Disclosing Unanticipated Medical Outcomes

Institute for Healthcare Communication - Canada
Disclosure of commercial support for the Institute

- Institute for Healthcare Communication
  - Is supported in part by grants from Bayer HealthCare Corporation

- This program was developed in part with a grant from:
  - The Permanente Foundation

- The Institute does not permit discussion of label or off-label use of products in any programs
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The IHC-C is supported in part by grants and in-kind support from:

- The College of Family Physicians of Canada
- Cancer Care Ontario
- Canadian Cancer Society - Ontario Division
- Merck Frosst Canada
Objectives

- Understand the rationale for disclosure and its role in resolution
- Appreciate others’ perceptions of the situation including patients, families, clinicians, administration, attorneys and liability insurers
- Consider steps to take before, during and after an unanticipated outcome
The skills we will cover are those used throughout Canada, Australia, UK and the US.

Consult your risk managers and CMPA in specific instances.

Your Health Authority has its own disclosure procedures and resources to guide you.
An unexpected (unanticipated) outcome directly associated with the care provided that results in harm.
“Accidents, injuries or complications occur in all health care settings. Disclosing these incidents stems from principles focused on the right of clients to the facts about their care and treatment and concurrent ethical, moral and legal responsibility of health care workers to inform affected individuals.”

BC Provincial Guidelines
“Purpose of the Guidelines”
Patients experience two types of disappointment

- The disappointing unanticipated medical outcome
- The disappointing way the healthcare providers behave after the unanticipated outcome
  - Research suggests patients are more forgiving of the first disappointment than of the second

(Hickson, 1992; Beckman, 1994; Vincent, 1994; Kraman, 1999; Gallagher, 2003, 2007)
Malpractice suits are not an inevitable result of unanticipated outcomes

- Reduce the impetus for the patient and family to go outside our relationship:
  - Rebuilding rapport and trust
  - Resolving disagreements
  - Negotiating fair settlements when appropriate

(Lester, 1993; Vincent 1994; Hamm and Kraman, 2001; Mazor, 2004; University of Michigan Health System, 2006; Children’s Hospital of Minneapolis, 2006)
Disclosure of harm is required

- Accreditation Canada: Required Organizational Practice (Jan 2006)
  "Implement a formal (transparent) policy and process of disclosure of adverse events to patients/families, including support mechanisms for patients, family, and care/service providers."

- A legal responsibility
  - Courts have established a duty of disclosure (Shobridge v Thomas 1999 BCJ No. 1747)
Alberta Patient Safety Survey

“95% felt physicians should be required to tell the patient or the patient’s family if a preventable medical error resulting in serious harm is made in the patient’s care”

“Of the 37% who had experienced a preventable medical error, 95% of respondents said they or their family members didn’t sue the health care professional for malpractice.”

Health Quality Council of Alberta, 2005
“Patients require knowledge of harm experienced, whether from their disease process or from events related to their health care delivery. When things have gone differently than expected, most patients want information, and an apology if mistakes were made, and if so, assurance that steps are being taken to prevent similar harm to others.”

Dr. Gordon Wallace; CMPA Information Sheet; September 2006
Canadian Medical Protective Association Information Sheet – March 2005
Unanticipated outcomes
Important distinction

Unpreventable
- Natural progression of underlying medical condition
- Inherent risk of investigations or treatments

Preventable
- System failure(s)
- Provider performance

Unanticipated outcome
We must determine the cause if we are to disclose

- Biological variability
- Uncorrected “unreasonable” expectations
- Low probability risks & side effects
- Wrong judgments without negligence
- Individual errors, process and system breakdowns, equipment malfunctions
Hindsight Bias and the Substitution Test

- It is seldom that all contributors to an event are clearly known initially – generally a more thorough investigation is required.
- **Hindsight bias makes outcomes appear to have been more predictable after they are known.**
- **Substitution Test:** a similarly trained person, in the same situation. Would they have been expected to recognize the unreasonable risk of harm?
- Resources: Published Standards / Guidelines / Protocols / Procedures, Organizational or Professional

Disclosure raises concerns

- Makes patients more aware of problems
- Counter to the “self-preservation” instinct
- Could increase number of claims
- Potential impact on our reputations
- Causality hard to assess
- Very hard to do emotionally and practically!

(Studdert 2007; Banja J. 2006)
Adverse events happen frequently and many people are aware

- 8th leading cause of death in the US
  (To Err is Human – IOM Report 1999)

- Medication errors contributing factors in over 7,000 deaths annually
  (Institute of Medicine, 1999)

- 7.5% of people in Canadian hospitals experience an adverse event.
  
  37% judged highly preventable
  (Baker, Norton et al 2004)
Illustration B: Determining the Type of Event and the Requirements for Disclosure

Event in Patient’s Healthcare

- Harm has occurred

Initial Disclosure
Initial communication required as soon as reasonably possible

Analysis

Harm is found to result from or be from a combination of:
- Natural progression of patient’s underlying medical condition
- Inherent risks of investigations or treatments*
- System Failure(s)
- Provider Performance

Post-analysis Disclosure**

A Potential for Harm Exists or No Harm is Apparent

- Event Reached Patient
  - Generally need not be communicated unless ongoing safety risk for that patient, or patient already aware

- Close Call***
  - The event did not reach the patient

Potential for Harm Exists
- Should be disclosed to the patient

No Potential for Harm
- Generally should be communicated

* Refers to harm known to be associated with the investigation or treatment
** Management in consultation with providers to determine what further information is to be disclosed.
*** It is strongly encouraged that close calls be reported to healthcare organizations
When to discuss potential or actual unanticipated medical outcomes

- **BEFORE**: prior to treatment
- **DURING**: as concerns arise
- **AFTER**: unanticipated outcome
AFTER unanticipated outcome

Four aspects to address:

- Immediate care of the patient
- Your own emotions
- Developing clarity re: what happened
- Preparing for and having a discussion with patient/family
Patients and families have 3 questions that must eventually be answered:

- “How did this happen?”
- “What are you doing about it now?”
- “What is the future impact?”

Listen for which one is most important to address at any moment.

- But each must be addressed eventually.
Initial acknowledgment and/or when unpreventable outcome “ALEE”

- ANTICIPATE and ADJUST
  - start with expression of sympathy
- LISTEN to understand the patient’s & family's thoughts and feelings
- EMPATHIZE and normalize without defensiveness
- And then offer to EXPLAIN
Anticipate

• Imagine what the patient/family might be thinking and feeling

• Adjust your approach accordingly
  • Who is invited, how you begin, where you meet, what information to have ready

• Start with “I’m sorry”, expressing regret for what happened

  “I am sorry that you have had such difficult news. We were all wishing for a different outcome.”
Listen

• Patient/family will tell you what must be addressed.

• Invite their story by open-ended questions
  - “How can I/we be most helpful to you right now?”
  - “Tell me what happened after we spoke last…”
  - “What have you been told so far?”
Empathize

- Seeing and feeling the situation from their perspective and communicating that awareness.
- Empathy is conveyed (or not!) by body language, voice tone, words and actions.

“I can understand why you might think that this could have been prevented. This is very different from what we were all hoping for. Would it help if I explain?”
Which “I’m sorry”

- Benevolent expression of sympathy for situation.
  
  “I’m very sorry you and your family have had to endure so much pain this last week.”

- Apology accepting responsibility.
  
  “I’m so sorry that my actions have resulted in you and your family having to endure so much pain this last week.”
Explain and answer questions

- Ask: “Would it be helpful for me to explain what we were thinking and seeing up to that point?”

- Describe facts and answer questions willingly “It is my job to be sure that your questions are answered.”

- Empathize with frustrations without joining in “It sounds like that was a frustrating experience up in diagnostic imaging.”
Unanticipated outcomes

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Post-Analysis Disclosure**

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TEAM steps to resolution

- Truth, transparency and teamwork
- Empathy for impact on patient/family
- Apology and Accountability to prevent management until resolved
  - Exemplary patient care
  - Emotional support for all involved
  - Ongoing communication
  - Help in recovery from injury (e.g., practical, financial)
Balancing Patient’s Right to Information and Organization’s Right to Protected Section 51 Review

- Section 51 allows hospital and mental health facilities to convene a committee to review and make recommendations protected from discovery by patient/attorney
  - was not intended to hide from patients the facts of their care
  - facts could be obtained through medical records and subpoena of staff involved

BC Evidence Act (RSBC 1996)  
Chapter 124
When to start initial disclosure?

- The disclosure needs to be timely and prompt
  - Delaying magnifies problems
  - Disclosure may involve a series of discussions

- Don’t wait for all the “facts”
  - “Here is what we know now and we will keep you informed as we learn more”

- Don’t wait for a complaint or questions
Disclosure Process

[Diagram of the disclosure process]

**Preparing for Initial Disclosure**
- Who will be present?
- What are the facts?
- When will initial meeting occur?
- Where will disclosure take place?
- How will disclosure occur?

**Initial Disclosure**
- Provide facts
- Explain care plan
- Avoid speculation
- Express regret
- Outline expectations
- Arrange follow-up
- Identify contact
- Document

**Conclusions from Completed Analysis**

**Post-analysis Disclosure**
- Provide further facts and any actions taken
- Express regret/say sorry as appropriate
- Document

**Include family or support person with patient’s permission**

**Use clear, straightforward words and terms**

**Be open and sincere**

**Be culturally sensitive**

**Clarify understanding**

**Provide time for questions**
Team composition for subsequent meetings depends on purpose

- Decide whose presence
  - conveys concern and regret?
  - can answer clinical questions?
  - can answer administrative questions?
  - can answer financial questions?
  - who does the patient/family want to hear from?
Formal disclosure meeting to complete the process

Planned with appropriate people in your organization, as well as HCPP/CMPA agreement

- A number of facility staff included to accomplish TEAM process
- Family alerted to reason for meeting, who will be present and invited to bring whomever they wish.
- Usually chaired by senior manager.
- Best if clinicians involved in adverse event can participate, explain, apologize and describe practice changes
What you cannot disclose to patient & family

- Disciplinary actions or culpability of clinicians
- Self-critical analyses conducted under Section 51 hospital committee which may include:
  - Peer review
  - Quality Assurance records
  - Health System Safety Analysis or Root Cause Analysis

Clinicians should be involved in the disclosure, rather than being disclosed about
If investigation concludes the event was *Preventable* and the patient was harmed

- **Truth, transparency and teamwork**
- **Empathy for patient/family experience**
- **Apology and accountability to prevent**
- **Management until resolution of all aspects**
  - Exemplary Patient care
  - Emotional support for all involved
  - Ongoing communication
  - Help in recovery from injury (e.g., practical, financial)
Process in Your Organization

- Review of your health region / organizational Policy and Guidelines

- Resources available to help you analyze a situation, provide advice and assist
Resources

National Disclosure Guidelines (CPSI)
www.patientsafetyinstitute.ca

Disclosure Policy and Resources
www.bcpsqc.ca
# Checklist for Disclosure Team Discussion

This checklist may be useful for identifying tasks to be completed or delegated during a meeting of the disclosure team prior to speaking with the patient and his or her support person(s).

## Support Person

The support person(s) may be any individual the patient identifies as the nominated contact person about his/her care and may include family, a friend, a partner or those caring for the patient. Information about an adverse event resulting in harm will be given to a patient’s identified support person(s) in appropriate circumstances, taking into account the patient’s wishes, confidentiality and privacy requirements, and the organization’s internal policies. In cases of a dispute between family and partners or friends about who should receive information, the patient’s expressed wishes are paramount.

### Identification of Key Individuals

- Notify / consult all relevant health care professionals involved in the adverse event.
- Identify person(s) to take responsibility for the initial disclosure conversation with the patient:
  - Name(s):
    - Known to the patient
    - Familiar with the adverse event and care of the patient
    - Good interpersonal and communication skills
    - Has a relationship with the patient (e.g., most responsible physician)
    - Received disclosure training
- Support person(s) (e.g., family member) for patient identified and available:
  - Name(s) & Contact Info:
  - Relationship to Patient:

### Initial Disclosure Conversation:

Content should include:
- An appropriate apology
- Established and agreed upon known facts (don’t include speculation, opinion or blame)
- Patient’s questions/concerns
- Consequences of harm and any side effects to look for
- Discussion of ongoing care
- What happens next (investigation of adverse event and feedback to be expected)
- Arrangement for future meetings
- Contact details in case of further concerns or questions

Timing (as soon as possible following discovery of harm) taking into consideration:
- Clinical condition of the patient (ongoing clinical care needs must be managed)
- Availability of key staff and support person(s)
- Availability of patient’s support person(s)
- Patient preference
- Privacy and comfort of the patient
- Emotional and psychological state of the patient

### Emotional Support Checklist:

- Patient and family members
- Disclosing health professional
- Health care professionals involved in the adverse event

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Notes:

Adapted with permission from the Accredited Council for Safety and Quality in Health Care and the Health Quality Council of Alberta.
Who should I identify as a support person?

- Someone you are comfortable with and can talk to easily.
- Someone to whom we can give personal information about you.
- Someone able to take the time, if necessary, to be with you.

Who will talk to me?

The person who talks to you about what happened will be someone who:
- Has been involved in your care and knows the facts.
- You are comfortable with and can talk to easily.
- Can contribute to action to try to stop the problem from happening again.

Every patient has the right to be treated with care, consideration and respect.

We respect this right, and we’re committed to improving the quality and safety of the care we deliver. That’s why we have a disclosure policy to help patients who have been harmed during their health care treatment.

This brochure aims to inform you and your support person(s) about the disclosure process. It also tells you what to expect if harm occurs during your health care experience.

We are committed to helping you recover from any harm that may occur during your care, and work hard to improve the care we deliver each and every day.