DISCLOSURE TOOLKIT

Department of Advocacy and Clinical Risk

Disclosure Toolkit

Risk Management

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Introduction

The Ottawa Hospital firmly believes that there are ethical, professional and legal imperatives for its physicians and other health practitioners to provide full and frank disclosure of all adverse outcomes and adverse events to the patient.

Disclosure, an embedded component of quality health care, refers to the communication of information regarding an adverse outcome or adverse event. Historically physicians have been disclosing adverse outcomes with their patients as they discuss the patient's diagnosis, prognosis and outcomes with treatment. The purpose of disclosure of an adverse outcome or adverse event is to provide the patient with complete information about their care so that the patient can then make informed choices related to their care.

A culture of safety is one that discloses unanticipated outcomes to patients. This culture is based on transparency, honesty and respect. Sharing of bad news is difficult. It is more difficult when the harm may have been caused by something we have inadvertently done. This toolkit presents an overview of the steps that one should take in preparation for and when disclosing preventable adverse events and includes tools and resources to assist the health professional in the development of skills related to disclosure.

In keeping with The Ottawa Hospital's non-blame, non-punitive philosophy disclosure does not imply assignment or acceptance of fault.

The College of Physicians and Surgeons (CPSO) and the College of Nurses of Ontario (CNO) are supportive of disclosure of preventable adverse events. The CPSO's position is "that patients are entitled to be informed of all aspects of their health care. This includes the right of a patient to disclosure of harm that may have occurred to him or her in the course of receiving health care."

Not only is disclosure of preventable adverse events the right thing to do and what our patients expect, there is a legislative requirement to do so when the incident is considered critical. Effective July 1, 2008 Regulation 965 of the Public Hospitals Act requires that the hospital have a system in place for disclosure of every critical incident.

*For **quick reference tools** refer to the following appendices:*

Disclosure of Adverse Events (one pager) Appendix A
Procedural Flowchart for Disclosure of Preventable Adverse Events Appendix B
Disclosure Preparation Check Off List - Appendix C
Disclosure Documentation Check Off List – Appendix D

Definitions

An **"Adverse Outcome"** is any of the following:

- development of a new temporary or permanent disability during therapy;
- an unanticipated prolongation of hospitalization (where prolongation can refer to an entire admission or a readmission); or
- an unanticipated death.

An **"Adverse Event**" is an adverse outcome that is due to health care management as opposed to progression of natural disease.

A **"Preventable Adverse Event"** is one that is felt to be due to an obvious error in management or system flaw

Critical Incident as defined by the Canadian Patient Safety Dictionary, and used for the purposes of the TOH Critical Incident Review policy, is an incident resulting in serious harm (loss of life, limb or vital organ) to the patient, or the significant risk thereof (i.e. near miss). Incidents are considered critical when there is an evident need for immediate investigation and response. The investigation is designed to identify contributing factors, system or process deficiencies, and the response includes actions to reduce the likelihood of reoccurrence

"Critical Incident" (as defined by Regulation 965 of the Public Hospitals Act, for purposes of mandatory disclosure) means any unintended event that occurs when a patient receives treatment in the hospital,

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

Disclosure is the imparting by health care workers to patients or significant others of information pertaining to any health care event affecting (or liable to affect) the patient's interests. The obligation is proportional to the degree of actual harm to the patient (or realistic threat of such) arising from an untoward event. There may be situations in which information cannot be disclosed due to Quality of Care Information Protection Act (QCIPA) legislation – see Frequently Asked Questions (pg 16) for details.

Surrogate can include any person(s) designated by the patient, or the appropriate substitute decision makers when a patient is incapable.

Legal, Professional and Ethical Obligations

Legislation

Regulation 423 (in force July 1, 2008), amended Regulation 965 of the Public Hospitals Act, requires that the hospital have a system in place for disclosure of every critical incident. Factual content of the disclosure (facts, consequences, actions taken to patient) must include:

(a) the material facts of what occurred with respect to the critical incident;
(b) the consequences for the patient of the critical incident, as they become known; and
(c) the actions taken and recommended to be taken to address the consequences to the patient of the critical incident, including any health care or treatment that is advisable.

There is a legislative requirement for the hospital's Board of Governors to ensure that the CEO has a "system" for further disclosure to the person of the systemic steps, if any, that the hospital is taking or has taken in order to avoid or reduce the risk of further similar critical incidents, subject to the QCIPA and recording the content and date of this further disclosure.

Reports of any critical incidents with respect to the patient, including the information disclosed and when any disclosure was made are part of the health record. This includes the inpatients, outpatients, and those patients only in for diagnostic procedures.

Refer to Government of Ontario E-Laws:
http://www.e-laws.gov.on.ca/html/regs/english/elaws_regs_900965_e.htm#BK1

Hospital Polices and Procedures

The Administrative policy Disclosure of Adverse Events and Adverse Outcomes, ADM VIII 370 clearly states the hospital's position on disclosure. At The Ottawa Hospital we firmly believe that there are ethical, professional and legal imperatives for its physicians and other health practitioners to provide full and frank disclosure of all adverse outcomes and adverse events to patients (or their surrogates) as soon as reasonably possible after they occur.

The Ottawa Hospital requires that for all adverse outcomes and adverse events, the disclosure should involve at least a discussion between the attending practitioner and the patient (or their surrogates); and that this discussion should be documented in the medical record.

For the subset of adverse events that are preventable, the Ottawa Hospital requires a more formal disclosure process, which may include the involvement of the Risk Management department.

This policy does not apply to errors that do not harm patients (i.e., near misses). These particular occurrences may not require disclosure to patients in all cases and should be left to the individual clinical judgment of the attending physician (or designate), the clinical director/manager and professional chief.

Refer to the Administrative Policy and Procedure Manual available on the hospital Infonet:

http://infonet/documents%5Fpp%5Fadmin/Administrative%20Policy%20and%20Procedure%20Manual/08.%20Patient%20and%20Community%20Relations/Disclosure%20of%20Adverse%20Events%20and%20Outcomes%202003.pdf

Professional Position Statements

The **College of Physicians and Surgeons** (CPSO) policy on Disclosure clearly identifies the professional responsibility of the physician related to disclosure. "Patients are entitled to be informed of all aspects of their health care. This includes the right of a patient to disclosure of harm that may have occurred to him or her in the course of receiving health care." 1

The policy reads: "When a physician becomes aware, while treating a patient, that the patient has suffered harm in the course of receiving health care, he or she should consider whether the harm does or can be reasonably expected to negatively affect the patient's health and/or quality of life. If it does, then it is the physician's obligation to inform the patient about the harm sustained.

Refer to Appendix E "CPSO Disclosure of Harm" policy and CPSO website: www.cpso.on.ca/policies/disclosure.htm

The **College of Nurses of Ontario (**CNO) also supports open disclosure of errors. "How a facility deals with a health care error can either exacerbate an already painful incident or, through disclosure, promote openness, healing, learning and prevention. According to research by the Institute for Safe Medication Practice (ISMP) Canada, Healthcare Papers and The Royal College of Physicians and Surgeons of Canada, open disclosure is the most effective way to deal with an error. Below are some tips that employers can use to help staff manage these situations." 2

Refer to Appendix F CNO's Guide on "Best Practices in Disclosing Health Care Error" and CNO website: www.cno.org\new\notices\disclosing_error.htm

[1] www.cpso.on.ca/policies/disclosure.htm
[2] www.cno.org\notices\disclosingerror.htm

Canadian Council on Health Services Accreditation (CCHSA)

With a goal of creating a Culture of Safety, CCHSA has identified Disclosure as a Required Organizational Practice (ROP) for health care organizations to have in place a policy and process for disclosures of adverse events.

According to CCHSA " Core elements of disclosure normally include discussing the adverse event itself, acknowledging/apologizing for the adverse event, reviewing the actions taken to mitigate the circumstances, discussing the corrective action to prevent further adverse events, and answering the patient/client and/or family's questions." [3]

Court Findings (Case Law)

Courts recognize an obligation/duty to inform patients of adverse events, if "a reasonable person in the patient's position would want to know" (Picard L. Robertson G, Legal Liability of Doctors & Hospitals in Canada, 3rd edition, 1996.) The duty to inform is based on the "trust" relationship, between health care professionals and their patients. Failure to respect this duty may void the patient's consent to subsequent treatment, resulting possibly in a court finding of battery. It may also lead to punitive damages if the conduct is deliberate and highly unethical.

Ethical Obligations

"Truthfulness means speaking or acting without intending to deceive"(College of Nurses of Ontario). Patients must have complete and truthful information to be informed. It was previously believed that patients could be harmed by knowing the details of their illnesses. Such beliefs are now seen to be paternalistic. Patients have the right to and will benefit from full disclosure. "Honesty builds trust, which is essential to the therapeutic relationship" for all providers and patients." [4]

[3] http://www.cchsa-ccass.ca/default.aspx?page=139
[4] CNO Practice Standards - Ethics

Barriers to Disclosure

Barriers to disclosure are numerous but in most cases they are related to a lack of knowledge about the process and benefits and the multiple fears associated with telling a patient that something has gone wrong.

The following have been identified as common barriers:

- Discomfort with having this type of conversation
- Fear of:
    - Loss of respect from the patient
    - Loss of self esteem and self confidence
    - Loss of job or position
    - Censure, loss of prestige or respect from colleagues
    - Malpractice lawsuits or request for compensation
- A genuine belief that it is in the best interests of the patient to not be informed
- Attitudinal barriers – (e.g. perfectionism)
- Disclosure challenges ones integrity, courage and humility

Benefits of Disclosure

Despite the barriers that may exist to disclosure there are many established benefits that far outweigh the consequences of not disclosing.

- Informed patients means informed choices in care
- Preserving or reestablishing the trust relationship
- Opportunity to express regret and assuage one's conscience
- Potentially reduced risk of litigation or punitive actions for non-disclosure
- Patients who find out after the fact, that an adverse event was not disclosed may react with anger and the courts will also see this in an unfavorable light

Preparing for Successful Disclosure Conversation

For a quick reference regarding preparation for disclosure see "Disclosure Preparation Check Off List "Appendix C

Who should disclose?

The responsibility for disclosing an adverse event or outcome to a patient/surrogate generally rests with the attending physician. There may be situations when the attending physician will not or cannot take the lead role in the disclosure discussions (i.e., physician unavailable, physician declines to participate in disclosure discussions). In addition, there may be situations where the attending physician is not the appropriate person to participate in the discussions (i.e. physician feels he/she does not have the requisite communication skills). In such situations, the attending physician's designate (another physician) will provide the initial disclosure and any subsequent communications, if necessary, with the patient and/or their family.

A disclosure that is done because one is compelled to do it will be obvious to the patient/surrogate and result in a greater erosion of trust. Proper understanding of the rationale and benefits of disclosure can help you prepare for this difficult discussion. The risk management staff can assist with preparation for the disclosure discussion.

A resident or a medical student is required to report to his or her supervising physician any adverse outcome or adverse event. The supervising physician must bring the matter to the attention of the attending physician who is responsible for disclosing to the patient (or their surrogate).

If the adverse outcome or adverse event is related to care provided by a non-physician, but is related to care provided by another regulated health professional, then responsibility for disclosure will rest with the Clinical Director/designate and/or Professional Health Chief in partnership with the attending physician or designate.

Where the adverse event is related to care provided by a non-regulated provider, responsibility for disclosure will rest with the Clinical Director/Department Director/designate in partnership with the attending physician.

Care of the Caregiver

The emotional impact of being a part of an adverse event may impede one's ability to objectively disclose. Being involved in an adverse event that (potentially) caused harm to a patient can be very difficult and even traumatic for the caregiver and in some cases may be experienced as an ethical dilemma. Consideration should be given by the individuals involved to consulting the Clinical Ethicist, Employee Assistance Program, Spiritual Services or Professional Support Services for counseling, crisis intervention and support.

Acknowledging strengths and weaknesses

The individual intending to disclose should consider whether he/she has the necessary skills and knowledge of the disclosure process to lead the conversation. Potential participants must determine where their strengths and weaknesses lie and are encouraged to contact the Risk Management department for guidance on preparing for the discussion.

Before you disclose:

- Know the facts and discuss with team
- Review the chart
- Prepare yourself emotionally
- Know what you will say
- Consider apologizing or expressing regret depending on the facts
- Anticipate the questions that will be asked
- Have a plan of care
- Refer to "Disclosure Preparation Check Off list" (Appendix C)
- Refer to "What Patients and Families Want" (page 10)
- Remember that disclosure is a process and may not be a one-time event.

Refer to "Good Communication -The Key to Successful Disclosure" Appendix G, for tips on effective communication.

When and where the disclosure conversation should occur:

- Choose a time that is best for the patient and family. Disclosure should take place as soon as practically possible after the event has occurred, or has been identified, with consideration of the patient's clinical condition. Set aside enough time for explanations and to allow for questions from the patient and the family. Promptly disclosing promotes ongoing trust in the relationship and may reduce the chance of litigation.

- Choose a meeting location that is comfortable and offers privacy for the patient and eliminates interruptions.

- Provide a supporting atmosphere by allowing patient to invite family members to be present. Consider the seating arrangements and availability of items for comfort (e.g. tissues, water).

What types of events should be disclosed?

There is no legal obligation to disclose a near miss. Disclosure of non-significant events is discretionary and is dependent on the potential for harm. The greater the risk of harm the greater is the duty to disclose to the patient. Disclosure is clearly required where harm can reasonably be expected to the patient's health or quality of life.

To whom should disclosure be made?

(a) to the affected patient (if the patient is capable);
(b) if the affected patient is incapable, to a person lawfully authorized to make treatment decisions on behalf of the patient; or
(c) if the affected patient has died,
    i. to the patient's estate trustee, or to the person who has assumed responsibility for the administration of the patient's estate, if the estate does not have an estate trustee, or
    ii. to a person who was lawfully authorized to make treatment decisions on behalf of the patient immediately prior to the patient's death, or who would have been so authorized if the patient had been incapable.

What Patients and Families Want:

- A sharing of information in a sincere, empathetic manner and a genuine expression of regret for what has occurred.
- A disclosure that is done in person, not by phone, fax or email
- The truth – the facts that you know now
- A commitment to meet again, if necessary, to share additional information
- They will want you to take responsibility. This does not have to mean an admission of guilt or error, but rather an admission that you are responsible for their care and are there to explain what you can.
- An apology (refer to "Apologizing, Doing the Right Thing the Right Way" pg. 13)
- They will want to know what can be done now to remedy the problem created by the adverse event.
- Share with the patient/family what is being done to ensure that this will not happen to other patients (where applicable).
- The question of compensation may come up and you should be prepared to address it. Speak with the Risk Manager and/or Canadian Medical Protective Association for guidance on this aspect.
- Listening time must be provided to allow the patient, family or surrogate to express to you, how they are feeling about the event and related issues. This component of the discussion is essential.

Suggested Conversation Outline

Once all of the information above has been considered the conversation should be initiated with the patient and or surrogate.

- Starting the conversation: Ensure that your timing is right:
    - Is the patient well enough (capable) of understanding the conversation?
    - If the patient is not capable disclosure should take place with the surrogate.
    - Is the patient or family too distraught to have this conversation now? If so, offer it at a later date.
- It is often advisable, depending on the degree of severity, to have a family member present with the consent of the patient.
- Do not assume that the patient already has a full understanding or even knowledge of the adverse event or its impact.
- Tailor the discussion to the patient's level of understanding – watch for signs of understanding.
- Pace the conversation. Patients can saturate easily and may be very fatigued from the course of events.
- Validate that the patient /surrogate understands what occurred and it's potential consequences.
- Always remain truthful.
- Describe the known facts of the adverse event in a non-judgmental manner
- Outline the implications for the patient's health and subsequent care.
- Avoid speculations or attribution of blame
- If you don't have all the answers, say so. If you are awaiting further information tell the patient/surrogate when you expect to receive it, and when you will share it with them.
- Provide an expression of regret and if appropriate an apology *Note, this is not an admission of liability or fault (Refer to"Apologizing, Doing the Right Thing the Right Way - pg. 13.)
- Explain changes or plans made to reduce the risk of a repeat event
- Ending the conversation:
    - Summarize the information provided
    - Go back over the key questions that were asked
    - Review plans for follow up – who, when, where and what, if anything, the family or patient is expected to do
    - Advise patient/surrogate that you will be available for further questions or a further meeting if appropriate
    - Offer additional help that is available at the hospital – e.g. Social Work, Spiritual Care
    - Repeat your expression of regret, sympathy and support as applicable

The chart may be shown to the patient/surrogate. If the patient/surrogate requests a copy of the chart those involved in the disclosure should facilitate access to a copy for the family or surrogate.
A further meeting should be held with the family as more information becomes available.

Sample Disclosures:

Incident	Classified As:	Disclosure
Wrong side surgery	Critical incident	Disclosure should be done by the Attending Physician in consultation with Risk Management
Tracheotomy airway obstruction related to placement of valve. Patient required transfer to ICU	Serious incident	Incident should be reported by the Respiratory Therapist to Professional Chief and Attending Physician. Disclosure should be done by the Attending Physician along with the Professional Chief. Consult Risk Management.
Death of Newborn Infant related to delay in diagnosis and treatment.	Critical Incident	Disclosure should be done by the Attending Obstetrician/Midwife in consultation with Risk Management.
Patient inadvertently received 10 times the ordered dose of epinephrine. Pt required transfer to ICU. Family was not willing to meet with Attending Physician.	Serious Incident	Disclosure should be done by Head of Medical service.
Nurse inadvertently administered IV Heparin instead of IV Insulin to the patient.	Moderate incident	Disclosure should be done by attending physician with clinical manager or director depending on outcome for patient
Nurse inadvertently administers Tylenol # 3 to pt with known allergy to Codeine. No adverse outcome for patient.	Minor incident	Nurse should report the incident to the Clinical Manager and Attending Physician. Determination as to who is the most appropriate person to disclose will be determined by the Clinical Manager and Physician.
Physician writes order for penicillin. Pharmacist notes patient has allergy to penicillin. Physician's order is rescinded	Near miss incident	No Disclosure is required.

Apologizing – Doing the Right Thing the Right Way

The Canadian Patient Safety Institute notes " where it is clear that a healthcare provider or healthcare organization is responsible for or has contributed to the harm from an adverse event, it may be appropriate to acknowledge that responsibility and to say sorry." [5]

An apology is about the patient and his/her family but it can also benefit the caregivers. An apology for the sake of apologizing will be seen as such, and may result in a further loss of trust and the associated fallout such as complaints to the college, media or litigation. For an apology to be received as authentic it must arise from a sense of humility, honour and ethics.

"The most important reason a patient with a bad outcome decides to sue his or her doctor for malpractice is not a lapse in the quality of care….but how the doctor talks with the patient."[6]

Acknowledging regret is not necessarily admitting guilt

Extending an apology does not mean an admission of guilt. It is simply an expression of emotion, not a legal conclusion. "The use of words that express or imply legal responsibility such as negligence or fault, or reference to failing to meet the standard of care, should be avoided."[7] *(CPSI May 2007)*

Done correctly, an apology may have the following benefits

- Reestablish trust between the caregiver(s) and the patient/surrogate
- Reduce the risk of a college or media complaint and or litigation
- Reduce the discomfort the caregiver is feeling

When is an apology appropriate?

- When the outcome was unexpected
- When an error has occurred or may have occurred
- When the patient's trust in the care giver(s) has been eroded
- When the expectations of the patient and or surrogate were unmet

Components of a Successful Apology

- Sincerity, empathy and honesty – words alone are ineffective, rather it is the way that the apology is expressed that will determine the impact
- Expression of regret for the experience (e.g. "I am so sorry that this happened to you.")
- Acknowledgement of the personal pain of the patient and or family

[5] *Canadian Patient Safety Institute (CPSI) May 2007)*
[6] Jama Feb 1997
[7] CPSI May 2007

- If nothing could have been done differently an apology for the experience is still appropriate, along with an explanation.
- If there is no doubt that an error has occurred, acknowledge that there has been an error. Do not ascribe blame to someone else unless it is your responsibility to do so (i.e. You are that person's supervisor or a hospital representative assigned to do so.)
- Express remorse for the part you played in the event.
- If it is unclear whether or not an error has occurred, say so. As noted above, explain that you will update the patient as more information becomes available.

Refer to Appendix H "Sample Apologies" for examples of effective apologies

Documentation

Disclosure discussions concerning preventable adverse events and critical incidents must include:

- The material facts of the event,
- The impact of the occurrence and consequences for the patient as they become known,
- The actions taken and recommended to be taken to address the consequences to the patient of the occurrence, including any health care or treatment that is advisable.

The above disclosure information, including date and time of disclosure, must be documented in the Health Record (in-patient and out-patient record, including those patients attending solely for diagnostic procedures)

Additional considerations for disclosure and documenting disclosure should include:

- Offers of assistance, including support of Social Work, Spiritual Care, Ethics Consultation Service, Advocacy and Clinical Risk
- Information that is objective and factual, free from speculation or blame, and presented in a caring and compassionate manner
- The cause of the event, if known
- Expression of regret that the adverse event or adverse outcome occurred.
- Plans for a review to identify causal factors and prevent its recurrence
- Names of individuals present at the disclosure meeting and relationship to patient
- Discussion points including: reaction/questions of participants; a statement indicating that the patient (or the surrogates) will be kept informed of new information as it becomes available.
- Whether the patient refuses to receive the disclosure information
- Any request to review the patient's health record.

Refer to Appendix D "Disclosure Documentation Check off List – A Quick Reference Tool"

Refer to TOH Administrative Policy Disclosure of Adverse Events and Outcomes ADM VIII 370

http://infonet/documents%5Fpp%5Fadmin/Administrative%20Policy%20and%20Procedure%20Manual/08.%20Patient%20and%20Community%20Relations/Disclosure%20of%20Adverse%20Events%20and%20Outcomes%202003.pdf

Frequently Asked Questions (FAQs)

Can information discussed during a QCIPA review be disclosed?
There may be circumstances in which there is information protected under the Quality of Care Information Protection Act (QCIPA) which cannot be disclosed, except in the circumstances set out in QCIPA. Quality of care information is defined in the legislation as information collected by or prepared for a Quality of Care Committee for the sole or primary purpose of assisting the committee carrying out its functions or information that relates solely or primarily to any activity that quality of Care Committee carries on as part of its functions. Facts are disclosable, opinions are not. Consult Risk Management for guidance.
What information should be included in a disclosure conversation?
A disclosure discussion concerning adverse events/outcomes should include information on: • the facts of the adverse event or adverse outcome; • the cause of the event if known; • the impact and consequences of the occurrence to the patient; and • the proposed treatment plan. The information should be provided in an objective and factual manner, free from speculation or blame and presented in a caring and compassionate manner. With preventable adverse events the discussion should include a statement of regret for the adverse event/outcome; plans for review to identify causative factors and prevent its recurrence; and offers of assistance including support to Social Work, Spiritual Care and Advocacy and Clinical Risk. Refer to the policy “Disclosure of Adverse Events and Adverse Outcomes” # ADM VIII 370, in the Administrative policy and procedure manual.
How should I respond if the patient or surrogate asks about financial compensation?
There may be cases where compensation is appropriate. This, however, is handled by the insurers for the hospital and staff and/or physician. The process to involve the insurers is initiated by the Risk Management Department when it is hospital related or by the physician when it is physician related. Ideally, in cases of disclosure where compensation may be a consideration, the practitioner will have contacted the Risk

Manager at the time of the event, and this will have been discussed with the person doing the disclosure ahead of time. Patients/surrogate/families should be told that the individual must contact their insurer regarding compensation and ask the patient/family/surrogate to write a letter to the physician and hospital asking for compensation. The insurers will then open a file and initiate their review to determine whether compensation will be provided.

Who is responsible for the disclosure of an adverse event?

The responsibility for disclosing an adverse event or outcome to a patient (or their substitute decision maker) generally rests with the attending physician. There may be situations where the attending physician will not or cannot take the lead role in the disclosure discussions, or the attending physician is not the most appropriate person to participate in the discussions. In such situations, the attending physician's designate (another physician) will provide initial disclosure and any subsequent communications, if necessary, with the patient and/or their family. If the adverse outcome or event is related to care provided by a regulated health professional other than a physician, then responsibility for disclosure will rest with the appropriate Clinical Director/Department Director/Professional Chief in partnership with the attending physician.

What if the patient or family wants to tape, type or write notes during the disclosure conversation?

This type of request can increase the caregiver's level of discomfort and should be considered on a case-by-case basis. On occasion the family will arrive prepared to record the discussion and the caregiver will not have the benefit of considering this scenario in advance. In the spirit of openness and honesty one should strongly consider proceeding despite the discomfort, as to do otherwise might send the message that we will not stand by what the hospital and providers have said.

What resources are available to assist in preparing for a disclosure conversation?

A Consultant in the Department of Advocacy and Clinical Risk will provide guidance on the Disclosure Policy and Procedure. For serious and or critical preventable adverse events, the Department of Advocacy and Clinical Risk must be notified of the incident and consulted in advance of a disclosure discussion with a patient/substitute decision maker. Additional resources are available in the policy "Disclosure of Adverse Events and Adverse Outcomes" # ADM VIII 370 and in this toolkit.

What should be documented in the chart related to disclosure of adverse events?
Documentation of the disclosure discussion to the patient/SDM should include the following information: • Date/time/place of discussion; • names and designation of individuals present and relationship to patient; • discussion points including reaction/questions of participants, proposed treatment and follow up plan; • any offers of assistance made and the response of the patient/SDM; • whether a patient refuses to receive the disclosure information; • and any request to review the patient's health record. The policy "Disclosure of Adverse Events and Adverse Outcomes" # ADM VIII 370, in the Administrative policy and procedure manual includes an outline as does this toolkit in Appendix D.
What if the patient or family decline attendance for the disclosure conversation?
As under certain circumstances disclosure is required by law, and is also recognized as beneficial for many reasons. If faced with this situation, providers are advised to contact CMPA and/or Risk Management. Efforts to disclose should be documented on the patient record.

Links & Related Topics

- Disclosure of Adverse Events and Adverse Outcomes ADM VIII 370 (Ottawa Hospital) http://infonet/documents%5Fpp%5Fadmin/Administrative%20Policy%20and%20Procedure%20Manual/08.%20Patient%20and%20Community%20Relations/Disclosure%20of%20Adverse%20Events%20and%20Outcomes%202003.pdf
- College of Physicians and Surgeons of Ontario http://www.cpso.on.ca
- College of Nurses of Ontario, http://www.cno.org
- Ontario College of Social Workers and Social Service Workers http://www.ocswssw.org
- Public Hospitals Act http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90p40_e.htm
- Quality Care Information Protection Act (QCIPA), 2004 http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04q03_e.htm
- Personal Health Information and Protection Act, 2004 http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm
- Substitute Decisions Act, 1992 http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_92s30_e.htm
- Health Care Consent Act, 1996 http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_96h02_e.htm
- Canadian Medical Protective Association http://www.cmpa-acpm.ca
    - *Information Letter*, December 2006. "The value of good communication"
    - *Information Letter*, September 2006. "How to apologize when disclosing adverse events to patients"
    - *Information Letter*, March 2005. "Disclosing adverse events to patients: Strengthening the doctor-patient relationship"
    - *Information Letter*, March 2003. When things go wrong, the patient needs to know

References

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- Ethics, Practice Standard, College of Nurses of Ontario http://www.cno.org/docs/prac/41034_Ethics.pdf
- When Mistakes are Made, College of Nurses of Ontario, Communique, March 2003 http://www.cno.org/pubs/mag/cmqVol28no1.pdf
- Best Practices in Disclosing Health Care Error, College of Nurses of Ontario: http://www.cno.org/new/notices/disclosing_error.htm
- CCHSA Patient/Client Safety Goals and Required Organizational Practices (ROPs), Evaluation of Implementation and Evidence of Compliance, Version 1 2006 Standards, August 2006
- Risk Management Pearls, American Society for Healthcare Risk Management, 2005, Chicago Il.
- Controlled Risk Insurance Company Limited/Risk Management Foundation. (CRICO/RMF) www.rmf.harvard.edu/education-interventions/materials-for-instructors/disclosure
- Disclosure of Adverse Events: Legal Responsibilities, Pierre E. Roger, Borden Ladner Gervais LLP, Dec, 2, 2004
- Public Hospitals Act 1990 http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90p40_e.htm
- Public Hospital Act, 1990, Regulation 965, http://www.e-laws.gov.on.ca/html/regs/english/elaws_regs_900965_e.htm
- Healing Words – the Power of Apology in Medicine, Dr. Michael Woods, MD, Doctors in Touch, 2004
- Draft National Guidelines for the Disclosure of Adverse Events, Canadian Patient Safety Institute, May 2007 .*http://www.patientsafetyinstitute.ca/Disclosure.html*

Appendices

Appendix A - Disclosure of Adverse Events – A Quick Reference Tool

There are ethical, professional and legal imperatives for physicians and other health practitioners to provide full and frank disclosure of all adverse outcomes to their patients. Disclosure, an embedded component of quality health care, refers to the communication of information regarding an adverse outcome, adverse event or critical incident.

The position of the College of Physicians and Surgeons of Ontario is "that patients are entitled to be informed of all aspects of their health care. This includes the right of a patient to disclosure of harm that may have occurred to him or her in the course of receiving health care." [8] "The Canadian Medical Protective Association has for many years encouraged member physicians to disclose to patients the occurrence and nature of adverse outcomes as soon as is reasonable to do so after their occurrence." [9]

Not only is disclosure the right thing to do and what our patients expect, there is a legislative requirement to do so when the incident is considered critical (Regulation 423, amended Regulation 925, Public Hospitals Act in force July 1, 2008). The Ottawa Hospital's non-blame, non-punitive philosophy and policy on disclosure do not imply assignment or acceptance of fault.

Proper preparation for a disclosure discussion with a patient or surrogate, will improve the likelihood of a conversation that meets the needs of all involved – patient, family, surrogate and the care team. "Just in Time" Disclosure education is available through the Risk Management Department.

Steps in Disclosure: (for a more detailed guide refer to TOH Disclosure Toolkit available on TOH Infonet under Advocacy and Clinical Risk)

1. Prepare yourself adequately prior to the disclosure conversation.
    - Have you advised the appropriate TOH people of the event? (Risk Management must be notified if the event is serious or critical.)
    - Are you the right person to do the disclosure?
    - Do you have the skills to do the disclosure and if not, have you asked for assistance?
    - Have you arranged to have another TOH MD or TOH employee with you during the conversation?
    - Have you discussed the case with the care team?
    - Do you know the facts?
    - Do you know what you are going to say?
    - Have you anticipated questions and prepared answers?

[8] www.cpso.on.ca/Policies/Disclosure.htm
[9] Disclosing Adverse Events to Patients: Strengthening the Doctor Patient Relationship, CMPA, March 2005

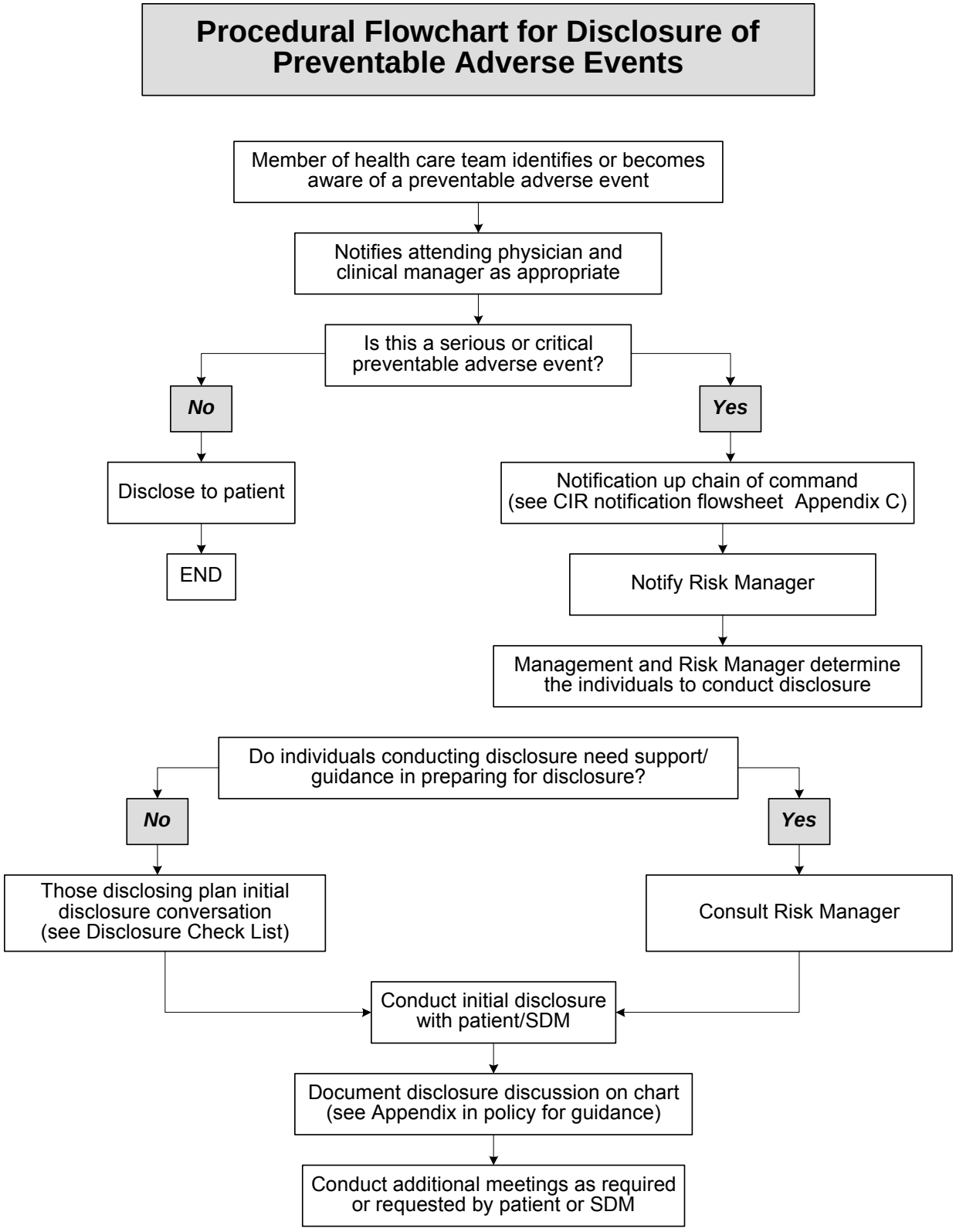
2. Meet with patient/surrogate

- Ensure privacy for the discussion
- Convey an expression of regret/apology
- Provide all known facts of the event, recognizing that additional information may become available at a later date
- Be mindful of your body language and the words your use
- Monitor the patient/family/surrogate to ensure that what you are sharing is understood
- Give the patient/family/surrogate time to ask questions, listen to their comments
- Clearly outline next steps – care, review, feedback on additional findings and changes to be made to reduce risks
- Summarize before ending the conversation and determine if an additional meeting is required

3. Document - Refer to the Disclosure policy (Appendix A) for guidance as to content of required documentation (as mandated under the Public Hospitals Act).

4. Take care of yourself – Adverse events and disclosure conversations can have a profound affect on the caregivers and it may be advisable to seek support. Refer to Preparing for Successful Disclosure Conversation, Care of the Caregiver.

Appendix B – Procedural Flowchart for Disclosure of Preventable Adverse Events



Appendix C - Disclosure Preparation Check list - A Quick Reference Tool

For consideration following an adverse event and prior to disclosure a discussion with patient:

Have you:

- ☐ Reviewed Disclosure Policy (ADM VIII 370)
- ☐ Determined disclosure is necessary
- ☐ Considered involving the Risk Manager
- ☐ Considered reporting to your Insurer
- ☐ Determined that you are the right person to do the disclosure
- ☐ Acquired the necessary communication skills to lead the disclosure discussion
- ☐ Considered the “W”s (when, where and with whom)
- ☐ Prepared what you are going to say
- ☐ Anticipated questions (know the facts)
- ☐ Considered apologizing or expressing regret
- ☐ Obtained a copy of the Disclosure documentation tool

Refer to Disclosure Policy (ADM VIII 370)

http://infonet/documents%5Fpp%5Fadmin/Administrative%20Policy%20and%20Procedure%20Manual/08.%20Patient%20and%20Community%20Relations/Disclosure%20of%20Adverse%20Events%20and%20Outcomes%202003.pdf

Appendix D - Disclosure Documentation Check off List - A Quick Reference Tool

Items in italics are <u>required by legislation</u>

- □ Date time and place of disclosure meeting
- □ Names of those present
- □ Facts of what occurred - *" the material facts of what occurred with respect to the critical incident"* Material facts are those facts that are considered important or essential.
- □ Actions taken (or to be taken to understand how the event occurred)
- □ *The consequences for the patient of the critical incident, as they become known*
- □ *The actions taken and recommended to be taken to address the consequences to the patient of the critical incident, including any health care or treatment that is advisable*
- □ Responses to questions answered
- □ Transfer of care to another physician/Involvement of other health care professional
    - Considered
    - Discussed
    - Planned
    - Completed
- □ Offers of assistance made (as appropriate)
    - Social Work
    - Spiritual Care
    - Advocacy and Clinical Risk

  (Indicate acceptance or rejection of offers)
- □ Name of individual who will follow up with patient/surrogate where appropriate
    - Contact number
- □ Other issues
- □ Patient/surrogate requested chart - Yes/No
- □ Signature of health care practitioner

Appendix E – The College of Physicians & Surgeons of Ontario – Policy on Disclosure

Disclosure of Harm #1-03

Approved by Council: February 2003

Publication Date: May/June 2003

To be Reviewed By: February 2008

Key Words: Disclosure, Error, Communication

Related Topics: CPSO Policy, Consent to Medical Treatment

College Contact: Physician Advisory Service

Purpose

The purpose of this policy is to affirm the College's position that patients are entitled to be informed of all aspects of their health care. This includes the right of a patient to disclosure of harm that may have occurred to him or her in the course of receiving health care.

It is not the intent of the policy to address issues concerning the cause of the harm suffered by a patient or the attribution of blame. The policy is about disclosing harm *to a patient*, not reporting to a third party the fact that harm occurred.

Scope

This policy applies to all physicians, regardless of practice setting or type, who become aware, while treating a patient, that the patient has suffered harm in the course of receiving health care.

Definitions

For the purposes of this policy, the following definitions apply:

1. Harm

> Harm is defined broadly as an unexpected or normally avoidable outcome that negatively affects the patient's health and/or quality of life, which occurs (or occurred) in the course of health care treatment and is not due directly to the patient's illness.

2. Disclosure

Disclosure means the acknowledgement and discussion of a negative outcome with the patient or his or her authorized substitute decision maker. It does not mean reporting the facts of the harm to a central reporting body or institution for the purposes of analysis or education.

3. Most Responsible Physician

The physician who has the final responsibility and accountability for the medical care of a patient.

4. Supervisor

A clinical teacher who is delegated by his or her respective training programs to guide, observe and assess the professional activities of trainees. Supervisors may or may not be the Most Responsible Physician [1].

College Policy

Principles

The College Council is mindful of the following key principles:

1. The patient is entitled to be kept informed about his or her health care. This includes information about harm suffered in the course of receiving health care.
2. The obligation to disclose harm flows from the fiduciary nature of the physician-patient relationship. It is part of the physician's obligation to maintain the patient's best interests and the patient's entitlement to professional and ethical health care. This entitlement arises primarily out of respect for the patient as a person. Disclosure of harm not only respects the autonomy of the patient, it also ensures that the patient can access timely and appropriate interventions for the harm suffered.
3. The patient is entitled to be informed about harm suffered even when such disclosure might prompt a complaint or a claim. Failure to keep the patient informed of all pertinent health information, except by the choice of the patient, is a failure to respect the autonomy and the well being of the patient.
4. Professional judgment is required to determine when an unintended outcome of care does, or can be reasonably expected to negatively impact a patient's health and/or quality of life and therefore is significant enough to require disclosure.
5. Not all harm is preventable. Harm can arise from a variety of causes and is not necessarily an indicator of substandard care.

The Disclosure of Harm

When a physician becomes aware, while treating a patient, that the patient has suffered harm in the course of receiving health care, he or she should consider whether the harm does or can be reasonably expected to negatively affect the patient's health and/or quality of life. If it does, then it is the physician's obligation to inform the patient about the harm sustained.

The disclosure of harm may be made to the patient directly or through his or her authorized substitute decision maker **(Consent to Medical Treatment)**. The disclosure should take place as soon as reasonably possible, taking into account the clinical and emotional condition of the patient. It should be made in a sensitive manner taking into consideration the patient's personal, social, religious and cultural needs. In addition to reviewing the attached Appendix regarding "how to disclose", the physician may wish to contact his or her medical malpractice protection provider for advice on how to discuss with a patient issues relating to harm.

A physician-in-training (i.e., a medical student or resident) who has disclosed to his or her Supervisor and/or the Most Responsible Physician that a patient has sustained harm through the health care provided to the patient has fulfilled his or her obligation in this regard. If the physician-in-training is not satisfied with the response of the Supervisor and/or Most Responsible Physician to the disclosure of harm, he or she may discuss the issue with their Program Director, or take other steps he or she considers necessary to ensure that the patient is fully informed about the harm sustained.

During the disclosure discussion or after the disclosure has taken place, the patient may decline any further discussion of the health care encounter where the harm occurred. In such cases, the physician is discharged from the obligation to ensure that the patient is kept informed.

Where the patient requires treatment for the harm that was sustained, the physician's discussion with the patient should be accompanied by suggestions for appropriate follow-up or, if necessary, a plan for treatment. Where appropriate, the physician should offer to refer the patient to another physician for a second opinion about the harm sustained or transfer the patient's care to another physician.

The physician should document fully in the patient's health record that the discussion with the patient has taken place. If the patient has declined to have a discussion with the physician, the physician should document this and the reasons for non-disclosure as well. The College is aware that many health care institutions have policies on disclosure of harm that physicians are obliged to follow. For physicians working in these institutions there may be additional obligations with respect to disclosing harm, including reporting requirements.

Appendix - Recommendations on How to Disclose Harm

CPSO Council acknowledges that frankly disclosing harm may not be easy for physicians. It is hard to admit when something has gone wrong, but when doctors don't reveal harm; the lack of disclosure may cause further harm. Indeed, research suggests that candor may have a protective effect against malpractice claims.

Physicians should take the lead in disclosure rather than waiting for the patient to ask.

Disclose as soon as the harm is detected or as soon as reasonably possible when the patient's condition is stable and/or the patient is able to comprehend the information.

When communicating with your patient, it is best to avoid speculation and to focus on what is known about the event at the time of the discussion. Answer questions from your patient to the fullest extent possible and to the best of your abilities. Unanswered questions ought to be noted and prompt and thorough responses sought. It may be worthwhile to elicit questions or concerns and address them at the time of the conversation or at some later time.

One way to disclose is to include a short, objective and factual summary of the event. It is best to do this in non-technical language that the patient can easily understand.
As this policy is not about "fault", try to avoid attributing blame to specific individuals or providing simple explanations as to "cause" or responsibility. A timely and empathic expression of sorrow or regret and condolences may be appropriate and should not be construed or taken to be an admission of liability or fault.
Discussing a plan of care that addresses the harm is of equal importance. If your patient requests or prefers to be cared for by another physician it may be appropriate to transfer the care of the patient to another physician.

If you are unsure of what to do; call the CMPA or the Physician Advisory Service at the CPSO.

For further information on disclosure, you can consult the following resources:

- http://npsf.org/
- http://www.ahrq.gov/qual/errorsix.htm
- http://bmj.com/cgi/collection/medical_error_patient_safety
- http://qhc.bmjjournals.com/cgi/content/full/11/1/7-a
- http://www.medicalerrorreduction.com/
- http://www.medicalerrors.ca

[1] Residents or Fellows often serve in the role of clinical teacher, but are not the Most Responsible Physician in patient care.

www.cpso.on.ca/policies/disclosure.htm (refer to link for current version as under revision)

Appendix F – College of Nurses of Ontario: Best Practices in Disclosing Health Care Error

How a facility deals with a health care error can either exacerbate an already painful incident or, through disclosure, promote openness, healing, learning and prevention. According to research by the Institute for Safe Medication Practice (ISMP) Canada, *Healthcare Papers* and The Royal College of Physicians and Surgeons of Canada, open disclosure is the most effective way to deal with an error. Below are some tips that employers can use to help staff manage these situations.

1. **Be Prepared:** Have open disclosure policies and procedures. Provide staff with education and training — such as simulation exercises — on how to handle disclosure. Consider having staff members who have had experience disclosing errors mentor others.

2. **Have a key contact person or team:** Key individuals or teams need to be ready and available to help staff deal with adverse events. Planning how to deal with an occurrence and clearly outlining the roles and accountability increases the likelihood that an adverse event will be handled professionally. It also ensures that the focus will be on the needs of the client and her/his family.

3. **Disclose as soon as possible:** The health care professionals directly involved in the client's care should speak to the client as soon as she/he is physically and emotionally stable. If the client is deceased, disclose to the family as soon as possible.

4. **Choose an appropriate setting:** The setting should be as private and comfortable as possible to facilitate communication and to avoid distractions.

5. **Acknowledge that a mistake has been made.**

6. **Describe the course of events, using non-technical language.**

7. **State the nature of the mistake, the consequences, and the corrective action taken.**

8. **Express regret and apologize, if appropriate.**

9. **Elicit questions or concerns and commit to addressing them.**

10. **Provide follow-up to the client:** Indicate what steps the health care facility will undertake to follow up on the incident and let her/him know when she/he can expect further information.

11. **Provide support and guidance to staff:** It is emotionally devastating for health care professionals to realize that their error has harmed a client or caused a death. Health care professionals are sometimes referred to as the "secondary victims" of error, and their personal and professional suffering can be worsened by a lack of support.

12. **Learn what happened:** Research has shown that most health care errors are not the result of negligence, are not random, and result from human and systems errors. Taking an open approach to identifying the cause of error can help organizations design system improvements to "make it easier do the right thing."

13. **Communicate the incident:** Help prevent future errors. Contact other facilities that may be at risk for committing the same error. E.g. in a case of medication error using an experimental drug, contact other facilities participating in the clinical trial. Report medication errors to ISMP Canada's Medication Errors Reporting Program.

College of Nurses of Ontario, When Mistakes are Made, Communique, March 2003, http://www.cno.org/pubs/mag/cmqVol28no1.pdf

Appendix G – Good Communication –The Key to Successful Disclosure

When having a disclosure conversation it is essential that the patient senses sincerity, empathy, openness and honesty. Although this toolkit cannot teach one to be a good communicator, it will provide a reminder of some of the basics of effective communication.

- Proper preparation – Review the material above to ensure you are fully prepared. A lack of preparation not only can increase your discomfort, but may be interpreted as a lack of caring.
- Do not use slang or jargon.
- Consider the need for a language interpreter if there may be a language barrier.
- Consider the patient's level of education and ability to understand.

- Be cognizant of your body language, tone of voice, cadence and speed – It is frequently said that words are less than 10% of a communication. Voice and body language account for the remainder.

  - Sit down with the patient/family/surrogate (do not stand in the doorway)
  - Make eye contact
  - Be aware of your facial expressions, posture, gestures and mannerisms
  - Use direct body orientation – face the patient, do not turn partially away
  - Uncross legs and arms
  - Speak slowly and clearly

- Listening – active listening (a show of empathy)
  - Encourage questions
  - Give the speaker time to talk (studies show that physicians typically cut patients off from telling their story at 18 seconds)

Appendix H – Sample Apologies

What works	What does not work or help the situation
"I'm very sorry that you and your family have been through so much in the past few days."	"Sorry about what has happened."
"I am sorry that this incident has occurred. It is unclear at this point what caused it. Be assured we will look into this and will follow up with you."	"Things happen, we are all very busy you know."
"I'm sorry that this incident has occurred. I was not directly involved but am following up to better understand the circumstances of the incident. We will meet tomorrow when I have more information to provide to you."	""Sorry that this happened, I did what I was supposed to do, It is not my fault."
"I regret that these events have occurred and am sorry for the situation you are now experiencing. Let's talk about how we can help you right now."	"It is unfortunate that this has happened but it is time to move on."
"I realize now that there was a breakdown in communication between us and am sorry that I did not make sure you were fully understanding my instructions."	"I feel bad that this has happened, but if you had only told me how much medication you were taking I could have told you that was wrong."
"I am sorry for the delay that you have encountered. Be assured I will review this matter with the goal of improving our processes to ensure there are no further delays."	"I'm sorry for the delay. My nurse did not bring your lab results directly to my office. If she had of, you would have been admitted sooner."