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CORPORATE POLICY, STANDARDS and PROCEDURE

POLICY TITLE		NUMBER
DISCLOSURE OF UNANTICIPATED MEDICAL OUTCOMES		TBA
AUTHORIZATION	**DATE APPROVED**	**CURRENT VERSION DATE**
Executive Committee	November 2007	February 2016

DATE(S) REVISED / REVIEWED SUMMARY

Version	Date	Comments / Changes
1.0	November 2007	Initial Policy Released – Entitled " Disclosure of Harm to Patients"
2.0	April 2009	Revised
3.0	February 2016	Revised and renamed to "Disclosure of Unanticipated Medical Outcomes"

INTRODUCTION

Fraser Health is committed to providing quality and safe health care which includes establishing and sustaining effective relationships between the health care team and those we serve. This is demonstrated through effective communication between the health care team and the patient [1] and by promoting an organizational culture constantly focused on understanding and improving our systems and processes.

In spite of the dedicated efforts of health care providers and Fraser Health's established quality and safety systems, situations may arise where patients are harmed [2] while receiving health care or services. In these situations, Fraser Health and its health care providers are committed to an open, transparent disclosure process. Disclosure enables a timely and effective response to the patient's immediate care needs, supporting the patient's physical and psychological healing. It is essential to restoring the relationship between the health care team and patient and in re-establishing trust and confidence in the health care system and its providers. Timely disclosure also assists in the professional growth, psychological healing and learning of health care providers. It is for these reasons that Fraser Health has established a systematic process for disclosure of incidents that range from 'near harm' to 'actual harm' resulting in a negative impact on the patient. This process reflects best practices in the health care industry and consistency with national and provincial guidelines [3].

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[1] The term 'patient' is used to represent patients, clients and residents of Fraser Health and their representatives. It is recognized that often the patient's family or substitute decision-maker should be included in the disclosure process. Consideration to including a patient's family when disclosing harm or near- harm is made according to applicable legislation such as the Freedom of Information and Protection of Privacy Act (FOIPPA) and the Adult Guardianship Legislation: Health Care Consent and Care (Facilities) Act.

[2] The term 'harm' is defined for the purpose of this policy as an unexpected or normally avoidable outcome that negatively affects a patient's health and/or quality of life and occurs or has occurred during the course of receiving health care or services from Fraser Health. It is also referred to in the literature as an 'adverse incident'

[3] Please see References at the end of this document.

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Fraser Health's disclosure process is comprised of the following steps:

- Acknowledgement of the harm;
- Appropriate apology and acceptance of responsibility for follow-up where applicable;
- Immediate care and attention to mitigate effects to the patient, and their family;
- Systematic analysis of root causes of the harm to guide improvement efforts;
- Timely feedback to, and feedback from, the patient and family regarding actions taken to prevent re-occurrence of the harm; and
- Support for both the patient and health care provider(s) involved.

PURPOSE OF THIS POLICY

The purpose of this policy is to:

- explicitly state Fraser Health's commitment to open communication between the healthcare team and the patients and families involved in an incident that they have been or may have been harmed as an integral component of the therapeutic relationship;
- affirm Fraser Health's commitment to applying a systematic approach to disclosing harm to patients;
- provide guidelines to assist the health care team in the disclosure process; and
- ensure effective support mechanisms for patients, their caregivers and the health care team [4].

This policy is comprised of the following elements:

- Circumstances under which disclosure must occur;
- Circumstances under which disclosure should occur;

[4] Fraser Health has adopted the Institute for Healthcare Communication's "Disclosing Unanticipated Medical Outcomes" model and approach. A Disclosure Leadership Team comprised of certified 'situation managers' has been established to coach and support individuals and teams across Fraser Health in planning and engaging in disclosure conversations with patients and their families. Members of this Team can be reached by contacting the Fraser Health Quality Improvement and Patient Safety office.

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- Responsibility for disclosure and follow-up;
- Support for patients and the health care team;
- Documentation of interaction with patient and family;
- Disclosure of a harm incident which involves more than one facility and/or is multi-jurisdictional; and
- Disclosure of harm affecting multiple patients.

POLICY

Fraser Health Staff and Physicians are responsible to work together to ensure that appropriate disclosure to patients or their representatives is a routine part of the response to a harm incident. More broadly, information about preventable harm incidents or near-misses should be shared between facilities and health authorities (on an anonymous basis) in order to increase patient safety throughout the health care system. Individuals that will be involved in the disclosure process should receive, or have completed training in Disclosing Unanticipated Medical Outcomes prior to engaging in the disclosure process with patients and families. Disclosure training workshops are run regularly through the Department of Quality and Safety. Please contact the Executive Director or Executive Medical Director of the department for more information on this training.

Circumstances under Which Disclosure *Must* Occur

Disclosure to patients and/or families *must* occur in the following situations by the member(s) of the health care team deemed most appropriate under the circumstances surrounding the harm incident:

- Any adverse incident which has resulted in harm, injury or complication due to health service delivery such as the administration of an incorrect dosage of a medication.
- A medical or NSG error
  - Exceptions may exist where there is serious risk of significant harm to a patient as a result of disclosure but a decision not to disclose must be made within a structured process and must involve more than one individual (e.g. the disclosure team or an ethics review process).

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Circumstances under Which Disclosure *Should* Occur

Using professional judgment, disclosure to patients *should* occur in the following situations by the member(s) of the health care team deemed most appropriate under the circumstances surrounding the near harm incident:

- Any incident whereby:
  - the patient has *nearly been harmed* (near-misses or errors that could have caused harm but were intercepted *before* they reached the patient); ***and***
  - remedial steps are required to address any immediate care needs of the patient; **and/or**
  - the patient's perspective on the near-harm incident might provide insight into the circumstances which could be used to improve care processes.

Please note: The decision to disclose an adverse incident resulting in near-harm is a matter of clinical and professional judgment and requires consideration of many factors. The underlying principle to guide such decision is *benefit to the patient.*

Apology made by Fraser Health Staff and Physicians

An apology is an important part of the disclosure conversation. This applies for an apology made by or on behalf of a person in connection with any incident that has occurred at Fraser Health.

- does not constitute an express or implied admission of fault or liability by the person in connection with that matter,
- does not constitute an acknowledgment of liability in relation to that matter for the purposes of section 24 of the *Limitation Act*,
- does not, despite any wording to the contrary in any contract of insurance and despite any other enactment, void, impair or otherwise affect any insurance coverage that is available, or that would, but for the apology, be available, to the person in connection with that matter, and
- must not be taken into account in any determination of fault or liability in connection with that matter.

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Despite any other enactment, evidence of an apology made by or on behalf of a person in connection with any matter is not admissible in any court as evidence of the fault or liability of the person in connection with that matter.

What should be Disclosed?

- only facts may be disclosed. Facts may be obtained from the health record and from health care providers with direct knowledge of the incident;
- information that is free of speculation; and
- actions taken to eliminate or minimize the risk of a similar incident.

What cannot be Disclosed?

- discussions that took place during quality improvement or assurance deliberations in keeping with the BC Evidence Act; and
- identity of other patients or information that could potentially lead to the identification of other patients.
- any disciplinary actions taken involving staff or physicians

Responsibility for Disclosure and Follow-Up

The patient's most responsible physician and the senior administrator, in consultation with the health care team, will determine the appropriate person(s) to disclose the harm incident to the patient. In all situations, a physician must be involved in the disclosure to address the medical concerns of the patient.

Criteria for designation as the most appropriate person(s) to lead the disclosure process are to:

- be knowledgeable about all aspects of Fraser Health's disclosure policy, process and resources;
- demonstrate skill in application of Fraser Health's disclosure process;
- be knowledgeable about the consequences of the harm and resulting changes in the care plan; and
- be deemed to be the most appropriate member of the health care team to lead disclosure to the patient and/or family.

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Timeline for Disclosure and Follow-Up

Communicating about the Unanticipated Adverse Outcome within 24 to 48 Hours of Discovery of the Event

Most cases will be handled by the responsible physician (i.e., generally the general physician (GP) (outpatient) or attending physician (inpatient)). The most responsible handler of the case should have training in the DUMO process. In all planned discussions with the patient and/or patient's representative, it is preferable to have at least one other staff member present, (e.g. administrative physician, the appropriate Health Plan/Hospital administrator or another designated individual/s). The administrative leadership in the area were the disclosure will take place will take place will organize the logistics for the disclosure with the appropriate parties.

In the case were event(s) need to be disclosed around nursing practice, the assigned nurse, unit manager, and Director will be the most responsible parties for disclosure. This unit manager and Director should also have training in the DUMO process for disclosure.

The Site/Community Executive Director and Site Medical Director along with the Clinical Vice President must be made aware of the events that will be disclosed, prior to the disclosure discussion for both above disclosure cases.

The discussion should be held as soon as practical after the patient's immediate health care needs have been addressed. Factors to consider in this decision include the patient's physical and emotional readiness to participate and whether consent from the patient must be obtained to discuss the situation with patient's representative.

Throughout this phase of the process, phone calls should be returned promptly, commitments kept, and descriptions of what processes we use to analyze and review our systems to help minimize the chance of such an event recurring.

The Situation Management Team should recognize that the patient/family may have a number of future interactions at different times and places within our system and, to the extent possible, provide assistance and direction to various stakeholders on what can and cannot be shared, as well as to identify the appropriate contacts(s) to whom to redirect patient/family questions and concerns.

To Whom Should Disclosure Occur

In all circumstances where a patient is competent, disclosure should occur with the patient and whomever else the patient wishes to be present. If a patient is temporarily not able to consent or understand then only those permitted by law can be involved in the disclosure

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process. In cases of incapable adults or children, or when a patient has died, only those permitted by law can be involved in the disclosure process.

Support for Patients and the Health Care Team

Counseling, spiritual services or other forms of support available within the organization should be offered to patients (including family members) regardless of whether they make the request. Should the patient request more detailed long-term support, information must be provided on how to facilitate this request. Support should also be offered to health care provider(s) involved in the harm incident where appropriate.

Pre-Disclosure Documentation

A complete, accurate and factual account of the disclosure process is the responsibility of the most responsible physician or senior administrator and is documented in the patient's health record including the following:

- objective details of the harm incident
- the patient's condition immediately before and after the time of the incident
- medical intervention and patient response
- notification of physician(s)
- time, place and date of the Disclosure meetings
- identities of all attendees
- consent(s) obtained
- facts presented
- offers of assistance and the responses
- questions raised and the responses given
- plans for follow-up including key contact information for an appointed contact person

Documentation of disclosure in the health record is done separately from and in addition to the completion of an incident report which is a record of the facts known at the time of the harm incident [5].

[5] Reporting of the harm incident requires the completion of a Patient Safety and Learning System (PSLS) incident report form. Guidance on incident/safety incident reporting is available from the Quality Improvement and Patient Safety Consultants across Fraser Health. In addition, a link to the PSLS website and an e-learning module is located on the Fraser Health Intranet.

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Post-Disclosure Documentation

The medical record should contain a complete, accurate record of clinical information pertaining to the unanticipated adverse outcome. As applicable, this should include:

- objective details of the situation, written in neutral, non-judgmental language;
- the patient's condition immediately prior to the event;
- the intervention and patient response;
- notification of the GP/Attending Physician;
- information shared with the patient and/or patient's representative following the event.

If applicable, state in neutral terms why any information was withheld. Documentation should avoid speculation about the cause of the event and blame of individuals involved in the event. Incident reports, event analysis, and the like should not be included or referred to in the medical record to avoid waiver of the privileges that attach to those documents and analyses. Under no circumstances should the medical record be altered. Late entries about an event should clearly be labeled as such.

Disclosure of a Harm Incident Which Involves More than One Facility or Jurisdiction

If it is determined that a harm incident has occurred in a facility other than the one currently providing care all involved facilities must participate in identifying the facts and contribute to disclosure. Managers of the identifying facility should inform their senior administrator who will contact his or her counterpart in the originating facility to discuss which facility will:

- inform the patient;
- lead the disclosure fact-finding process; and
- lead the analysis, if required.

If two or more Health Authorities are involved in a harm incident or if the incident crosses provincial boundaries, legal counsel and/or the Health Care Protection Program should be contacted for advice.

Disclosure of Incident to Multi-Patients

Sometimes a single patient incident leads to discovery that others may have been affected. At

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times, there may be an incident where the outcome of harm is uncertain until an incident analysis has been completed. When a multi-patient incident is discovered, Fraser Health Senior Executive will designate an individual experienced in disclosure to plan and coordinate disclosure processes. Multi patient disclosures may include complex privacy and legal considerations. Appropriate consultation and clarification is required in the planning process.

When it has been decided that multi-patient disclosure is warranted, every effort will be made to disclose the incident to the patients before providing public information, however it must be recognized that media may report the information very quickly and that disclosing to the patient first may not always be possible. Consultation with the Fraser Health Communications leaders should be initiated to plan any public disclosure that may be required.

Multi-patient disclosure involving harm:

- Follow the same process as individual disclosure process when possible
- Individual disclosure should be planned so that all involved patients receive information at approximately the same time
- If individual disclosure is not practical initially, follow the public notification process as directed by communications and then follow up with the individual disclosure process

Multi-patient disclosure where it is unknown whether harm occurred:

- Disclosure can occur by telephone, registered letter or in person as appropriate
- Provide opportunity for follow up if future questions arise

SCOPE

This Policy applies equally to all individuals associated with Fraser Health including:

- Employees
- Volunteers
- Physicians with privileges at any facility
- Medical staff including physicians on contract, resident and clinical trainees
- Students in clinical placements
- Health service providers as defined in contractual agreements governing their service mandate

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UNDERLYING PRINCIPLES

Fraser Health and its staff, physicians and volunteers are guided by the following principles:

Ethical and Moral Responsibility

The management of harm incidents and patient safety hazards is an integral component of patient-centered care and the therapeutic relationship. Fraser Health has an ethical and moral responsibility to be open and transparent with its patients in situations whereby patient may have been harmed while receiving care or treatment.

Health Professional Standards

Fraser Health acknowledges and respects existing health professional standards and practices that relate to the disclosure process and to support for health care providers in a harm or near-harm incident. Actions to support health care providers are based on the 'Just Culture' policy to ensure:

- health care providers are not discriminated against due to involvement in or reporting of a harm incident;
- health care providers are supported when distressed by a harm incident;
- health care providers may (and perhaps should) contact their professional organization for advice;
- that the reasonable expectations of professional competence and behaviour are known to all health care providers. These expectations and competencies include:
  - accountability for personal behaviour; and
    - an understanding that inappropriate professional behavior such as drug abuse, intentional violations of policy or sabotage are not tolerated.

Applicable Legislation

Fraser Health acknowledges and complies with the applicable legislation relating to disclosure specifically:

- to protect the privacy of the patient (e.g. The BC Freedom of Information and Protection of Privacy Act);
- to be mindful of obligations to protect personal information as set out in the *Freedom of Information and Protection of Privacy Act* when disclosing information to anyone

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other than the patient or the patient's legally authorized representative;

- to protect the information collected and used for the purposes of quality assurance Section 51 of the BC Evidence Act);
- Quality assurance records **may not** be used as the source of information communicated to a patient or their representative when disclosing a harm incident ;
- to ensure the information communicated in a discussion about a harm incident comes only what has been already recorded in a patient's health record and/or from those involved in the incident itself and is factual, not speculative;
- to protect and promote the health and safety of the public by ensuring that information about harm and near-harm incidents are shared anonymously between health care bodies in order to promote safety across the health care system; and
- to comply with Bill 31: The Apology Act.

RELATED POLICIES

Disclosing information to patients who may have been harmed is one cornerstone of Fraser Health's patient safety policies.

- **Just and Trusting Safety Culture**

  A commitment that Fraser Health will:

  i) be fair and transparent in assessing system and process failures;

  ii) not discipline staff, physicians and volunteers for harm that occurs as a result of unforeseen incidents ;

  ii) analyze and learn from all reported harm and near misses; and

  iii) improve safety throughout Fraser Health.

- **Reporting Harm and Near-Harm Incidents**

  A requirement for all staff, physicians and volunteers to report all patient harm to Fraser Health. Reporting of near-harm is also encouraged. The purpose of reporting is to create the opportunity for learning and making improvements to safety throughout Fraser Health.

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- **Informing Stakeholders of Safety Issues**

  A commitment that Fraser Health will be open and transparent. Fraser Health will be guided by its responsibility to inform the public and other stakeholders of safety issues where there is real or perceived risk to the health of the individual or where a safety issue may adversely impact public confidence in the healthcare system. This commitment will be undertaken following all of the Organization's legal obligations to protect the privacy of the patient, staff, physicians and volunteers.

DEFINITIONS

Adverse Event (incident) - an unexpected and undesired incident which results in injury (also referred to as **harm** or complication) and is directly associated with the care or services provided to the patient rather than the patient's underlying medical condition.

- This definition is adapted from the Canadian Patient Safety Dictionary with the recommendation that the context of its use be described. In this case, care or services refers to all aspects of the health care system and not just the medical decisions and actions of physicians or nurses. It does not include situations where unexpected or undesired incidents occur which are related to the Client's underlying medical condition.

  Example: *The side rails were left down on the bed of a patient suffering from epileptic seizures. The patient fell and was injured.*

  In the context of this document adverse incidents include both **preventable** and **unpreventable** incident. The inclusion of both as defined below ensures consistency in disclosing all Adverse Events.

- ***Preventable Adverse Event*** (incident) - An injury that results from error or systems failure such as giving the wrong medication, misreporting a test result or leaving the side rails down.

- ***Unpreventable Adverse Event*** (incident) - An injury with no apparent avoidable cause given the current state of scientific knowledge such as the hazards of high risk therapies or rare but known risks of a treatment.

Disclosure - disclosure is the process used by health professionals to inform a patient of a specific harm incident and the implications of that incident, if any, for the course of the

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patient's care.

Harm - an unexpected or normally avoidable outcome that negatively affects a patient's health and/or quality of life, and occurs or has occurred during the course of receiving health care or services from Fraser Health.

Nearly Harmed - is defined as a situation where there was a high likelihood (greater than 25%) an adverse incident would occur and a patient would have been harmed but the potential for harm was recognized and a successful action was taken which prevented actual harm. These situations are often referred to as 'close calls', 'near misses' or 'near hits'.

Most Responsible Physician - the physician with day-to-day responsibility for the patient's health.

Patient - an individual who receives care or services from a health care agency within a Health Authority in British Columbia. This definition is inclusive of patients, residents or clients in their respective acute, residential or community settings. This may include their families and, where appropriate, substitute decision makers.

Senior Administrator - a person in a senior management position within the facility such as an Executive Director or Medical Director.

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

Court includes a tribunal, an arbitrator and any other person who is acting in a judicial or quasi-judicial capacity.

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