs and wants when things go wrong. "We need to be told that something has gone wrong and we want healthcare service deliverers to be open and involve us in the investigation to find the root causes".

At the healthcare service delivery level, patients and families who wish to contribute knowledge gained or lessons learned have often found few effective pathways for doing so. Particularly after a patient safety incident has occurred, a “wall of silence” may descend and productive interaction may cease. When patients register concerns, their actions often are perceived as adversarial threats or unscientific anecdotes that lack evidence, rather than potential knowledge contributions.

Although there are notable exceptions, at the policymaking level patient participation tends to be marginalized, often by well-meaning leaders who assume patients to be unable to appreciate the complexity of healthcare. Such an approach fails to take into account that many patients/families offer the richest resource of information related to patient safety incidents as many have witnessed every detail of systems failures from the beginning to end.

Patients who choose to partner with healthcare policy makers and providers are highly knowledgeable, motivated and eager to contribute. Patients engaging with the healthcare system to advocate change, approach this role with a profound sense of responsibility and desire to help create a care system that is safe, honorable and compassionate for patients and healthcare workers alike. Patients advocating within the system are here to challenge healthcare to be truly patient-centered – especially when it is resistant to change or slow to make safer care a priority — but most fundamentally, patients and families are ready to partner.

However, patient engagement is now receiving more attention because of new programs, organizations and networks that have been developed to focus on the patient role in patient safety. Patients For Patients Safety Canada, Patient Voices in B.C., Patients Canada, The Empowered Patient Canada Society, Best Medicines Coalition, Canadian Patient Coalition, are active patient organizations in Canada that work towards an increased role for patients in their own and all aspects of patient safety.

This module examines initiatives to implement authentic disclosure programs in healthcare organizations as a foundation for effective patient engagement. It will then review six emerging areas where models or tools exist for proactively engaging patient energy as learning systems inputs, in the design of effective systems of care and in prevention. These emerging areas are:

- patient reporting of patient safety incidents and/or near misses;
- patient participation in patient safety incident analysis or other forms of investigation of patient safety incidents;
- patient and provider education and support for promoting active patient engagement, as opposed to passive patient compliance;
- rapid response team implementation by patients and visitors;
- establishing patient partnership bodies within healthcare organizations or communities; and
- explaining risk in ways that are more research-based and honest.

Disclosure and patient engagement

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Disclosure and patient safety

- Disclosure duty arises from basic ethical duties
- Disclosure crucial to provider-patient relationships
 - patients want promise of future prevention
 - “Trust can be re-earned when providers are honest and go the distance” - Rick van Pelt

One could make an argument that the disclosure of material facts after a patient safety incident is a matter of professional ethics, not patient safety, because it has little to do with preventing future harm. However disclosure and patient safety incident reduction have been contextually linked in the patient safety movement at least since the first major conference on error in medicine, which took place at the California-based Annenberg Center for Health Sciences in 1996.

In 2004 the “Canadian Adverse Event Study” identified patient safety incidents arising from the delivery of healthcare services as a significant problem in Canadian hospitals. Early in the mandate of the Canadian Patient Safety Institute (CPSI), established in 2002, it was recommended by The Legal and Regulatory Affairs Advisory Committee that CPSI provide leadership and support for the development of Canadian disclosure guidelines. The approach taken in developing these guidelines was to integrate ideas and concepts from the Disclosure Working Group discussions, expert presentations and stakeholder consultations. Additionally, a number of local, provincial/territorial, national and international best practices were reviewed and synthesized.

The Canadian Disclosure Guidelines, released in 2008, emphasize the importance of a clear and consistent approach to disclosure regardless of the variance in definitions across Canada related to harm and patient safety incidents; patients have a right to be informed about all aspects of their care. With the release of The Canadian Disclosure Guidelines and the requirement from Accreditation Canada standards that a Disclosure Policy and processes be in place for healthcare organizations, conversations about disclosure and the importance it holds for patients/families came to the forefront.

The forward for The Canadian Disclosure Guidelines was written by the national patient advocacy group, Patients for Patient Safety Canada. In part, the foreword states, “We believe disclosure is the responsibility of all healthcare providers and the right of every patient.”

There was notable change in the philosophy of disclosure since the Canadian Disclosure Guidelines were released in 2008, so much so, that a scant three years later the document

was revised to reflect these changes. With patient/family representation at the table as a full partner a stronger patient voice is heard throughout the revised document. So too, is the increased understanding of what the crucial elements are to achieve effective, satisfying disclosure following a patient safety incident.

Healthcare organizations across Canada are using the valuable information in the Canadian Disclosure Guidelines and working hard to develop and implement Disclosure policies that serve the interests of patients and providers alike.

The case study of Ben Kolb's death, which was the centerpiece of that 1996 Annenberg conference, presented a wonderfully detailed example of retrospective analysis of the factors that contributed to the child's death. But it was the stories of the anesthesiologist involved in the system failure, the hospital's Chief Executive Officer and the organization's risk manager on how they communicated with the family that had everyone on the edge of their seats. This suggests that a major underlying connection between disclosure of patient safety incidents and prevention of future harm is the focus of disclosure -- the trusting relationship between healer and patient embodied in the Hippocratic Oath and other iterations of professional healthcare ethics. When Ben Kolb's family learned the facts of what happened to their son, they wanted to know what the hospital was doing to make sure it did not happen to someone else. Indeed it was the promise to try to prevent future harm made to Ben's family during the disclosure process that prompted his providers to speak publicly about their experiences.

In addition, the shift toward patient-centeredness in healthcare brings into new relief for providers this question: What if I were in this patient's shoes? At the 1996 Annenberg Conference, each of Ben's providers who presented -- , healthcare executive, risk manager – reflected on being a parent as their reference point in a decision to treat the family the way they would want to be treated if it were their son who had passed away.

Frederick ("Rick") van Pelt is another physician in the United States who speaks publicly about his decision to apologize to his patient, Linda Kenney, after she went into full cardiac arrest caused by an anesthesia block administered by Dr. van Pelt during elective orthopedic surgery. Horrifying as it is, an injury is an opportunity to "go the distance" and strengthen the physician patient relationship in van Pelt's view. The conversations between he and Mrs. Kenney that ensued from disclosure led them both to better understand the other's needs for emotional and psychological support after such an event and prompted them to proactively fill the gap for both patients and providers in their own hospital community. (Their innovative solution, Medically Induced Trauma Support Services, is discussed later in this module.)

Disclosure and what must be disclosed

Slide 9

What must be disclosed

- ❑ “Revelation; that which is disclosed, told, or revealed; the impartation of secret information” Timmreck, 1997
- ❑ Terminology not always used consistently
- ❑ Rules of thumb:
 - how would I want to be treated?
 - what is the right thing to do?

Slide 10

Disclosure definitions

- ❑ Harmful incident = an incident which resulted in harm to a patient
- ❑ Patient Safety Incident = an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.
- ❑ Systems failure = an inherent latent or active condition that contributes to a patient safety incident.

“Disclosure” or “open disclosure” refers generally to informing patients and their families of bad outcomes of medical treatment, as distinguished from bad outcomes that are expected from the disease or injury being treated. The term has been critiqued by some as being too imprecise, in that the word “disclosure” is often used in healthcare to reference publishing quality indicators of various kinds as well as to reporting data or events to appropriate authorities. *When Things go Wrong, Responding to Adverse Events, a Consensus Statement of the Harvard Hospitals* issued in 2006, takes the position that disclosure in essence is effective communication between providers and the casualties of the adverse events and, therefore, that “communication” is a more accurate term. But “disclosure” continues to be the most commonly used term in most patient safety discussions and will be used here.

Disclosure is a professional obligation, long established in the ethical codes of healthcare. Some also refer to it as a moral obligation, with the guiding moral question being, “What is the right thing to do?” “What would I want if I or my loved one were harmed by medical treatment?” This is the question that healthcare providers need to ask themselves so they can understand why honest and open disclosure is so important.

There is substantial debate about what must be disclosed and, again, confusion over terminology. Some of the difficulty stems from a rather entrenched tendency within discussion of patient safety to use the terms “error” and “injury” as if they referred to the

same thing. For the purposes of this curriculum, a discussion on patient safety terminology can be found within the glossary.

Disclosure needs of patients

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Patients and disclosure

- Vast majority want to know the truth when an event or near miss occurs
- 98% of patients expect physician to acknowledge harm, regardless of severity (Mazon 2004, Witman 1996)
- Patients want the full facts about patient safety incidents (Gallagher 2003)
- As the severity of a harmful incident increases, patients expect more substantial information, and say they are more likely to litigate if not given it (Id.)

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Disclosure process needs

- After a harmful incident, patients want disclosure that includes:
 - an explanation
 - admission of responsibility
 - apology
 - prevention of similar events in the future
 - in some cases, reprimand/ compensation

Vincent 1994 and numerous subsequent studies

It is clear that patients – or, in the case of the patient’s death or incapacity, their families – want and expect disclosure of patient safety incident. Many studies confirm this fact. Ninety five percent of the respondents felt that it should be required to tell the patient or the patient’s family if a preventable patient safety incident resulting in harm is made in the patient’s care. Patients want the full facts about adverse events and near misses when they occur. Gallagher’s 2003 research also suggests that as the severity of the injury increases, patients expect more substantial explanations and are more likely to litigate if they do not get them. Candor about patient safety incidents may lessen, rather than increase, the medico legal liability of the healthcare professionals and may help to alleviate the patient's concerns.

The specifics of what patients want in the disclosure process also are clear and surprisingly consistent from study to study, starting with the ground-breaking work of Charles Vincent in 1994. After a patient safety incident, patients want disclosure of an event that includes:

- an explanation of what happened;
- an admission of responsibility;
- an apology;

- the assurance of prevention of similar events to others in the future; and
- in some cases, punishment and compensation.

Do patients or their families have a right to disclosure?

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Disclosure rights

- A Comprehensive Disclosure Policy is a requirement for hospitals, long term care facilities and Regional health authorities to achieve accreditation
- Statutory obligation on organizations to disclose critical incidents in Quebec and Manitoba
- Underlying ethical obligation in codes of ethics for physicians, nurses and health care executives

Patients do have a right to disclosure of a patient safety incident. Accreditation Canada standards specify that healthcare organizations must implement a formal and transparent policy and process of disclosure of patient safety incidents to patients, which includes supportive mechanisms for patients, family and care or service providers.

Most professional codes of conduct specifically require disclosure. Patients have a right to relevant information about all aspects of their care and healthcare providers have a corresponding obligation to provide that information to patients without being asked and to answer their questions.

Patients and families who had been harmed by the healthcare system in Manitoba lobbied the provincial government and were successful in obtaining legislation pertaining to disclosure of details of a critical incident.

The RHA Amendment and Manitoba Evidence Amendment Act notes as follows:

53.2(2) if a critical incident occurs.....the regional health authority, corporation or organization must ensure that.....appropriate steps are taken to fully inform the individual as soon as possible, about:

- (i) the facts of what actually happened
- (ii) its consequences for the individual
- (iii) the actions taken....to address the consequences....

To date, 8 Canadian provinces and one territory (British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, and Nunavut) have adopted "apology legislation". The Uniform Law Conference of Canada and the CPSI have both encouraged all provinces and territories to enact apology legislation.

One of the objectives of apology legislation is to reduce the concerns about the legal implications of making an apology. The protection afforded by the apology legislation is substantially similar from province to province. It typically provides that an apology:

- does not constitute an admission of fault or liability
- must not be taken into consideration in determining fault or liability
- is not admissible as evidence of fault or liability

The protection extends both to legal proceedings before courts and proceedings before tribunals or quasi-judicial bodies, such as regulatory authority (College) disciplinary committees or coroners'.

It remains to be seen whether mandatory disclosure, as in Manitoba, and Apology Legislation will have the desired impact of increasing disclosure rates. Will providers and organizations be more comfortable issuing an apology and initiating disclosure discussions knowing that the apology is not an admission of liability? It should be noted, however, that if the incident analysis determines system or provider failure a contributing factor then responsibility should be acknowledged and liability is a possibility.

Patients and families have expressed the concern that Apology Legislation may result in less than sincere apologies after a patient safety incident. With close attention to the concepts of patient and family centered care and employment of the “substitution theory” (how would you want to be treated?) this concern should be negated.

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Scope of obligation ...

- Canadian Medical Protective Association (CMPA)
 - encourages discussion of poor clinical outcomes, including harmful incidents (communicating with your patient about harm)
 - should harm occur, disclose it to the patient

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... Scope of obligation

- Canadian Nurses Association
 - admit mistakes and take all necessary steps to prevent or minimize harm arising from a harmful incident

The foundation for the right to disclosure is in professional ethics. The Canadian Medical Protective Association (CMPA) has for many years encouraged members to disclose to patients the occurrence and nature of a patient safety incident as soon as it is reasonable to do so.

However, this advice has sometimes been confused with CMPA guidance to limit direct communication with patients if a patient has initiated a legal action.

The Canadian Medical Association Code of Ethics states, “Take all reasonable steps to prevent harm to patients; should harm occur, disclose it to the patient”. It also directs that physicians should provide patients with the information they need to make informed decisions about their medical care and their questions should be answered to the best of the physician's ability. Every reasonable effort should be made to communicate in a way that the information is understood.

The Canadian Nurses Association Code of Ethics states, “Nurses admit mistakes and take all necessary actions to prevent or minimize harm arising from an adverse event. They work with others to reduce the potential for future risks and preventable harms”.

The Royal College of Physicians and Surgeons of Canada in 2002 called for healthcare systems to promote disclosure on safety issues to all partners including patients. With the development and publication of The Canadian Disclosure Guidelines in 2008 healthcare systems across Canada took a closer look at disclosure and began adopting disclosure policies.

Reviewing nationwide practices on patient safety incident disclosure found a few licensing bodies had ratified policies for disclosure and discussion of negative outcomes during patient care. The College of Physicians and Surgeons of Saskatchewan requires the physician to disclose any patient safety incident to the patient or his or her representative as soon as possible during care, with ten guidelines on the steps in purposeful disclosure.

The College of Physicians and Surgeons of Manitoba requires the physician to avoid all speculations and state plain facts as known at the time when disclosing.

In 2003, after lengthy deliberation, the College of Physicians and Surgeons of Ontario approved a policy that made disclosure of harm to patients a standard of practice, even in circumstances when such disclosure may result in a complaint or a malpractice insurance claim. A special aspect of the Ontario College policy is the guideline for medical trainees (i.e., students or residents), who are advised to report a patient safety incident either to their supervisor or to the 'most responsible physician'. (The policy also specifies that the patient is free to refuse discussion of the event.)

A contractual right to disclosure may also be established through the policy development process of a healthcare organization. For example, the Veterans Health Administration in the United States has a longstanding policy providing for full disclosure of patient safety incidents to the patient and family.

Conceivably, the right to disclosure could be enforced by a country's judicial system either as a contractual right or as part and parcel of the legally recognized standard of care established by the health profession. To date, there are no clear precedents in Canada for establishing such a right in the courts. The highly developed consensus among ethicists and patient safety experts are likely to be highly persuasive sources for future courts presented with a claim for damages arising from the failure to disclose.

The culture of malpractice suits continues to grow. Suits filed solely for monetary considerations abuse the tort system and set an unacceptable trend. Blame and retribution may have their place, but society's interests are best served by creating a trusting environment that promotes honest disclosure of patient safety incidents. To restore trust successfully and perhaps lower malpractice claims, both the public and healthcare providers must avoid the 'shame and blame' game. The other challenge lies in achieving a balance between a non-punitive approach to patient safety incidents and the need for a process that includes accountability and suitable compensation for patients. We suggest that this balance can be achieved by a system-based patient safety incident disclosure program.

How well is disclosure being done now?

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Disclosure rates ...

- Only about 25-30% of physicians actually disclose patient safety incidents (Blendon 2002, Wu 2003, Chan 2005)
- Often given only after patients press for details (Chan 2005)

Slide 17

... Disclosure rates

- Content of disclosure also varies widely
 - surgeons reported disclosing 57% of clear cut, harmful incidents, but only 27% of complications (Chan 2005)
 - physicians often use carefully chosen language that avoids responsibility (Gallagher 2003)

Disclosure is a dynamic field that is now receiving a great deal of attention, so hopefully the practice of disclosure is steadily increasing. The Canadian Medical Protective Association (CMPA) offers educational resources to help physicians and trainees meet

their patient's clinical, information and emotional needs after an unanticipated poor clinical outcome. As well, the Institute for Healthcare Communication (IHC) <http://healthcarecomm.org> offers a full range of educational, coaching and consulting services for communication skills development.

The research however reveals substantial discomfort and resistance. A ballpark estimate, based on the snapshots that a number of studies provide, is that full disclosure happens in only about one third of cases where it may be warranted. In a 2002 study in the US, Blendon estimated a disclosure rate of about 30%. In 2003, Wu found that 24% of physicians in training discussed adverse events and their surrounding circumstances with the patient or family. Chan found in 2005 that surgeons reported disclosing 57% of clear cut, harmful errors, but only 27% of complications, and that disclosure was often made only after patients pressed for details. Some studies suggest that more experienced physicians disclose more often, but the results are mixed (Wei 2006). Gallagher found in 2003 that physicians often use carefully chosen language in disclosing that avoids statements of responsibility. This remains true today in the disclosure climate of Canada. Avoiding the acknowledgement of responsibility, where applicable, denies the patient/family of one of their basic and most important needs following an adverse event.

Again, it should be emphasized that these statistics are indicators only, and most likely moving ones at that, given prioritization of disclosure as a fundamental step in achieving patient-centered care. The studies should be used to understand the extent of the cultural anxieties and barriers outlined below as a prelude to effectively addressing them.

Four common barriers to disclosure

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4 barriers to disclosure

- ❑ Education
- ❑ Fear to harm
- ❑ Fear of repercussions
- ❑ Cultural norms

Ethical considerations

- ❑ Does an individual's contribution to an incident involving several sources of error trigger a duty to disclose?
- ❑ Is a physician obligated to disclose systems failure?
- ❑ When witness to a harmful incident is a physician obliged to disclose when the colleague refuses to do so?

Wiel 2006

To summarize our discussion so far, patients clearly want disclosure and there appears to be a clear right to it. Yet we know that providers do not disclose completely or regularly. Why not?

The default explanation is usually “fear of liability.” A frequent second reason, arguably derivative of the first, is “advice of legal counsel.” But the inhibiting factors are more complicated than these simple reactions capture. Organizations that have adopted thorough disclosure policies still must rely on individual people in the organization to initiate and complete the process, and it is usually a physician involved in the patient safety incident or one with an established relationship with the patient who is called upon to say what must be said. The depth of anxiety about disclosure is underappreciated. It's helpful to think about the barriers that need to be addressed in four buckets:

1. the education barrier – physicians or other individuals called upon to disclose do not know how or when to do it;
2. the fear of harm barrier – healthcare providers and healthcare organizations often justify the failure to disclose completely by concern for causing further distress to a patient;
3. the fear of repercussion barrier – healthcare providers and healthcare organizations consciously or unconsciously fear litigation, reputation loss, loss of or increased cost of liability insurance coverage, shame or other harm; and
4. the cultural norms barrier – healthcare providers and healthcare organizations are advised not to disclose by their peers or indirectly discouraged by unspoken cultural norms.

Education barrier

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Education barrier

- Do providers know what to do?
 - medicine tends to regard talking and listening as basic functions which need not be learned (Liebman/Hyman 2005)
 - adult healthcare workers may lack training in effective communication skills

While the Canadian Medical Association Code of Ethics provides strong directives for physicians, they lack precision regarding a number of situations healthcare organizations who experience systems failure routinely face. For example:

- How much of an individual's contribution to an event involving several causal factors triggers that individual's duty to disclose?
- If it produced a patient safety incident, is a physician obliged to disclose a patient safety incident he/ she witnessed a colleague making? What if that colleague made a patient safety incident such as administering a wrong medicine that you – the one now with the ethical dilemma -- caught and addressed before it seriously harmed the patient?
- Is a physician obligated to disclose an injury caused by faulty equipment, hospital acquired infection- the source for which may not be clear- or other situations that may not easily reduce to human error?

Most healthcare providers have not been trained in the basics of effective communication. Medicine tends to regard talking and listening as basic skills that need not be learned and few undergraduate medical schools require education in communications skills. Most physicians report that they have no such training at any point in their education. It is no wonder they are reluctant or anxious about their ability to perform well in this area.

Fear to harm barrier

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Fear to harm

- Therapeutic privilege in delaying disclosure is justified, but narrowly
- "Delay" must be temporary only

Despite consistently strong indications that almost all patients want the facts after a patient safety incident, therapeutic privilege continues to be recognized. There is evidence that patient confidence in treatment can have a strong "placebo effect." The question is whether trust in the provider can or should be the placebo. Providers often believe it can be and, by extension, that patient awareness of physician fallibility may be harmful to patients if it undermines trust. Surgeon author, Atul Gawande, has raised the further provocative question about whether a physician's awareness of his/her own fallibility can be debilitating to his/her future performance as well.

Clearly the recognition of therapeutic privilege presents what ethicists call moral hazard, in that it presents a justifiable exception to accepted practices that providers may tend to overuse.

In regards to withholding information from patients: The practice of withholding pertinent medical information from patients in the belief that disclosure is medically contraindicated is known as "therapeutic privilege." It creates a conflict between the physician's obligations to promote patients' welfare and respect for their autonomy by communicating truthfully. Therapeutic privilege does not refer to withholding medical information in emergency situations, or reporting medical errors.

Withholding medical information from patients without their knowledge or consent is ethically unacceptable. Physicians should encourage patients to specify their preferences regarding communication of their medical information, preferably before the information becomes available. Moreover, physicians should honor patient requests not to be informed of certain medical information or to convey the information to a designated proxy, provided these requests appear to genuinely represent the patient's own wishes.

All information need not be communicated to the patient immediately or all at once; physicians should assess the amount of information a patient is capable of receiving at a given time, delaying the remainder to a later, more suitable time,

and should tailor disclosure to meet patients' needs and expectations in light of their preferences.

Physicians may consider delaying disclosure only if early communication is clearly contraindicated. Physicians should continue to monitor the patient carefully and offer complete disclosure when the patient is able to decide whether or not to receive this information. This should be done according to a definite plan, so that disclosure is not permanently delayed. Consultation with patients' families, colleagues, or an ethics committee may help in assessing the balance of benefits and harms associated with delayed disclosure. In all circumstances, physicians should communicate with patients sensitively and respectfully.

Fear of repercussions barrier

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Fear of repercussions

- Providers fear:
 - exposing one's fallibility
 - economic losses
 - reputation losses
 - liability
 - fear of exposure (personal and organizational)
 - fear of having to accept responsibility and be accountable
 - reluctance to admit an error was made

Kadane 2006 and many others

Provider repercussion concerns can be summarized as:

- fear of liability exposure and its attendant costs such as increased insurance premiums or lost income due to time devoted to defense of claims;
- other economic costs, such as loss of referrals;
- fear of reputational loss;
- fear of exposure, both at the personal level and at the organizational level;
- fear of having to accept responsibility and be accountable, which might lead to disciplinary action, loss of license, etc.; and
- reluctance to admit a patient safety incident occurred.

These are the most obvious inhibitors to disclosure and, again, often the ones articulated by providers or their legal counsel. While these fears generate powerful and sometimes overwhelming feelings, ethically it is not permissible to act on them. Ethical, patient-centered care requires that honesty trumps fear of harm to or loss by the provider.

Cultural norms barrier

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Cultural norms

- Internal physicians disclosure
 - 10% of cases in Internal Medicine M&M discussed errors (Biddle 1990)
 - 34% of cases in Surgery M&Ms discussed errors (Thompson 1992)
 - 54% of physicians in training report discussing their errors with supervisors (Wu 2003)

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Cultural norms

- Physicians need to tell someone
 - 88% of physicians in training discussed errors with a non-supervisor physician (Wu 2003)

If liability exposure, economic loss or public loss of face were the determinative reasons healthcare providers do not disclose, we should expect to see more open discussions of error in confidential, legally sheltered, peer review protected processes. In fact, several studies suggest that physicians do not disclose patient safety incidents to their peers thoroughly either. In 1990 Biddle found that only 10% of cases in internal medicine morbidity and mortality conferences discussed patient safety incidents by providers. Among surgeons, Thompson found in 1992 that a patient safety incident was discussed only 34% of the time at morbidity and mortality conferences. Even when these incidents are discussed in morbidity and mortality conferences, a 2003 study by Pierliussi concluded that few participants personally acknowledged that a patient safety incident occurred. . In the same year, Wu found that only 54% of physicians in training reported discussing patient safety incidents and the potential for errors with their supervisors.

Interestingly, Wu also found that 88% of trainees did discuss patient safety incidents and failures with non-supervisory colleagues and 58% told a non-medical person. While far from determinative, these studies suggest that perhaps providers do need to discuss their patient safety incidents with someone, but may be more comfortable outside the

established peer review processes – the very places designed to be the safe places where such discussions can occur.

What really keeps disclosure from happening?

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Disclosure

- ❑ No reassurance that disclosure prevents lawsuits
- ❑ Fear that the physician-patient relationship will not survive the disclosure conversation due to trust loss (Witman 1996)
- ❑ Guilt about the harmful incident, the failure to meet self- or patient expectations of competence/perfection, keeping mistake secret (Wei 2006)
- ❑ Shame, the emotionally powerful “henchman of guilt” (Wu 1993)

Slide 26

Manifestation of barriers

- ❑ Avoidance
- ❑ Disclosure needing to be orchestrated or done by someone else, like administration or chief of staff in 70% of cases? (Wu 1993)
- ❑ Physicians “confessing” to a peer or non-medical person

Slide 27

Cultural challenge

Failure to disclose is multi-factorial, deeply entrenched and not changing fast, despite clear patient expectations

Again, the barriers and studies discussed above are snapshots of a dynamic field. With that said, they point to a tangle of provider concerns that need to be understood and addressed at the organizational level:

First, there are skill, organizational support, and personal comfort deficits in most settings where individuals are called upon to break bad news about patient safety incidents. Despite accumulating evidence about what patients want after a patient safety incident,

providers still lack confidence about relationships with patients surviving a disclosure process.

Second, strong feelings associated with disclosure continue to support an inference that the process increases liability exposure, although there is no evidence supporting this belief. Indeed, just the opposite seems to be true. Patients for Patient Safety Canada, Co-chair, Donna Davis, shares, “Many of the patients and family in our organization convey that the only reason they have, or are considering litigation is to get answers that they feel the health organization and its staff, are withholding from them. All we really want is an apology and to know what happened.” In cases where the event has resulted in the death of the patient this is especially true. Suing can never replace the loved one, no amount of money can make it right or assist in healing-only compassion and total honesty by those involved in the event can help the injured parties of these preventable errors. Providers continue to yearn for a kind of guarantee that disclosure will prevent lawsuits, even though they also recognize that this is an unrealistic expectation in a society where people have the right to sue.

Could no-fault insurance which was the subject of a landmark 1990 report, *Liability and Compensation in Health Care*, crafted by former University of Toronto president Robert Prichard provide the guarantee that providers are looking for? The report's recommendations were largely based on the premise that the increasing numbers of lawsuits and size of settlements meant the tort-based system was heading for an affordability crisis. That crisis, however, failed to materialize as there was not the influx of claims that there were in other countries. Prichard's report, in turn, disappeared onto library shelves, as has the Health Council of Canada's 2006 annual report, which recommended that a no fault system, be re-examined so that healthcare providers "are more open to disclosing patient safety incidents and the potential for errors with their supervisors and injured patients can be compensated without having to sue the provider." As no-fault compensation has not been introduced in Canada to date the question above remains unanswered.

Third, when a patient safety incident occurs it may trigger guilt about the event itself or the failure to meet a patient's or one's own performance expectations, as well as shame, described by Wu as the “powerful henchman of guilt.”

All of these factors manifest in avoidance behaviors such as ducking known obligations and “confessing” to a work friend or personal friend instead of disclosing to the patient or a professional supervisor. As a last informative snapshot, consider the findings of 2007 study by University of Iowa researchers Lauris Kaldjian et al, who sought to measure the gap between what physicians say they would do regarding disclosure of patient safety incidents and what they actually do. The survey revealed several key pieces of information:

- 97% of faculty and resident physicians in academic medical centers said they would disclose an error that produced minor harm and 93% would if the outcome was major harm such as disability or death;
- however, only 41% reported had actually disclosed a minor injury event and when death or disability was the outcome, the rate was just 5%;
- among respondents, 19% also reported having made a patient safety incident resulting in minor injury and not disclosing it and 4% acknowledged not disclosing a major injury event; and
- more than half of the respondents' answers indicated they had never made even a minor patient safety incident at any time during their careers.

Clearly, the cultural anxieties around disclosure are still present, ten years or more into the patient safety movement. Failure to disclose is multi-factorial, deeply entrenched and not changing fast, despite clear patient expectations. What do we do?

Promoting apology: is that the solution?

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A right to apology ...

- ❑ Not a legal right
- ❑ Arguably a moral or contractual right
- ❑ If apology is freely given, it can be tremendously healing for all concerned
- ❑ If required, it will not be freely given
- ❑ If not freely given, the healing power is undermined

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... A right to apology

- ❑ Patients want it and may sue if they perceive they may obtain it through this route
- ❑ Ethicists concern: apologies given only to escape liability are not sincere
- ❑ The two types of apology

So far our discussion has focused solely on disclosure of material facts, a fundamental ethical obligation that healthcare providers owe their patients. Apology after a harmful patient safety incident has occurred is a related concept that is often discussed, and sometimes confused, with disclosure. Some of the overlap stems from the fact that patient research underscores a strong desire for both apology and disclosure of facts after a

patient safety incident and, when apologies are made it is commonly in the context of a disclosure conversation or process.

It must also be recognized that there are two distinct types of apology. One type of apology is when events happen unexpectedly in a patient's care that result in an unanticipated outcome but are not related to the care that the patient received. Another kind of apology is required when harm occurred due to what was or what was not done in the course of care for the patient. Saying, "We are sorry for the loss of your loved one" is completely different than saying, "We are sorry for the part we played in the death of your loved one." If acknowledgement of responsibility is accepted and verbalized to the patient/family early in the process, when the facts show this to be the case, the rest of the process- apology, honesty, transparency will come more easily. If the conversations constantly skirt the accountability aspect it will complicate the rest of the process and make these conversations much more difficult. Patients and families can sense when information is being withheld, this creates frustration, anger, and mistrust which impedes progress of the disclosure, healing and learning.

A key distinction is that receiving an apology is not generally considered a patient right. One could characterize it as a moral or human right, in the sense that a person who has been wronged by another might be thought to "deserve" an apology. And some policy statements on disclosure include a promise or commitment to apologize that, arguably, could be enforced as a contract. But the essence of apology is that it is an expression of regret that is voluntarily offered, not required. One must consider the Apology Legislation in the eight provinces and one territory where they are present. As questioned earlier in this module, does the fact that this legislation "protects" the apology given to a patient following a patient safety incident, in that the apology cannot be used in litigation, make the apology less than sincere? Only if the apology is accompanied by full disclosure and meets the needs of the patient/family is the apology effective.

In the United States, organizations which have made a commitment to doing disclosure and offering apology have found that, contrary to the conventional fear, it did not increase liability exposure. The experience of the Veterans Healthcare Administration and the University of Michigan Healthcare System has been well studied. Both show a decrease in the average payout of claims. For the veterans' system, claims frequency stayed roughly constant before and after disclosure, but it decreased at Michigan. Michigan also documented a reduction in the average time to resolve a claim from 1000 to 300 days, which resulted in a two thirds reduction in legal defense fees. Both systems attribute these results as benefits of putting the patient/family first, doing complete disclosure and offering apology in almost all cases. The statement from Co-chair, Donna Davis of Patients For Patient Safety Canada, seen earlier in this module, would appear to support this finding.

Successful, cost saving initiatives have created an enthusiasm for disclosure and apology in the patient safety community that, on its face, seems like something of a silver bullet.

Patients clearly want disclosure and apology, so offering it meets their needs. In addition, it saves money and reduces litigation. Win/win! What could be better?

However, this raises another moral hazard, in that they create motivation to apologize as a risk management strategy, not as a sincere expression of regret. Ethicists such as Lee Taft are now weighing in, questioning the use of apology in this manner, underscoring the risk of eviscerating the healing power of apology if it is used to gain advantage for the person/organization apologizing. The same question is posed about the effect of the Apology Legislation now adopted in several provinces. Will the protectionist nature of the legislation create insincere apologies that are self-serving for the provider/organization? Will providers and organizations see apology as “being enough” and not follow through with the support and compensation that patients and families still need? This newly adopted Apology Legislation will require close monitoring to evaluate the effect it has on disclosure and compensation.

Legal policy scholars such as O’Hare also are questioning the social value of apologies that motivate injured parties to forgive too easily and not bring compensation claims against those responsible for producing said injuries. Those uncompensated costs are then shifted to families and society in ways that may not be optimal. Moreover, O’Hare worries that if apologies are used as a quick fix to escape financial accountability, the motivation to make change to avoid future injuries of the same type will be diluted. The Prichard Report recognized this serious potential outcome and recommended Quality Assurance programs and greater accountability by professionals to maintain standards of best practice through required ongoing education.

The Consensus Statement of the Harvard Hospitals states that the primary impetus for disclosure and apology is moral judgment, and nothing more:

We approach these issues from the patient’s point of view, asking, “What would I want if I were harmed by my treatment?” While hospitals and caregivers may have competing interests, including legitimate concerns about legal liability, our frame of reference is the simple question, “What is the right thing to do?”

With respect to the decision to offer an apology, the rule of thumb is doing it sincerely.

Communications training for physicians, administrators and other healthcare providers

The medical profession long has recognized communications as a weak point among healthcare providers and effective communication between clinician and patient is a necessity, not an option.

The lack of formal training frequently is revealed by professionals making assumptions or taking a patient's words at face value instead of trying to determine the true meaning behind a statement. Frustration and anger on both sides result. Effective communication

with patients and the healthcare team can improve patient outcomes and satisfaction. Conversely, failures in communication may lead to patient harm, misunderstandings, complaints and lawsuits. (CMPA, Communicating with your patient about harm)

The Institute for Healthcare Communication <http://healthcarecomm.org> recognizes the importance of good communication between clinicians and patients. Their mission states:

The Institute for Healthcare Communication (IHC) advances the quality of healthcare by optimizing the experience and process of healthcare communication.

We accomplish this by:

- 1. Creating and disseminating innovative educational programs and services*
- 2. Advocating for the importance of communication as an essential aspect of healthcare*
- 3. Engaging in collaborative research on communication in healthcare*
- 4. Partnering with other leading organizations that share our vision*

The Canadian Medical Association includes the significance of effective communication in its Code of Ethics, “*Make every reasonable effort to communicate with your patients in such a way that information exchanged is understood.*”

Liebman and Hyman recommend training sessions to familiarize health professionals with the complexities of meaningful communications. The basic content of such a session is discussed in PSEP – Canada Module 3: Communication: Building Understanding with Patients and Caregivers, and includes learning how to formulate the right questions, to avoid defensiveness and to express concern about the issues at the center of a patient's statements, all techniques that tend to diffuse anger by making a person feel respected and understood. The Canadian Patient Safety Institute established a Teamwork and Communications Working group who were delegated the task of identifying gaps and providing tools to improve communication between health providers and between health providers and patients/families. The resulting *Canadian Framework for Teamwork and Communication* provides best practice advice and tools for improving communication in the healthcare setting.

Further resources which highlight the importance of teaching communication crucial for disclosure conversations include Sukulich et al., 2014 and Piper et al., 2014.

Establish an organization-based team of experts

Training of healthcare workers is not enough, Liebman and Hyman say, because deaths or serious problems created by healthcare professionals occur rarely for any one professional, so individual clinicians use these skills infrequently and cannot keep the skills sharp. Instead, a team of hospital employees adept at communications should meet with the clinicians and administrators involved in a patient safety incident to anticipate questions and concerns, to make clear that disclosure is a process and usually not a one

conversation event, to formulate explanations that patients and families can understand and to determine the best way to support the patient or family. Essentially, this is a specialized consulting group, available to assist both disclosers and those receiving the bad news.

Offer authentic apologies

Liebman and Hyman's experience and mediation prompts them to emphasize the healing power of apology. They acknowledge provider concerns about risk, but counsel that the mediation process can be used to reduce those risks and support the disclosure process.

Use mediation techniques to guide/structure disclosure process

At the crux of the Liebman/Hyman recommendations lies mediation, a process that should be voluntary and agreed to be kept confidential by all parties up front, meaning nothing said can be submitted into evidence, and patients unhappy with the results retain the option to go to court. In their mediation model, the two sides meet face-to-face and the mediator helps them gain understanding, assess the strength of their positions, explore non-economic proposals that may be meaningful such as implementing changes in hospital policy to prevent future harm to others, and reach a settlement together. Both sides have the opportunity to ask questions and to express feelings. Because mediation is not focused on what can or cannot be proved or disproved, a good mediation session can occur within months of the patient safety incident instead of years. Any disclosure meeting with the patient/family should be scheduled at a time acceptable to the injured parties. Only they know when they are ready to speak about the event. This should be respected and observed; and because the health professionals hear the patients' and families' concerns and perspectives, improvements to hospital procedure can and should result.

Canadian disclosure guidelines

Slide 30

Canadian disclosure guidelines ...

- Guiding principles:
 - patient-centered healthcare
 - patient autonomy
 - healthcare that is safe
 - leadership support
 - disclosure is the right thing to do
 - honest and transparent

Slide 31

... Canadian disclosure guidelines

▢ Objectives

- facilitate patient/healthcare provider communications that respect and address the needs of patients and strengthen relationships
- promote a clear and consistent approach to disclosure
- promote interdisciplinary teamwork
- support learning from harmful incidents

The following is a framework for planning and engaging in a disclosure process.

1. Guiding principles

- Patient-centered healthcare
- Patient autonomy
- Healthcare that is safe
- Leadership support
- Disclosure is the right thing to do
- Honest and transparent

2. Objectives

- Facilitate patient/healthcare provider communications that respect and address the needs of patients and strengthen relationships
- Promote a clear and consistent approach to disclosure
- Promote interdisciplinary teamwork
- Support learning from harmful incidents

Slide 32

Present the facts

- ▢ Simple description of what happened
- ▢ State what is known about the outcome
- ▢ Next steps
- ▢ Sincerely acknowledge the patient's suffering
- ▢ Use an appropriate setting

3. Presenting the facts

- Simple description of what happened
 - No medical jargon
 - Speak slowly
 - Be aware of body language
 - Don't overwhelm with information or oversimplify

- What is known of the outcome at that point
- Describe the next steps
- Sincerely acknowledge the patient and family's suffering

Slide 33

Listen and acknowledge

- Active listening
 - allow ample time for questions
 - do not monopolize the conversation
- Acknowledge what you have heard
- Respond

4. Actively listening
 - Allow ample time for questions
 - Don't monopolize the conversation
5. Acknowledging what you have heard
6. Responding to any questions

Slide 34

Concluding the conversation

- Conclude the conversation (for now)
 - summarize
 - repeat key questions raised to get agreement
 - establish the follow-up
- Document
 - describe the underlying events
 - describe the discussion

7. Concluding the conversation
 - Summarize
 - Repeat key questions raised
 - Establish the follow-up
8. Documenting
 - Describe the event
 - Describe the discussion

The Harvard Hospitals Consensus Statement also offers this “model language” for at least the beginning of the disclosure conversation:

Let me tell you what happened. We gave you...instead of the...you were supposed to receive.

I'd like to discuss with you what this means for your health, but first I'd like to apologize.

I'm sorry. This shouldn't have happened. Right now, I don't know exactly how this happened, but I promise you that we're going to find out what happened and do everything we can to make sure that it doesn't happen again. I will share with you what we find as soon as I know, but it may take some time to get to the bottom of it all.

Once again, let me say how sorry I am that this happened.

Now, what does this mean for your health? You received only a fraction of the usual dose of..., so it is unlikely that you will have any adverse effects from the infusion. However, I would like to monitor you closely over the next weeks. In patients who receive a full dose, the side effects we expect include... We usually monitor patients for these side effects by... We treat these side effects by... I want to see you in my clinic tomorrow so we can...

Similar direction can be found in the Canadian Disclosure Guidelines, CMPA "Communicating about harm with your patient" and the Canadian Nurses Protective Society (CNPS) "Reporting and disclosure of adverse events".

Addressing emotional trauma support

Slide 35

Short term support

- Ask patients / families about their feelings
- Take all patient concerns seriously and address them completely
- Maintain the relationship
- Provide contact information for counseling
- Put all billing on hold pending analysis of the harmful incident

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Long term support

- Patients and families should be given phone numbers of all principals
- Disclosure is a process
 - home visits may be a good idea
 - consider covering accommodations if travel is required
- Provide longer term counseling if needed
- Consider reimbursement

For many patients, just being hospitalized places them in a vulnerable psychological state even when treatment goes according to plan. Post-traumatic stress disorder can occur even following procedures that strike providers as routine. When a patient experiences a preventable patient safety incident, it is normal for emotional trauma to be particularly severe.

Medically Induced Trauma Support Services (MITSS) is an innovative program started by Linda Kenney, a patient who went into full cardiac arrest in reaction to an anesthetic block during orthopedic surgery, and Rick van Pelt, MD, the anesthesiologist who administered the block. Dr. van Pelt initiated a conversation with Mrs. Kenney by letter after the event, which led to a meeting. As they exchanged experiences, both patient and anesthesiologist learned of the traumatic reactions the other had experienced following the event. MITSS, now housed at Brigham and Women's Hospital in Boston, was established to assist healthcare organizations in the implementation of programs to support provider, patient and family over both the short and long-term. The following recommendations, reflected in the Harvard Hospitals Consensus Statement which Mrs. Kenney helped prepare, reflects the MITSS approach.

- Patients and families should be specifically asked by members of the team assisting in their case about their feelings related to their injury and about any anxieties they have about future treatment and prognosis. Even when patients receive explanations, an apology, and an assurance that actions will be taken to prevent recurrence of similar future incidents, the emotional trauma and anxieties about future treatment may necessitate psychological treatment by social workers, psychologists or psychiatrists.
- Clinicians should be attentive to patients who say their treatment has harmed them, even when a complication appears to have resulted from the patient's disease. Given the risk of harm from medical treatment, such a claim should be considered seriously. The patient may have information healthcare workers lack or the patient may not fully understand the clinical circumstances.
- Following injury, it is important for clinicians to take extra pains to ensure continuity of care and to maintain the therapeutic relationship. Following an injury, patients and families need more support, not less, even though sometimes both patients and clinicians may feel a natural wish to distance themselves from one another.
- Patients and families should be provided with names, phone numbers and contact information of individuals of the institution who are available at all times to address their questions, complaints and concerns. These include individuals who can provide internal and external support and counseling, as well as financial counseling if needed. Financial pressures may contribute to emotional concerns. Coordination of psychological and financial support may be best served by individuals in the social work department. It is important that the care team discuss the support of the patient and family in advance.

- Healthcare organizations should investigate ways to provide support for short term expenses stemming from preventable patient safety incidents. If financial assistance is provided, it should be done promptly. An immediate response can make a substantial difference after an injury, whether it provides for childcare or disability aids or is used to alleviate lost income or other hardship.
- In addition to these shorter term responses, follow-up care should also be emphasized at this time. MITSS recommendations, again drawn from the Harvard Hospitals Consensus Statement, include
- The patient and family should be provided with appropriate business cards and phone numbers to facilitate easy access to the principals involved in the disclosure process.
- A series of follow-up encounters with the patient and/or family should be planned, both to check on their clinical status and to give them updates on findings from the investigation of their situation as well as on remedial actions taken. This is a natural part of disclosure which, as we have discussed, is a process, not an event. These meetings should occur not in an *ad hoc* way, but as scheduled, proactive overtures to the patient and family.
- A home visit may be indicated, particularly if extensive follow-up must be communicated. If the patient is invited back to the organization for such meetings, the patient's or family's needs in terms of transportation, meals and overnight lodging should be accommodated by the organization. Provide a neutral meeting location as it may traumatize the patient/family further to go back to the place where the event occurred.
- Needed long-term psychological and social support should be provided.
- Continuing reimbursement for injury-related expenses may be indicated.

Too often the word “discharge” means just that to a healthcare organization and this can create a sense of abandonment that adds to the frustration and anger patients and families already are experiencing. For all of these reasons, an organizational structure for well-managed follow-up as outlined here can be an important aid in the recovery from traumatic injury.

Although not discussed in detail here, the MITSS model also extends to the short and long-term emotional support needs of healthcare workers involved in a patient safety incident, the so-called “second victim,” which also are considerable. Tools for establishing such a program are available at the MITSS website, www.mitss.org.

Patient reporting of patient safety incidents

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Patient reporting

- Patient reporting is an increasing focus
- Accreditation Canada Required Organizational practices (ROPs) supports patient and family reporting
- Resources are available for patients to report

Accreditation Canada 2015

A Canadian example of legislation that supports the means for patients and families to report concerns and encourage them to do so is found within the 2011 Excellent Care for All Act (ECFAA) - Bill 46 - of Ontario. The Act requires that healthcare organizations develop patient relations processes to address and improve the patient experience. Healthcare organization should establish an internal reporting mechanism for patients who wish to provide feedback concerns about safety. Currently, patients/families can take concerns to Patient Advocates, Client/Quality Care Coordinators or Patient Ombudsmen and Regulatory bodies.

Accreditation Canada's Required Organizational Practices provide standards and guidelines to support patient reporting and engagement.

Two systems in Canada provide venues for patients and families to become more knowledgeable and take responsibility for their health, namely:

- The ISMP Canada patient reporting website, www.safemedicationuse.ca which was launched in June 2010 and provides a venue for patients to report medication incidence, and;
- The Canada Vigilance Program which is Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse reactions to health products marketed in Canada. <http://www.hc-sc.gc.ca/dhp-mps/medeff/vigilance-eng.php>.

The value of patient reporting of patient safety incidents

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Value of patient reporting

- Patients see things providers do not
- Patients experience harmful incidents after discharge
- Patients may be less reluctant to report a patient safety incident
- Involving consumers in reporting offers providers chance to discuss risk and the opportunity to contribute to safety

Patient reports can help increase safety knowledge; although significant progress in this area has not been realized and patient perceptions and knowledge remain an untapped source of information. The World Health Organization, the United Kingdom, Australia and other nations emerging as leaders in patient safety work have recognized that patient engagement in reporting incidents associated with their own care or a loved one's care can bring otherwise unidentified issues and factors to bear on healthcare organization's ability to understand what the holes in their safety nets are, identify root causes, and mitigate harm.

Patient reports are uniquely valuable because they can provide information across the health system, whereas most of the other sources tend to be focused on particular healthcare workers or organizational care settings which see patients only periodically. For example, patients may experience injuries that do not manifest until after discharge from a hospital and therefore are not readily captured as reportable incidents by that healthcare organization. Patient reports also offer great potential to highlight problems across the transitions between care settings, e.g. between clinic and hospital or hospital and pharmacy, such as miscommunication and delayed or missing tests and reports. Given the fragmentation of contemporary health systems, it is likely that these problems are under-reported. Patient and lay caregivers may also witness incidents such as falls that busy, multitasking healthcare workers just miss. They may also serve as a reminding function to clinicians who work in the same environment day to day and see risk associated behaviour so routinely – poor hand hygiene for example -- that it becomes “normalized” and, therefore, not appreciated as significant enough to report.

It is well understood that currently incidents and near misses are grossly under-reported by providers to data collection sources that have authority to take remedial action. The fear-based or legal barriers that chill provider willingness to report are not likely to impede patient reporting.

As discussed earlier, patients and families who have experienced a patient safety incident report a high desire to see remedial action taken to prevent future harm to others, and preliminary research suggests that patients will report patient safety incidents when there

is a pathway to do so. In a 2005 Swiss study by Agoritsas, 94% of patients filling out a hospital experience survey completed an added section on safety concerns, and 51% reported an undesirable event. If reporting pathways were established and made known, it seems logical to infer that patient reports of patient safety incidents and near misses will materialize.

Finally, including patients in reporting schemes can serve to promote the culture change objectives of systems-based patient safety work that currently seem so intractable. Because many healthcare professionals and provider organizations are reluctant to fully discuss the inherent riskiness of healthcare services with the public, the existence of a reporting pathway would serve a culture changing educational function by helping create a shared mental model with patients and the public at large learning about the continuous challenge of managing complex, dynamic risk in healthcare. As in other steps forward toward transparency, it is reasonable to infer that once patients are engaged in understanding the importance of reporting -- by them as well as by providers and healthcare regulators -- their trust that inherent healthcare risk is being optimally managed would increase. However, simply reporting is not enough. Following through with gathering and identifying data of similar events, analyzing the factors involved and developing and implementing preventative action is the absolute requirement to improve patient safety. One initiative that is being developed is the Hospital Harm Indicator (HHI), a new patient safety measure developed jointly by the Canadian Institute for Health Information (CIHI) and the Canadian Patient Safety Institute (CPSI) in consultation with leading patient safety experts. It is being designed to assist organizations to identify patient safety improvement priorities and track progress over time.

How should patient reports be encouraged?

The Australian Council's *Complaints Management Handbook for Healthcare Services* includes a number of sample documents included in the tools section of this curriculum, including:

- Sample Complaints Policy and Procedure;
- Sample Consumer Feedback Brochure;
- Sample Consumer Suggestion for Improvement Form;
- Sample Complaint Follow-up Form;
- Sample Letter Acknowledging a Complaint;
- Sample Letter Confirming a Complaint has been Resolved;
- Sample Self-Assessment Guide for Healthcare Services Organizations; and
- Better Practice Guidelines for receiving such complaints is a valuable tool.

Patient engagement in patient safety incident analysis

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Patient engagement in analysis

- A patient advocate represents the family
- Patient / family
 - contribute information
 - participate directly
 - receive the report and action plan as allowed for by law
- Consumers trained to participate to ensure the consumer perspective

The life of Donna Davis, who works in healthcare, was irrevocably changed when her son died following a head injury when the care he received did not provide him with the best chance of recovering from that injury. At the time of the case review into their son's death they were not included in the discovery of the details surrounding his death. If they had been, the hospital would have become aware of details that were not forthcoming from the providers. Six years following the death of their son the Davis' were able to meet with the health organization and present a list of fifteen recommendations. One of the recommendations was to include the patient/family in the case review (now known as the patient safety incident analysis). Their argument was: How can the analysis be complete if the family is not interviewed about what they experienced and saw at the bedside. There are a number of ways in which patients can be involved in the analysis of patient safety incidents or systems failures that could produce them:

- the patient and/or family participates in the analysis of the event that affected that patient;
- the patient and/or family contributes information about the event to be considered during the analysis process;
- an independent (not an employee of the hospital/organization) patient advocate may, at the request of the patient/family participate in the analysis (to represent the patient/family interests);
- ensure that the patient and/or family participates in the committee that receives the report of the analysis findings and action plan; and
- patient participation in proactive risk assessments, such as Failure Modes Effect Analysis (FMEA).

The Etchegaray, Ottosen et al Millwood (2014) supports patient and family involvement in patient safety incident analysis and disclosure while recognizing that it must be a structured process to be effective and successful.

The PSEP – Canada Module 16: Canadian Incident Analysis Framework also recognises the importance of the patient/family contribution in incident analysis and provides a “tip”

sheet for providers and organizations, written by patients and families giving their perspective of what is needed by patients and families in the incident analysis process.

Likewise, the 2011 revision of the Canadian Disclosure Guidelines includes “Disclosure Principles”, written by patients and families who have gone through the disclosure process. These Disclosure Principles provide guidelines for healthcare providers, inter-professional teams, organizations, and regulators to ensure that the patients’ right to be informed, if they are involved in a patient safety incident, is respected.

Proactive engagement to preventing an patient safety incident

Patient/family engagement in safety work is a hot topic, driven in recent years by the growing belief that, when it comes to safety, the system cannot fix itself. Healthcare policymakers are hopeful that patient demand for safer healthcare will increasingly be a source of incentive for safer care, thereby expediting progress on reaching social goals for reduced patient safety incidents.

Dr. Ward Flemons, of Calgary, raises the question, “At what point do healthcare organizations involve patients in the patient safety journey?” Shall they be asked to meet the organization at the summit when the route to get there has already been determined, or should they be invited to join the organization at the base camp and become part of the climbing party? Patients who are active members of their own care can become another powerful defense, effectively protecting themselves and other patients from harm. The healthcare team need to include the patient right at the beginning of planning care and at every decision point along the care continuum.

Further, patients and families also need to be included at the system level with involvement in the development of policies, process and protocols and not at the end when all discussions and decisions have occurred. Capital Health in Nova Scotia sought patient/family input when they developed disclosure training for their staff. The disclosure vignette and related educational material was critiqued by a family representative who had experienced disclosure to determine if the vignette and training material were effective and ‘real.’

Sun Country Health Region in Saskatchewan had a patient/family representative at the table in 2014 when revisions were made to the regions Disclosure policy to bring it up to date, ensuring that the policy reflected the needs of patients and families and the region.

Development of opportunities

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Development of opportunities

- Consumers receiving more guidance on safety indicators to use in choosing where to get services
- Patients are being given more opportunities to participate in ensuring the safety of their own care
- Patients are more informed and knowledgeable about their care due

In Canada some provinces/territories have mandatory reporting of patient safety incidents and some have mandatory public reporting of infection rates. In some provinces there are websites that tell a surgeons area of expertise and wait times, but we fall short of informing the public about safety indicators. At this time, in many places in the US, public access to data is a clear trend however, this is not occurring consistently in Canada.

The Canadian Patient Safety Institute (CPSI) launched Canadian Patient Safety Week as a national annual campaign in 2005 as part of its mandate to build and advance a safer health system for Canadians. The goal of Canadian Patient Safety Week is to increase awareness of patient safety issues and share information about best practices in patient safety.

CPSI relies on the efforts of thousands of healthcare professionals, patients and families to help spread the message Good healthcare starts with good communication. The mantra for Canadian Patient Safety Week is “Ask. Listen. Talk.” CPSI provides access to patient safety tools and resources such as presentation templates, tips sheets, ideas for celebrating the week, promotional items and much more. Understanding the concept behind the “Ask. Listen. Talk” campaign, and others like it, will help to ensure that opportunities to promote patient and family engagement are not missed.

Another emerging area in patient engagement development is strategies for including patients and providers as part of the care team and capitalizing on their self-interest in achieving good outcomes for themselves and their loved ones, see PSEP – Canada Module 7a: Patients as Partners: Engaging Patients and Families for an in-depth look at this area.

An example of engaging patients in initiatives with positive outcomes is the *Safer Healthcare Now!* campaign which led to patient and community engagement in medication management in the five healthcare facilities, including the Cumberland Regional Health Care Centre (CRHCC) of Cumberland County in Nova Scotia. It began the “Did you bring your list” information campaign which continues today. Signage was displayed in all ER’s and the primary health clinics. Collaboration between three

Community Health Boards and the Cumberland Health Authority resulted in the design and distribution of a medication management wallet card. Engaging patients in the patient safety agenda was a “win-win” for all.

It should be noted that there is little hard evidence to date for the success of prospective patient engagement efforts and, as noted in the introduction to this module, some systems thinkers have raised concerns about shifting responsibility for healthcare tasks to patients.

On the other hand, as noted above, there is a body of evidence that shows patients who play active roles in the management of chronic health conditions seem to enjoy better outcomes over patients who play a more passive role in care. Proponents of patient engagement in patient safety are basically extrapolating from these studies, the inference being that patients more actively engaged in managing risk will reduce preventable patient safety incidents.

Patient and family awareness

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Strategies for engagement

- ❑ Educate patients about risk
- ❑ Encourage patients to “speak up”
- ❑ Lots of new programs
 - few based in research
 - will they work?

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Ask. Listen. Talk.

- ❑ Canadian Patient Safety Week is a national annual campaign to increase awareness of patient safety issues
- ❑ The core message of CPSW is that good healthcare starts with good communication

Most efforts to engage patients have focused on an approach that combines two strategies:

1. awareness raising/education about the risks of preventable harm, and
2. encouragement to speak up to providers about safety concerns.

Alberta’s “It’s OK to Ask” and Manitoba’s “It’s Safe to Ask” campaigns are two Canadian examples.

Many patient information brochures are available in institutions, clinics, and pharmacies. How many of these were developed with patient input? Just because health providers speak to patients all the time it doesn't mean that it is understood what they need or want to know. Bringing the patient to the table at the beginning of the development of these materials will exemplify the organizations sincere adoption of patient- and- family centered care plus ensure the information patients want and need is provided in a clear way that resonates with them- the receivers of the information.

A particularly good resource for patient education material on medication use is the Institute for Safe Medication Practices Canada (ISMP Canada), which has over ten years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. ISMP Canada provides useful information for patients on the following topics:

- general advice on safe medication use;
- lessons to be learned from past errors;
- preventing drug errors in children;
- safe medicine through *the ISMP Medication Safety Newsletter for Consumers*; and
- ISMP Patient Safety Brochure.

How do we get patient engagement education to work?

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Normalization of passivity

- Silence about patient safety incidents
- Failure to include patients in PS and QI
- Paternalism
- Lack of training to engage patients
- Lack of time or economic incentive to engage patients

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Getting engagement to work

- Picker Surveys show patients felt they had:
 - not enough involvement in decisions
 - no one to talk to about concerns
 - no clear explanations for why tests or treatments were being suggested/given
 - insufficient info for lay caregivers
 - insufficient information about recovery

The challenge, not surprisingly, is cultural and systemic – more specifically, the traditional care model that sees patients as passive recipients of care must be modified. Patients share in these cultural attitudes and historically see themselves this way as well, so their attitudes must be part of the shift.

Merrilyn Walton, a University of Sydney-based researcher and author, has identified the following culture or systems-based factors as contributors to patient passivity:

- quality improvement activities that rarely take into account the patient perspective;
- the historic silence about patient safety incidents and risk in healthcare;
- the paternalistic nature of the patient-provider relationship, including the belief that patients either will not understand or do not want to know;
- lack of time or economic incentive to engage in patient education; and
- lack of training to engage with patients.

Research by the Picker Institute of Europe about patient experiences in healthcare reveals some of the sources of their sense of passivity. In surveys of over a million patients in England and Wales between 1998-2005, patients reported:

- not enough involvement in decisions;
- no one to talk to about anxieties or concerns;
- tests and/or treatments not clearly explained;
- insufficient information for family or friends; and
- insufficient information about recovery.

In a thoughtful 2005 article, Entwistle evaluated current patient education programs. The findings are consistent with what is found in Canada. Even though patient engagement was the objective of the programs, there had been little input from patients during their development – draft messages were tested by sounding out colleagues and friends and none were formatively tested at the draft stage or formally evaluated upon completion. Including patients/families at the beginning of the development of materials for public education would close this gap and produce a patient friendly product.

- The advisories said little about what patients can expect healthcare providers to do in response to their speaking up, etc. – some were revised because of considerations of their acceptability to professionals. Providers need to be educated about patient engagement so they understand the importance of patient involvement and accept campaigns like “It’s Safe To Ask” that encourage patient/families to speak up: patient involvement leads to a better outcome.
- Patients were given little practical support to carry out the recommended actions, and health professionals’ response may render their attempts to act to secure their own safety ineffective. Provider education, leading to a patient centered culture change and acceptance of the patient as an active team member is essential.

- Some messages suggested an inappropriate shift of responsibility to patients. However, it is not about shifting responsibility, it is about including and accepting the patient as a part of the team.
- Advice that recommended checking on or challenging healthcare professionals' actions is particularly problematic because it conflicts with what patients think healthcare providers' expectations of their role is, i.e. compliance. Providers need to accept patient contribution for the purpose with which it is being given - that is improving patient safety and the care experience which is exactly the outcome that everyone desires.

Entwistle's research raises important concerns and underscores the importance of practical support by both the organization and healthcare workers for roles patients/families are being advised to undertake. This can only be achieved by a significant culture shift.

Innovative team- or systems-based approaches

Slide 45

Strategies

- Prompt patients to ask providers questions
- Patients must be engaged in the development of educational materials
- Honestly communicate all risks
- Explain "why" patients are asked to do something

A first and important shift in modifying a care model that perpetuates passivity depends on the kind of effective communication of risk by healthcare providers or other patient educators, as discussed in PSEP – Canada Module 3: Communication: Building Understanding with Patients and Caregivers. It may be equally dependent on the communication and interaction skills of patients, and these skills need to be systemically communicated and encouraged. Three promising approaches to systems-based encouragement of patient-engagement are profiled below:

Rapid response that patients can initiate

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Example: Condition H (help) ...

- Hotline provided for patients and visitors to call when there is
 - noticeable clinical change in patient and no clinical provider is present
 - breakdown in care
 - confusion about the care plan

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... Example: Condition H (help)

- Brochures developed with input from patient advocates
- Patients and family educated upon admission
- Program supported completely by the healthcare organization

At a hospital in Calgary, Sabina and Michel Robin lost their 7 month old daughter, Mataya, to misdiagnosis of an intracranial bleed secondary to idiopathic thrombocytopenia and multiple breakdowns in communication. Mrs. Robin believes that if the hospital had had a patient/family-initiated rapid response team, they would still have Mataya today. With the backing of the safety leaders of the Calgary Health Region and the influence of Mataya's story and others similar to hers, Rapid Response Teams, known as Code 66, have been established in the Calgary hospitals. Sabina has continued to dedicate her energies towards advocating for family initiated rapid response teams, particularly in the Childrens' Hospital in Calgary. There are many barriers to adopting such a safety system, staff apprehension of an increase in the number of unnecessary calls to mention one. The importance of the contribution of family and friends who know their loved one best cannot be discounted however. Programs such as Condition H, described in detail below, have a crucial role in the safety of patients.

The Condition H system originated at the University of Pennsylvania Medical Center which built upon its already strong commitment to the use of rapid response teams. Condition C (for "critical") and Condition A (for "arrest") codes traditionally have been activated by healthcare providers. Condition H is different: it asks patients and visitors to be part of the care team by alerting caregivers to clinical changes.

The Condition H (Help) program provides a hotline for hospital patients and their family members to call when there is:

- a noticeable, clinical change in the patient and the healthcare team is not present or not responding to the patient's or visitors' concerns, or
- a breakdown in how care is being managed or confusion about the care plan.

Nurses educate patients about the Condition H program upon admission. Every Condition H call brings a rapid response team immediately to the patient's bedside and includes a follow-up meeting the next day, which serves as a learning experience for the staff. A toolkit for implementing Condition H programs is available at:

<http://www.upmc.com/about/why-upmc/quality/excellence-in-patient-care/Pages/condition-h.aspx>

Organization-based patient and family advisory councils

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Advisory councils

- People who are supportive and objective
- Roles include
 - developing patient education material
 - policy development
 - facilities design
 - M & M conferences and grand rounds
 - committee participation
- Supported by the organization

Institutions such as the Kingston General Hospital, Saskatoon Health Region, the Dana-Farber Cancer Institute, Brigham and Women's Hospital and the Medical College of Georgia view patients and families as integral to designing everything from patient education materials to hospital policy to the architectural design of their plants. This is supported through the development of advisory councils as the foundation for effective trust, communication and teamwork among governance, administration, the staff and patients.

The Kingston General Hospital Patient and Family Advisory Council serves in an advisory capacity, providing input to and making recommendations on matters that impact the experience of patients and their families at Kingston General Hospital. Information and requests flow into the Patient and Family Advisory Council through hospital wide committees, councils or individuals seeking the perspective of patients. More information on the Council can be found at the following link:

<http://www.kgh.on.ca/en/aboutkgh/Patient%20and%20Family%20Advisory%20Council/Pages/default.aspx>.

The Saskatoon Health Region’s website highlights the importance of Client and Family Centred Care <https://www.saskatoonhealthregion.ca/patients/cfcc> and within this section can be found the link to the Patient and Family Advisory Council for the Region <https://www.saskatoonhealthregion.ca/patients/cfcc/Pages/Advisory-Council.aspx>.

According to *Patients as Partners, How to Involve Patients and Families in their Own Care*, a 2006 publication of Joint Commission Resources:

“The patient and family advisory council at Dana-Farber and Brigham and Women’s looks for members who are experienced in collaborating with professionals and with members of the broader community, who are comfortable expressing their opinions in a group, and who actively and openly listen to the opinions of others. They seek members who will be enthusiastic about the cancer cent and its mission, but who will also be able to view the center objectively and critically and to constructively express criticisms and suggestions. Potential members should be concerned not only with their experiences, but concerned broadly with the experiences of other patients and families.”

The Institute for Family-Centered Care provides extensive information on structuring advisory councils as well (www.familycenteredcare.org). It stresses the importance of having staff support for such groups with these key attributes:

“Key attitudes and qualities of a staff liaison include patience, perseverance, flexibility, listening skills, openness to new ideas, willingness to learn and to teach, the ability to work positively and proactively, the ability to see strengths in all people and situations and to build on these strengths, and a sense of humor.”

Community-based patient & family partnership councils

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Community-based councils

- ❑ Builds partnership that functions across the continuum of care
- ❑ Wisconsin pilot focused on medication use among seniors, accuracy of medication lists up 20% in two years
- ❑ Model uses Appreciative Inquiry

Appreciative inquiry

- Builds upon what a human system already does well, not its problems
- Recruits participants with:
 - what is your experience with healthcare
 - what have you accomplished as a member of a team
 - why are you interested in change
- Opens social processes to dialogue

Consumers Advancing Patient Safety (CAPS) is a nonprofit organization established in 2003 to pursue healthcare that is safe, compassionate and just through partnership between providers and consumers. Recognizing that most patients experience healthcare services across a continuum of delivery settings, CAPS has developed a model for community-based partnership councils.

Working with both CAPS and Midwest Airlines as partners, the Wisconsin-based Aurora Health System used this model to develop a countywide council of patient and provider partners focused on improving medication reconciliation and medication use among the elderly. Although championed and supported by the Aurora System, the council is designed to be a resource to all healthcare providers in the community who want to work with it. Council meetings are held in a government meeting center offsite from Aurora. A two-year pilot project concluding in 2007 showed a 20% improvement in the accuracy of medication lists kept by senior patients and their providers.

The CAPS model uses an organizational development methodology called Appreciative Inquiry (AI) designed to build on what a system does well, not its “problems.” AI is based on the belief that transformation arises from shifting who in a human system talks to who about what, and that the energy of a community moves in the direction of the questions asked. Whereas focusing on problems can be polarizing, inquiring into a community’s strengths and what has worked well for persons in that community, in both their personal and professional lives, moves them through past differences or resistance toward a positive future.

Both CAPS and the Aurora System have produced toolkits for building community-based partnership councils that are available at www.patientsafety.org.

Medically honest patient education

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Medically honest education

- Understands that consumers want to know about all risks e.g.
“neonatal jaundice can cause brain damage in rare cases” vs. “many babies get jaundice and its usually nothing to worry about”
- Fear as a motivational “gift”
- Use plain, direct language that is evaluated over time

Medically honest education understands that consumers want to know about all risks if they can reduce it. For example, there is a difference between saying “neonatal jaundice can cause brain damage in rare cases” and saying “many babies get jaundice and it’s usually nothing to worry about”.

Additionally, it sees fear is a motivational gift and uses plain, direct language that is evaluated over time. This helps break down the barriers to engagement rather than struggle against them.

Summary

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Summary

- Functional, compassionate disclosure is fundamental
- Patient engagement is an emerging field
- There must be organizational commitment
- Encouragement from providers for patients to ask questions
- Innovative patient engagement programs are beginning to show results

Having a committed, well-functioning disclosure program is crucial to patient engagement because it is fundamental to the provider-patient relationship and patient-centered care. Disclosure is a process that can be difficult, but it presents an opportunity for strengthening a relationship after harm. Healthcare organizations can learn valuable information from patients and families in the disclosure process, as well as through patient concerns or reports of safety incidents.

Patients eagerly want to reduce the risk of preventable medical harm and are finding new ways and opportunities to do so. They are interested in opportunities to assist and engage in ensuring the safety of their own care and that of their loved ones. However, there must

be organizational encouragement for patients to ask questions and patient education materials should be developed with patient input, then evaluated once implemented.

Effective patient engagement is an emergent area. Innovative programs include:

- engaging patients or patient representatives in patient safety incident analysis;
- establishing pathways and educating patients about their ability to summon rapid response teams;
- establishing organization-based patient advisory bodies;
- establishing community-wide patient advisory bodies; and
- developing better educational materials for patients that plainly inform them of risks, both big and small (e.g., Hand Hygiene, Safe Surgery Saves Lives, etc.).

Potential pitfalls

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Potential pitfalls

- Apologies are important - they must be sincere
- Resistance to disclosure appears to be deeply ingrained
- Consumer education materials may be too cautious in explaining risk
- Providers should not assume that they know what patients want in terms of educational material

1. Apologies are important to patients who have been harmed, but they must be sincere. Apologies that are too careful or not followed up with practice change to prevent future harm to others or not followed up with the continued support that the patients or families require can be dismissed as insincere.
2. Resistance to disclosure appears to be deeply ingrained; healthcare organizations should not assume that providers have the skills or confidence to do it thoroughly. Establishing in house expertise to consult with providers called upon to disclose is a promising approach. It should be noted that Accreditation Canada standards ask that healthcare organizations have a documented and coordinated process to disclose patient safety incidents to clients and families.
3. Patient education materials on patient safety topics produced to date may be too cautious in explaining risk. Therefore, they may not succeed in engaging patients.
4. Providers should not assume that they know what patients want in terms of educational material just because they talk to them frequently. Patients should be invited to participate at the beginning of material development. This will ensure the patient perspective is captured.

Pearls

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Pearls ...

- ❑ Patients and families want disclosure after a patient safety incident
- ❑ Mediation can be an effective tool for establishing a safe disclosure
- ❑ Disclosure should be done because it is the right thing to do
- ❑ Patients who are injured often need to be compensated and deserve to be

Slide 55




... Pearls

- ❑ Patients see things and are willing to share them
- ❑ Active encouragement for patients to ask questions is needed
- ❑ Engage patients in the development of patient educational materials
- ❑ In communicating risk, fear can be a gift if patients can do something
- ❑ Unlike researchers, patients do not analyze risk on a population basis

1. Patients and families clearly want disclosure after a patient safety incident or even a near miss, and providers who are not prepared to offer it are increasingly out of touch with their patients.
2. Mediation can be an effective tool for establishing a safe space to do disclosure.
3. Disclosure should be done because it is the right thing to do. In addition, evidence is accumulating that shows it will help defer not all, but some, lawsuits by defusing anger and restoring trust.
4. Patients who are injured often need to be compensated and deserve to be.
5. Patients see things busy providers do not and are willing to share them in incident analysis or report them to learning systems if given the chance.
6. Active encouragement for patients to ask questions is needed to overcome the passive role they expect to take.
7. Patients should be engaged in the development of patient educational materials to ensure that they succeed in engaging.
8. In communicating risk to patients, fear can be a gift if patients can do something practical to reduce the risk.

9. Unlike researchers, patients do not analyze risk on a population basis. They want to know all risks, frequent or rare, that they can do something about.

Toolkits

- **Building the Future for Patient Safety: Developing Consumer Champions – A Workshop and Resource Guide:** Consumers Advancing Patient Safety, Chicago, IL; 2007. Funded by the Agency for Healthcare Research and Quality (AHRQ) http://www.consumersadvancingpatientsafety.org/wp-content/uploads/2013/02/Consumer_Champions_for_Patient_Safety-pdf.pdf
- **Communicating with your patient about harm; Disclosure of Adverse Events,** Canadian Medical Protective Association booklet, accessible online at http://www.cmpa-acpm.ca/cmpapd04/docs/resource_files/ml_guides/disclosure/introduction/index-e.html 
http://www.cmpa-acpm.ca/cmpapd04/docs/resource_files/ml_guides/disclosure/introduction/index-f.html 
- **Reporting and Disclosure of Adverse Events,** Canadian Nurses Protective Society, accessible online at http://www.cnps.ca/upload-files/pdf_english/adverse_events.pdf 
- **Disclosing Unanticipated Medical Outcomes,** Insititute for Healthcare Communication, developed 2002; info@healthcarecomm.org
- **Expanding Patient-Centered Care To Empower Patients and Assist Providers:** Research In Action AHRQ Issue 5 2002 <http://archive.ahrq.gov/research/findings/factsheets/patient-centered/ria-issue5/ria-issue6.pdf>
- **Talking about Harmful Medical Errors with Patients:** University of Washington School of Medicine Seattle, Washington, USA <http://www.ihl.org/resources/Pages/Tools/TalkingaboutHarmfulMedicalErrorswithPatients.aspx>
- **Crafting an Effective Apology: What Clinicians Need To Know:** Joint Commission Resources: Patient Safety 5:7-8, Apr. 2005. <http://www.ingentaconnect.com/content/jcaho/jcpps/2005/00000005/00000004/art00005>
- **Open Disclosure Education and Organisational Support Package:** Open Disclosure Project 2002-2003, Australian Council for Safety and Quality in Health Care http://www.ranzcog.edu.au/documents/doc_download/257-open-disclosure-education-and-support-
- **Open Disclosure Guidelines:** NSW Health Australia Quality and safety Branch Open Disclosure Guidelines Sept. 20014. http://www0.health.nsw.gov.au/policies/pd/2014/pdf/PD2014_028.pdf

- **Disclosure of Adverse Events to Patients:** VHA Handbook 1004.08, Veterans Health Administration Washington, DC, October 2012. <http://www.ethics.va.gov/Handbook1004-08.pdf>

Resources

- **Patients for Patient Safety Canada:** <http://patientsforpatientsafety.ca/> 
- **Canadian Disclosure Guidelines:** Disclosure Working Group. Canadian disclosure guidelines: being open and honest with patients and families [Internet]. Edmonton (AB): Canadian Patient Safety Institute; 2011 [cited 2015 Mar 29]. 50 p. Available from: <http://www.patientsafetyinstitute.ca/en/toolsResources/disclosure/Documents/CP%20SI%20Canadian%20Disclosure%20Guidelines.pdf>
- **Disclosure Training Programs:** Canadian Patient Safety Institute <http://www.patientsafetyinstitute.ca/English/toolsResources/disclosure/DisclosureTraining/Pages/default.aspx> 
<http://www.patientsafetyinstitute.ca/french/toolsresources/disclosure/disclosuretraining/pages/default.aspx> 
- **Canadian Incident Analysis Framework:** Canadian Patient Safety Institute (CPSI), Institute for Safe Medication Practices Canada (ISMP), Saskatchewan Health, Patients for Patient Safety Canada, Beard P, Hoffman CE, Ste-Marie M. Canadian incident analysis framework [Internet].]. Edmonton (AB): Canadian Patient Safety Institute; 2012 Oct [cited 2015 Mar 29]. 133 p. Available from: <http://www.patientsafetyinstitute.ca/en/toolsResources/IncidentAnalysis/Documents/Canadian%20Incident%20Analysis%20Framework.PDF> 
- **CMPA-Canadian Protective Medical Association:** Canadian Protective Medical Association [Internet]. Ottawa: Canadian Protective Medical Association; [c2015]. Apology legislation in Canada: what it means for physicians; 2013 Apr [cited 2015 Mar 29]; [about 2 screens]. Available from: https://www.cmpa-acpm.ca/en/legal-and-regulatory-proceedings/-/asset_publisher/a9unChEc2NP9/content/apology-legislation-in-canada-what-it-means-for-physicians 
- **Canadian Framework for Teamwork and Communication (CPSI):** Teamwork and Communication Working Group. Improving patient safety with effective teamwork and communication: literature review needs assessment, evaluation of training tools and expert consultations [Internet]. Edmonton (AB): Canadian Patient Safety Institute; 2011 [cited 2015 Mar 29]. 24 p. Available from: <http://www.patientsafetyinstitute.ca/en/toolsResources/teamworkCommunication/Documents/Canadian%20Framework%20for%20Teamwork%20and%20Communications.pdf> 
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Module 7b Trainer's Notes

Principal message

The single most important message your audience should come away with is that *having a committed, well-functioning disclosure program is crucial to patient engagement*. As part of this insight, participants should understand that healthcare organizations can learn valuable information from patients and families in the disclosure process, as well as through patient concerns or reports of safety concerns.

Module overview

Despite being acknowledged as a public health priority in many countries for several years, there is widespread concern about the lack of progress on patient safety. Leaders cite the failure to engage consumers in patient safety work as one factor in delaying progress. Patients/families often see things that busy healthcare workers do not. When healthcare organizations fail to integrate patient involvement in managing systemic risk, they lose access to important knowledge that cannot be gained from any other source.

This module defines disclosure and states that not only do patients and families desire disclosure in the case of medical incidents, but they have a right to know why and how they were harmed. The module also outlines common barriers to disclosure in healthcare (lack of education, fear of harming patient, fear of repercussion, cultural norms). Toolkits and resources to combat these barriers and ensure disclosure are provided. Finally, the module lists different ways that patients can be actively involved, including patient reporting of patient safety incidents, patient involvement in the analysis of patient safety incidents, patient engagement in education and at the system level with involvement in the development of policies, process and protocol in healthcare organizations.

Preparing for a presentation

1. Assess the needs of your audience

Choose from the material provided in the module according to the needs of your expected participants. It is better for participants to come away with a few new pieces of information, well learned, than to come away with a deluge of information from which they can remember little or nothing.

2. Presentation timing

The suggested timing for each part of this module is:

Introduction	2-3 minutes
Trigger tape & discussion	5-7 minutes
Presentation	30 minutes
Debrief about teaching methods	5 minutes
Summary	2-3 minutes
<u>Evaluation</u>	<u>5 minutes</u>
Total	49-53 minutes

3. Number of slides: 55

4. Preparing your presentation

The text in the module was not designed to be used as a prepared speech. Instead, the text provides material you may want to use. The slides have been designed to trigger your presentation. Although the slides closely follow the text of the module, they do not contain all of the content. Their use presumes that you have mastered the content.

You may want to make notes on the slide summary pages to help you prepare your talk in more detail and provide you with notes to follow during your presentation.

Remember that you can adjust the slides to suit your presentation content, your style, and to make it feel fully familiar and your own.

Practice your presentation using the slides you have chosen, and speaking to yourself in the kind of language you expect to use, until it is smooth and interesting and takes the right amount of time. The most accomplished presenters and teachers still practice prior to a presentation; don't miss this step.

5. Preparing a handout for participants

The module text and slides in the **Participant's Handbook** were designed to be reproduced and provided to participants as a handout. Take the portion you need; they can be used in their entirety, module by module, or for just one specific topic. Please include the following in each set of handouts:

- **PSEP – Canada Front Cover Page;**
- **PSEP – Canada Acknowledgment Pages** (to acknowledge the source of the material);
- slides for **your topic**; and

- appendix material as relevant.

6. Equipment needs

- Projector, computer and screen
- Flipchart or whiteboard and markers for recording discussion points

Test your equipment beforehand to ensure that it works.

Review your video segments to assess which trigger videos or portions you would like to use.

Have a back-up plan so that if there is any equipment failure you can move without panic to your back-up plan. For instance, have in mind that:

- If the video fails, you can read the vignette of the trigger tape story;
- If the slides cannot be shown, you can refer to the hand out slides; and
- if flipcharts and markers are not available, you can have participants list items on their hand outs that you would have written up for all to see.

Making the presentation

1. Introduce yourself

If you have not already done so, introduce yourself. Include your name, title, and the organization(s) you work for. Briefly describe your professional experience related to the information you will be presenting.

2. Introduce the topic

Show the title slide for the module. To establish the context for the session, make a few broad statements about the importance of topic as a patient safety matter. Tell participants the format and time you will take to present the session. Identify the teaching styles that you intend to use.

3. Review the session objectives

Show the slide with the session objectives listed. Read each objective and indicate those that you are planning to emphasize.

4. Show the trigger tape

After reviewing the objectives for the session, show the trigger tape. It has been designed to engage the audience and provide an appropriate clinical context for the session. It was not designed to demonstrate an ideal interaction, but to “trigger” discussion.

Trigger tape content

Linda Kenney entered the hospital for ankle replacement surgery. Soon after her anesthesiologist, Dr. van Pelt, administered a nerve block, Mrs. Kenney suffered cardiac arrest. Mrs. Kenney's interview gives the patient point of view of an adverse event and, together with Dr. van Pelt's interview, provides a model of productive partnership between physicians and patients.

Keep in mind that the facilitator may choose to use any one of a number of trigger tapes. Since the vignettes are rich and overlap in their teaching points, it may make sense to do this, for instance if an audience has seen the trigger tape already or if a trigger tape from another source is easier for the audience to identify with.

A teachable moment: discussion after the trigger tape

After the trigger tape, ask the participants for their comments about the issues and the interaction they have just seen. To affirm what they contribute, consider recording the important points on a flipchart or overhead projector.

If the discussion is slow to start, you may want to ask more direct questions, like:

- Think of a time when a patient taught you something, reminded you of something or showed you something important you didn't know. What can we learn from that experience that will help us make it happen more often?
- Think of a time when you and a patient or family member accomplished something big working together that you couldn't have done on your own. What were the key ingredients of success?
- Think of a time when you, a family member or friend were a patient. What opportunities did you have to partner? What opportunities would you like to have had?

Use the discussion to set the stage for the material to follow. Do not let the discussion focus on a critique of the technical quality of the video or how "real" the players seemed. If the participants do not like something that was said or done in the video, acknowledge that there is always room for improvement and ask them how they would do it themselves.

Setting limits to discussion time

It is usually best to limit discussion of the video to no more than five minutes, then move on to the presentation. To help move on if the discussion is very engaged, try saying something like:

- let's hear two last points before we move on, and
- now that you have raised many of the tough questions, let's see how many practical answers we can find.

For the more advanced facilitator who is very confident of both the patient safety material and his or her pedagogic skills, it is possible to use the trigger tape as a form of case-based teaching and to facilitate the discussion to draw out the teaching points of the module. The hazard of this approach is that the discussion will not yield the desired teaching points. Feel free to return to the slides if this happens. If this approach is used, it is essential to write up the points on a flip chart as they arise, to fill in any gaps and to summarize at the end. Again, use this method with caution and only if you are really ready.

5. Present the material

Recommended style: interactive lecture

An interactive lecture will permit you to engage your audience, yet cover your chosen material within the time. You can use as your interactive components the trigger tape stimulated discussion, perhaps with some resulting case-based teaching.

Alternative style: role play

Conduct a role play using the case description below. The goal is to:

- experience the emotional and relational challenges presented by having been at the sharp end of an adverse event, and
- practice appropriate apology and experience the impact of it.

The role play can be conducted as a fishbowl, where three participants perform the role play in front of everyone, or within small groups. After completing the role play, facilitate discussion among the group. Possible questions include:

- To actors: What did you find difficult about your role?
- To group: What aspects went well and what didn't? How would you have handled a similar situation?

Case description

A 48 year old woman, Lisa, is being prepared for ankle replacement surgery and is receiving a nerve block with local anesthesia.

The needle hits a vein, delivering the local anesthesia to general circulation. She goes into full cardiac arrest. She is given CPR for 30 minutes before being transferred to the operating room, where her chest is opened up and she is put on a heart and lung machine. The woman's husband, expecting a routine surgery, is now told that his wife has a 50% chance of survival.

The anaesthesiologist who administered the block, Dr. Jones, and the injured patient do not communicate while the patient is in the hospital. He was instructed to continue on the hospital schedule administering very similar anesthesiology blocks to other patients. "It

was as if nothing had happened,” he says. The hospital discourages contact between the two following the woman’s discharge.

However, Dr. Jones is affected emotionally by the event and takes the initiative to write an apology letter to Lisa. He includes all of his contact information so that she can contact him should she choose to do so. She contacts Dr. Jones and lets him know that she is not angry. He feels an enormous weight lifted off of his shoulders once he has this conversation with her.

The patient becomes involved in advocacy to patients wishing to partner with health service organizations to improve patient safety.

In this role play, Dr. Jones and Lisa are meeting to discuss what happened. Dr. Jones apologizes and introduces the idea about making things better for other patients. Lisa thanks him for the candor and the apology and says she wants to consider the idea of working to improve the system.

Role – Lisa, patient

You have recovered and have gained a new appreciation for the fragility of life. And yet you have lots of questions about what happened. You are not an angry kind of person, nor a particularly altruistic one. Mostly you are disoriented and not sure what to make of the whole situation.

Role – Dr. Jones

You are still very distraught by the event. You feel terrible at the suffering you feel you are responsible for. You are feeling trapped by the hospital administration. You have difficulty concentrating at work and difficulty sleeping at night. You want to explain what happened to the person, Lisa, who was harmed. You have decided to do so against hospital advice. You were tremendously relieved to speak on the phone and discover that Lisa was willing to meet and talk it over.

6. Key take-home points

1. Patients and families clearly want disclosure after an incident or even a near miss.
2. Mediation can be an effective tool for establishing a safe space to do disclosure.
3. Disclosure should be done because it is the right thing to do. In addition, evidence is accumulating that shows it can help defer not all, but some, lawsuits by defusing anger and restoring trust.
4. Patients who are injured often need to be compensated and deserve to be.
5. Patients see things busy providers do not and are willing to share them in an incident analysis or report them to learning systems if given the chance.
6. Active encouragement for patients to ask questions is needed to overcome the passive role they expect to take.

7. Patients should be engaged in the development of patient educational materials to ensure that they succeed in engaging.
8. Unlike researchers, patients do not analyze risk on a population basis. They want to know all risks, frequent or rare, that they can do something about.
9. Apologies are important to patients who have been harmed, but they must be sincere. Apologies that are too careful or not followed up with practice change to prevent future harm to others can be dismissed as insincere.
10. Resistance to disclosure appears to be deeply ingrained; healthcare organizations should not assume that providers have the skills or confidence to do it thoroughly. Establishing in house expertise to consult with providers called upon to disclose is a promising approach.

7. Summarize the discussion

Briefly, review each part of the presentation. Recap two or three of the most important points that were discussed.

8. Debrief about the teaching method

Tell the group that it is time to consider the teaching method used, how it worked and what its limitations were. Ask them what other methods might work, and what methods would work best *for the topic* in their home institutions. Ask them to consider what method would work best *for themselves as facilitators* and for their *target audience*.