Disclosure of Adverse Events Policy

March 30, 2005

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Provincial Health Care Disclosure of Adverse Events Policy

NOVA SCOTIA
Health

POLICY:	Disclosure of Adverse Events		
BRANCH/DIVISION:	Quality and Safety Division		
APPROVED BY:	Program Delivery Group (HSQC)	**APPROVAL DATE:**	March 30, 2005
EFFECTIVE DATE:	December 15, 2005	**PAGES:**	17

1.0 Introduction

A client[*]-centred health care environment fosters open, honest and ongoing communication between health care providers and those they care for. Such communication provides adequate information for informed decision-making by clients about their care. Among the types of information relayed in a client-centred environment are the recommended plan of care, risks inherent in care, the positive and negative outcomes of diagnostic tests, treatment and interventions, and the effects of adverse events[†].

The focus of this policy is on one aspect of communication which is fundamental to maintaining safe care, specifically disclosure of information about adverse events.

The move towards effective open disclosure represents culture change. Although this will take time, it is essential that disclosure is practised immediately and continues while formal policies and support are developed.

This document is intended to assist organizations in creating or enhancing processes to communicate and support those who receive care and those who provide it when an adverse event occurs. Information is provided to enable organizations to develop their own policies, consistent with their unique philosophies of care, structures and terminology, while reflecting the specific legal, regulatory and administrative considerations pertinent to them.

Both requirements (mandatory) and considerations (discretionary) associated with disclosure are outlined.

It is not the aim of this policy to address issues concerning the attribution of blame or culpability.

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[*] The word "client" is used throughout this document as an alternative for other relevant terms such as patient, resident or others who receive care in the health system.

[†] An adverse event is an unexpected and undesired incident directly associated with the care or services provided to the client or the environment in which the care is provided.

2.0 Policy Statement

All designated organizations providing health care in Nova Scotia that receive public funds, are required to have a process in place to promptly inform clients of pertinent facts associated with adverse events.

This process requires maintaining a written policy that outlines the associated responsibilities, procedures and support.

3.0 Policy Objectives

The provincial policy on health care disclosure of adverse events aims[1] to assist organizations to:

- provide an environment where clients receive the information they need to understand what happened and to make informed decisions about their care

- create an environment where clients, care providers and managers all feel supported when adverse events occur

4.0 Application

This policy applies to the Nova Scotia Department of Health (DoH) and to Nova Scotia organizations receiving public funds to provide health care such as district health authorities, the IWK Health Centre, and N.S. DoH contractors providing emergency health services.

The support systems, risk management/quality frameworks and cultures of individual organizations may not currently foster disclosure. Development of the enabling environment for disclosure will take time. A written policy represents a first step in the commitment to open communication in a supportive environment. It is acknowledged that the training and systems necessary for full integration of a disclosure policy will take additional time.

5.0 Definitions

The following terms are used in the policy:

Adverse event[2] – an unexpected and undesired incident directly associated with the care or services provided to the client or the environment in which the care is provided.

Authorized decision maker - anyone who has legal authority to make decisions on behalf of an individual. This is often referred to as legal representative or substitute decision-maker and includes, but is not limited to, persons who have authority under the Hospital Act, Medical Consent Act, under a guardianship order, other relevant legislation or applicable health care agency policy (such as consent policy).

Client - an individual who receives care or service from agencies referred to in this policy; this includes those referred to as patients or residents and their families, where appropriate, and authorized decision-makers for the client.

Disclosure[3] – the imparting, by health-care workers to clients of information pertaining to any adverse event affecting (or liable to affect) the client's interests.

Near Miss[4] - an event or circumstance which has not affected the client nor caused harm but the potential for harm exists. This near miss "almost happened" but may not have reached the client due to chance, corrective action, and/or timely intervention.

6.0 Context

Communication about adverse events is critical to care as well as to the ethical and legal functioning of health care professionals and organizations. A number of barriers have existed to open disclosure of adverse events. First of all, it is a difficult process for those delivering the message. Delivering bad news requires a skill set for which many are not trained. Other barriers include lack of knowledge about reporting requirements, uncertainty about how to report events, a wish not to upset clients in their care, feelings of personal failure and fear of litigation or retaliation. Open disclosure has not always been encouraged in a systematic, organization-based way.

Health care consumers expect that every effort is made by the health care system to ensure that care is provided safely and according to acceptable standards. When adverse events occur, clients deserve candour. Failure to appropriately disclose adverse events may compromise individual and societal trust and could, in fact, have a negative effect in the context of malpractice claims.

To support continuous improvement of quality and safety in our health care system, enabling conditions must be created. These conditions include:

• stakeholder involvement	input from consumers and health care providers in developing safety policies and processes
	full involvement of clients in their care
	consumer information about measures that can contribute to health care safety
• standards	policies on reporting and analysis of near misses and adverse events
	policies on process of disclosure, roles and responsibilities, support for those involved in disclosure
• information	systems for reporting adverse events, collecting and analysing data

• capacity	education and skills training on the disclosure process, investigative methods and analyses, and improvement planning information-sharing about adverse events across the system so that all organizations can take appropriate preventive measures

7.0 Policy Content

This section outlines minimum requirements for inclusion in a written disclosure policy. These are policy requirements (mandatory). Where relevant, policy development considerations (discretionary) are offered which the organization should take into account in designing the discretionary components of their policies or in assisting in the development of the mandatory components.

7.1 Conditions Requiring Disclosure

Policy Requirements

7.1.1 The policy outlines the conditions that require disclosure. At minimum the facts of the event and its impact on the client and on the care must be disclosed when an adverse event occurs during the process of providing health care and results in client injury, death or negatively impacts health (real or perceived).

Policy Development Considerations

Organizations are encouraged to consider how they will handle situations of near misses.

7.2 Initial Disclosure Discussion

Policy Requirements

7.2.1 The policy provides direction to members of the health care team on the points to be covered in the initial disclosure discussion with the client. The initial disclosure discussion is part of an ongoing communication process. Many of the points raised in the initial disclosure discussion may need to be expanded upon in any subsequent communication.[5]

7.2.2 The initial disclosure discussion includes:

- the facts of the event and its outcome, known at the time
- the next steps to be taken in the care of the client
- any changes to the overall plan of care
- the offer of opportunities for further discussion

- a designated contact person for further discussion and support
- the support of other resources such as spiritual services, counselling, social work, etc. as relevant
- what the organization is doing to find out how the event occurred

7.2.3 Where a client needs more detailed long-term support, the organisation provides advice on how to gain access to appropriate resources

7.2.4 The policy provides direction to members of the health care team on who is involved in disclosure discussions. Disclosure is presented:

- to the client if he/she is competent and has the capacity to understand
- to the authorized decision-maker in the event that the client is not competent or does not have the capacity to understand
- to individuals within the organization as part of internal notification requirements
- by an initial disclosure team identified by the health care agency
- while respecting the client's wishes not to interact with specific members of the care team

7.2.5 The policy provides direction on other important aspects of disclosure such as:

- selecting an appropriate setting that is private, comfortable and free from interruptions
- conducting disclosure as soon as reasonably possible after discovery of an adverse event

Policy Development Considerations

Organizations may consider the appropriateness of an expression of empathy and regret for the harm that has occurred. This may provide for the acknowledgment of suffering and the opportunity for both parties to heal; however, empathy is sometimes controversial, potentially being construed as an admission of culpability. Many would argue that the risk is greater when the client/family feels that the provider is attempting to avoid blame or is insensitive to the suffering the event has created.[6]

Agencies may wish to include parameters around whether to disclose names of personnel involved in adverse events.

Policy Development Considerations cont'd.

Organizations must consider their capacity to provide support

- after regular working hours
- to clients with special needs.

Often post-event reviews and identification of relevant follow-up actions require significant time to complete in a thorough manner. The client should be told who will be his/her designated contact person for purposes of any further discussion.

Ideally, guidelines on communicating negative results will be provided for care team members.

Disclosure may need to be adjusted to reflect a) changes in capacity of the client and/or authorized decision-maker due to illness or b) expressed wishes not to be informed;
how the opportunity to have another individual(s) present during the discussion is extended to the client may be included in the policy or decided on a case-by-case basis; the disclosure policy may be linked with other policies which outline capacity to consent, and identification of appropriate decision-makers. The disclosure policy may be linked to other policies which provide advice on accommodations for special communication needs (e.g. language barriers, disabilities).

Consideration should be given to which member of the care team has the closest relationship with the client and can best explain the health outcomes and next steps and to how many organizational representatives to include . More than two organizational representatives can be overwhelming to the client and family[7]**.** Consistency in involvement may influence the consistency of information exchanged.

Options must be considered for handling disclosure in a sensitive and private manner to authorized decision-makers who are unable to be present for a face-to-face discussion.

Timeliness of disclosure must be balanced with considerations for accuracy and helpfulness of information available; there are some situations that require additional time for the discovery of accurate information and the coordination of the disclosure process. This circumstance is frequently associated with disclosure involving multiple clients, equipment failure, or the potential for the spread of nosocomial infection.[8]

Disclosure should not necessarily be delayed because all facts are not known, but the client should be made aware that this is the case, and a follow-up discussion should be planned to disclose any new facts that are discovered.[9]

Organizations may wish to seek input from their insurers and/or legal counsel in developing this section and the policy generally.

7.3 Documentation

Policy Requirements

7.3.1 A variety of mechanisms and locations may apply to the documentation of adverse events and the disclosure discussion. The policy outlines appropriate location, timing and technique for documenting:

- the event
- the disclosure discussion

Policy Development Considerations

Factual documentation of events, health outcomes and care interventions are part of the client's health or care record; opinion and supposition about causation or blame are not appropriate.

7.4 Support to Staff and Health care Professionals

Policy Requirements

7.4.1 The policy acknowledges the effects that an adverse event may have on care team members involved. The policy**:**

- provides information on the support systems available for care team members distressed by adverse events
- ensures that staff and health care professionals are not discriminated against because of their involvement in disclosure processes
- acknowledges that individual care team members may wish to or may have an obligation to consult with professional organizations or their indemnifiers prior to participating in disclosure

7.4.2 Any opportunities for individual coaching of care team members engaged in disclosure and the availability of guidelines on communicating bad news to clients should be outlined.

Policy Development Considerations

Organizations should plan how to convey the goals and steps of the disclosure policy to management, staff and physicians in a meaningful way.

7.5 Circumstances where Disclosure is Complex

Policy Requirements

7.5.1 Processes for disclosure become more complex in certain situations, for example where large numbers of individuals are involved or in cases where an adverse event may have occurred in an organization other than that in which it is identified. The policy outlines a process for decision-making when questions as to the advisability, scope and timing of disclosure arise and for processes to be followed when multiple individuals or jurisdictions are involved. (A sample ethics decision-making framework, to facilitate consideration of issues associated with disclosure, is included as Appendix B.)

The policy:

- establishes means to support thoughtful consideration of options based on ethical principles
- provides direction on variations from single client disclosure processes in situations where more than one client is involved
- outlines procedures whereby a receiving organization (which becomes aware of an adverse event occurring elsewhere) informs an originating organization of an adverse event

Policy Development Considerations

A comprehensive decision-making framework aims to assist in the step-by-step process of bringing the relevant stakeholders together, clarifying the issue, gathering and examining the relevant information, identifying possible response options, considering the burdens and benefits of each and to whom, selecting a response and implementing a comprehensive strategy, and evaluating the outcomes.

In multi-client situations serious consideration should be given to providing an opportunity for an in-person private meeting to every client involved to augment other options for initial contact (such as registered mail, telephone call).

In multi-jurisdictional situations cooperation and effective communication, within considerations of confidentiality, among all jurisdictions is key. Where immediate disclosure is not crucial to the client's health status, responsibility for disclosure should be established . Ideally, all impacted jurisdictions should be a part of disclosure discussions. If issues become difficult to resolve, the Department of Health may be approached to assist in facilitating the disclosure process.

7.6 Releasing Information to the Public

7.6.1 In some instances, an organization may determine that public disclosure of an adverse event or a near-miss situation should occur. In other cases, a third party may disclose the information. The Department of Health and health care agencies shall participate in collaborative communication planning when informing the public about adverse events which (1) involve multiple clients; (2) are perceived as a public health hazard; or (3) have the potential to undermine public confidence in the health care system.

7.6.2 The policy outlines lead responsibility within the organization for developing the communication strategy.

7.6.3 The privacy of the client must be protected when any public release of information is carried out.

7.7 Statutory and other External Reporting Obligations

7.7.1 In certain circumstances organizations may need to respond to a variety of external requirements for reporting about aspects of adverse events. The processes for notification should be clearly stated and relevant contact lists made accessible to care teams in order to ensure that an organization's legal obligations and other requirements are met.

Examples of external notifications include (but are not limited to) :

- Medical Examiner
- Professional Regulatory Bodies
- Department of Health
- Health Canada

8.0 Development Process

This policy was developed by the Disclosure Policy Task Group of the provincial Health care Safety Working Group. The Task Group was composed of health system stakeholders representing acute care, continuing care, a number of professional regulatory bodies, and policy staff of the Department of Health. The membership list is included in Appendix A. Drafts of the policy were shared with a broad array of stakeholders as well as subject matter experts who provided consultation.

9.0 Procurement Mechanisms

Copies of the Provincial Health Care Disclosure Policy can be obtained through the Department of Health:

Quality Division
Nova Scotia Department of Health
1690 Hollis Street
Halifax, NS B3J 2R8
(902)424-1690 or (902) 424-6405

10.0 Feedback Mechanisms

The Provincial Health Care Disclosure Policy will be reviewed on a regular basis and revised as required. Individuals are encouraged to contribute to the review process by submitting comments on such issues as clarity, content and format to the Department of Health:

Quality Division
Nova Scotia Department of Health
1690 Hollis Street
Halifax, NS B3J 2R8
(902)424-1690 or (902) 424-6405

11.0 Appendices

Appendix A. Disclosure Policy Development Task Group

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Appendix B. A Sample Organizational Ethics Decision-making Framework for Disclosure of Significant Adverse Events

used with permission of Jeff Kirby and Collaboration Team,
Department of Bioethics, Dalhousie University

Process steps

1. Identify & assemble relevant stakeholders. Consider:
   - 1.1 Inclusion of participant(s) from group(s) that will/could be most affected
   - 1.2 Inclusion of members of the public: citizens/'health-receivers' (non-employees of the health institution)
   - 1.3 Participant(s) from Department of Health & Health Canada, where appropriate

2. Identify the legitimate decision makers, e.g.:
   - 2.1 'Experts'
   - 2.2 Ad hoc committee/group consensus (if possible)
   - 2.3 EMT & CEO
   - 2.4 Board

3. Identify & reflect on:
   - 3.1 Values & ethical principles at play (& tensions/conflicts among them) (Refer to Box)
   - 3.2 Relevant ethical concepts

4. Identify the specific issue & its context from relevant standpoints/perspectives e.g.,
   - 4.1 Harmed or potentially harmed individuals & 'families'/most affected individuals & groups
   - 4.2 Involved health care providers
   - 4.3 Institution/organization
   - 4.4 Society/public-at-large

5. Gather & examine all relevant information; may include classification & quantification of risk (expert input):
   - 5.1 Perceived
   - 5.2 Theoretical
   - 5.3 Evidence-based, etc.

6. Identify & assess response options, through brainstorming & facilitated discussion of stakeholders

7. Identify burdens & benefits of response options & to whom

8. Choose a response option
    8.1 Includes articulation of values & ethical principles underlying choice
    8.2 Ensure that selected response is consistent with institutional core values

9. Develop & implement a comprehensive strategy. May include:
    9.1 Specific care plans for harmed individuals & groups
    9.2 Prevention of further occurrences: systems change, education, etc.
    9.3 Optimal communication with affected parties

10. Review the decision & monitor/evaluate the outcomes

Some background theory/information on values & ethical principles of relevance to disclosure of significant adverse events

Ethical principles at play (& tension) in disclosure:

Respect for persons

Truth: a primary value

- 'something we value for its own sake'
  - as individuals
  - as a society

Truthfulness & honesty: widely respected human virtues

Truth telling:

- A principle we try to live by
- A key component of institutional accountability

Fiduciary relationships:

- Usually involve power imbalances in knowledge & status
- Based on trust & its crucial component of truthfulness

Autonomy:

- Basically, the 'right to know' & make informed choices about our health care & treatment
- Types of autonomy
  - Individual autonomy:
    - Valorized/privileged since the mid-twentieth century
    - Paradigm shift in disclosure standards in mid-1990s (Dana Farber Cancer Institute case in Boston) leading to modern emphasis on 'patient safety' & current strong presumption in favour of disclosure
  - Relational autonomy:
    - Recognition that our identities & moral agency as individuals are constituted, in part, by our web of relationships with others
    - Choices and decisions we make affect, and are affected by, other key persons in our lives

Nonmaleficence

- As old as the Hippocratic oath : 'first, do no harm' or as little as possible (mitigate burdens)

Justice (types of)

- Formal justice (Aristotle)
  - Like individuals/patient populations should be treated alike and dissimilar individuals/patient populations should be treated dissimilarly
  - In order to justify different treatment, need to demonstrate a *relevant* difference between individuals/patient populations

  Formal justice corollary: Treating individuals or patient populations equally may be unjust if there are substantive, 'morally relevant' differences between them that should be taken into account
- Traditional distributive justice
  - Fair distribution of benefits & burdens
  - Also, fair distribution of scarce health care resources
  - Consider possible 'opportunity costs' of choosing one response option over another, e.g. to staff time & money allocated to other health care services
- Social justice
  - Some individuals & social groups are more vulnerable than others
    - Individuals as 'patients/health receivers'
    - Multiple other 'axes of social group oppression'
  - Important to consider the effects of decision-making on vulnerable individuals & social groups

12.0 Endnotes

1. Open Disclosure Standard, July 2003, Australian Council for Safety and Quality in Healthcare, p. 1.

2. modified from Royal College of Physicians and Surgeons of Canada, The Canadian Patient Safety Dictionary.

3. modified from Royal College of Physicians and Surgeons of Canada, The Canadian Patient Safety Dictionary.

4. Adapted from the Canadian Council of Health Services Accreditation, Reference Guide on Near Misses, 2004; and Capital Health, Risk Management pilot close call reporting system, (communication with B. Kiley, 2005).

5. Open Disclosure Standard, July 2003, Australian Council for Safety and Quality in Healthcare, p. 20.

6. Monograph part 3: Disclosure: What works now & What can work even better, American Society for Healthcare Risk Management , Febr. 2004, p. 8

7. Monograph part 3: Disclosure: What works now & What can work even better, American Society for Healthcare Risk Management , Febr. 2004, p. 7

8. Draft 1 Disclosure Policy Guideline, Saskatchewan Health, 2004, p.2

9. Draft 1 Disclosure Policy Guideline, Saskatchewan Health, 2004, p.3

13.0 References

Bryant, R. Davis, P., Lay-Yee, R., Scott, A. Preventable In-hospital Medical Injury under the "No Fault" System in New Zealand. Qual Saf Health Care 2003; 12:251-256.

Ebers, Alison G., Fraser, Victoria J., Gallagher, Thomas H., Levinson, Wendy, Waterman, Amy D. Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors. American Medical Association 2003, Vol 289, No. 8:1001-1007.

Firth-Cozens. Barriers to Incident Reporting. Qual Saf Health Care 2002; 11:7.

Gunter, Margaret J., Gurwitz, Jerry H., Martinson, Brian C., Mazor, Kathleen M., Reed, George W., Simon, Steven R., Yood, Robert A. Health Plan Members' Views about Disclosure of Medical Errors. Annals of Internal Medicine 2004; 140:409-418.

Lamb, R. Open Disclosure: The Only Approach to Medical Error. Qual Saf Health Care 2004; 13:3-5.

Liang, B. A. A System of Medical Error Disclosure. Qual Saf Health Care 2002; 11:64-68.

Millenson, M.L. Breaking Bad News. Qual Saf Health Care 2002; 11:206-207.

Monograph. Disclosure of Unanticipated Events: the Next Step in Better Communication with Patients. 2003 American Society for Health care Risk Management of the American Hospital Association.

Monograph. Disclosure of Unanticipated Events: Creating an Effective Patient Communication Policy. 2003 American Society for Health care Risk Management of the American Hospital Association.

Monograph. Disclosure: What Works Now and What Can Work Even Better. 2004 American Society for Health care Risk Management of the American Hospital Association.