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# DISCLOSURE OF ADVERSE EVENTS: THE LEGAL RESPONSIBILITIES

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## **I. Introduction**

Mistakes happen. This is an unfortunate, but undeniable, fact of life in a hospital. While efforts are continually being made to reduce mistakes, it is not realistic to expect that they can be completely eliminated. Following an adverse event<sup>1</sup> comes the difficult and delicate task of communicating with patients and their families.

Healthcare providers have recently begun to place a high value on the obligation to disclose incidents and adverse events to patients and their families. They value the trust that patients hold in their professions generally, and themselves as individuals. They recognize that openness in acknowledging errors in health care allows for education and the reduction of future adverse events. Open and honest disclosure is also the best method for healthcare providers to cope with adverse outcomes, allowing them a degree of closure following a traumatic event.

In addition to the moral and ethical reasons for disclosure, there are certain legal requirements of disclosure. This paper will address the current legal duties to disclose adverse events, the manner in which they should be disclosed, and the documentation of such disclosures. Finally, these recommendations will be put to practice by responding to an adverse event case study.

## **II. Legal Duties to Disclose Adverse Events**

Medical governing bodies have long recommended voluntary reporting of adverse events with only a handful of provinces and regulatory bodies mandating disclosure. This trend appears to be changing. Saskatchewan and Quebec have begun advocating for legislative reform while the Ontario College of Physicians and Surgeons just enacted a new policy on the disclosure of harm in February 2003.

### **(a) Government Legislation**

**Quebec** has proposed a new law, which would require healthcare workers to inform patients of any accident having occurred during the provision of services that has potential consequences for the users state of health or welfare. Quebec's Bill 113, fully "*An Act to Amend the Act Respecting Health Services and Social Services as Regards the Safe Provision of Health Services and Social*

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<sup>1</sup> Adverse events are unexpected negative outcomes that occur as the result of medical treatment, rather than a patient's illness. They may or may not be the result of negligent care.

*Services*” was assented to on December 19, 2002.<sup>2</sup> The Act also outlines that any person working in a hospital would be obliged to report to the executive director any incident or accident as soon as possible after becoming aware of it. The executive director is then obliged to report to a regional board.

**Saskatchewan** has introduced Bill 61, which would require the mandatory reporting of all medical errors to the province's Department of Health. Currently, "adverse events" are reported on a voluntary basis. The mandatory reporting regulations, which take effect this spring, are expected to allow the compilation of data and identification of problems, and issuance of advisories to health care personnel.<sup>3</sup>

### **(b) Professional Regulations**

Saskatchewan's proposed legislation is supported by the **College of Physicians and Surgeons of Saskatchewan**, which has adopted its own policy requiring physicians to admit mistakes to patients as quickly as possible. "It's an inherent part of professional integrity to be honest with people," explains Registrar Dennis Kendel. "If people are told quickly and honestly about an error, they might not be happy about it but they're much more likely to accept it than if they discover it later and it seems apparent that it's been covered up." The College's policy stresses that physicians must fully disclose an error to patients who might not otherwise suspect that one had occurred. The policy also requires that physicians disclose errors that were discovered and remedied.<sup>4</sup>

On February 28, 2003, the **College of Physicians and Surgeons of Ontario** released a new policy making the disclosure of harm to patients a standard of practice.<sup>5</sup> The new policy states that its purpose is to affirm the College's position that patients are entitled to be informed of all aspects of their health care, which includes the right to disclosure of any harm that may have occurred to him or her in the course of their health care.

The policy has a broad scope, applying 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 which is not due directly to the patient's illness. If the harm does or can reasonably be expected to negatively affect the patient's health and/or quality of life, it is the physician's obligation to inform the patient of the harm.

The policy outlines a number of suggestions on how to disclose an adverse event. Physicians are advised to take the lead in disclosure, rather than waiting for a patient to ask. The disclosure should be timely. Questions should be answered to the fullest extent possible, while avoiding speculation. The policy recommends that where appropriate, the physician should offer to refer

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<sup>2</sup> Quebec, 2002 c. 71 (assented to December 19, 2002), online: <<http://www.thecqinetwork.com/library/Bill113.pdf>> ["Bill 113"].

<sup>3</sup> See online: Canadian Medical Association Journal <[http://www.cma.ca/cmaj/cmaj\\_today/2003/01\\_02.htm](http://www.cma.ca/cmaj/cmaj_today/2003/01_02.htm)>

<sup>4</sup> *Ibid.*

<sup>5</sup> See online: College of Physicians and Surgeons of Ontario <<http://www.cpso.on.ca/Policies/disclosure.htm>>

the patient to another physician for a second opinion about the harm sustained or transfer the patient's care to another physician.

The policy requires physicians to consider any additional disclosure obligations which may govern them, including those of the institutions where they provide care.

The **Ontario College of Nurses** also supports the open disclosure of errors. The recent publication, "When Mistakes Are Made"<sup>6</sup>; opens with the statement that "dealing with errors immediately can ease the trauma for everyone." The article makes similar recommendations to that of the College of Physicians and Surgeons of Ontario with respect to how disclosure should take place, although disclosure is not described as mandatory. The article emphasizes nurses' responsibility to be familiar with their hospital's policies on disclosure in order to effectively respond to adverse events should they arise.

### (c) Case Law

Court decisions have been one impetus for the recent changes in provincial and regulatory rules on disclosure. In the last twenty years, numerous Canadian cases have confirmed that healthcare professionals have a legal duty to disclose unanticipated adverse events to their patients. The duty to inform is grounded in the "fiduciary" relationship between healthcare professionals and their patients, which requires the healthcare professional to act in their patients' best interest. Below are a few of the cases in which courts address these issues.

In *Shoebidge v. Thomas*<sup>7</sup>, the plaintiff developed a significant post-operative infection following surgery. It turned out that an abdominal roll used to pack the bowel away from the operative field had not been removed. The roll was discovered during a subsequent surgery. When the nurses inquired about an incident report, they were told by the surgeon that there should be "no paper work on this." The surgeon made no report of the mistake in his notes to the patient's chart, nor did he speak with the nursing supervisor or patient as he had assured the nurses that he would. The incident was not revealed until one of the nurses spoke with the hospital administration.

The British Columbia Supreme Court found equal liability between the scrub nurses and the surgeon for the fact that the roll was forgotten. However, only the surgeon was held liable for the failure to inform the patient of the error. While the nurses were obliged to complete an incident report, they were not liable for the delayed disclosure as they had accepted the surgeon's word that he would speak with the nursing supervisor and the patient. In addition, the Court made the unusual finding that the surgeon was liable for aggravated damages for deliberately concealing from the patient the source of the abdominal infection.

In *Gerula v. Flores*<sup>8</sup>, an orthopaedic surgeon accidentally operated on the wrong disc. Without informing the patient of the error, the surgeon convinced the patient to undergo a second operation for further pain relief. The Ontario Court of Appeal found the surgeon had

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<sup>6</sup> Pam Marshall and Paulette Blais, *Comunique* (March 2003) 8.

<sup>7</sup> (1999), 47 C.C.L.T. (2d) 73 (B.C.S.C.).

<sup>8</sup> (1995), 126 D.L.R. (4<sup>th</sup>) 506 (Ont. C.A.).

fraudulently concealed relevant information, making the patient's consent to the second operation invalid, resulting in a finding of battery. The withholding of information about the first surgery was an act of self-interest that breached the duty to act in the patient's best interests. The patient was awarded \$600 000 in damages including punitive damages of \$40 000 for the surgeon's "highly unethical conduct".

In *Vasdani v. Sehmi*<sup>9</sup>, a surgeon operated on the incorrect disc in a patient's spine. Instead of informing the patient of the error when it was discovered a year later, the uninformed patient underwent a second operation for his back pain. Dr. Sehmi's argument that his obligation to disclose no longer existed when the error was discovered, as another doctor had taken over the patient's care, was rejected by the Court. As part of his fiduciary obligation to the patient, Dr. Sehmi had an obligation to inform his patient of the adverse event for which he was responsible.

### **III. How to Disclose Adverse Events**

Having recognized a legal duty to disclose adverse events, a new series of questions present themselves. Who should be involved in the disclosure? When is disclosure appropriate? About what and how should patients be informed?<sup>10</sup> In what manner should they be informed? How should the event be reported?

#### **(a) Who Should Disclose?**

The responsibility for disclosing an adverse event generally rests with the most responsible physician, often the patient's attending physician. As the *Shoebridge v. Thomas* case makes clear, health practitioners should report any adverse events to their supervisors, regardless of the physician's responsibility. In the case that a physician does not disclose an adverse event to a patient, another supervisor will be required to intervene.

Where the event is most closely associated with a non-physician hospital employee, such as a nurse or other healthcare professional, the duty of disclosure will rest with the manager or director responsible for that area.

#### **(b) To Whom Should Disclosure Take Place?**

The question of to whom the disclosure should be made appears quite obvious. Disclosures should be made only to a patient and others that the patient chooses to have informed. The exception to this general rule arises where the patient is incapable of understanding the discussion. In that circumstance, disclosure must be made to the patient's substitute decision-maker in accordance with the *Health Care Consent Act, 1996*.

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<sup>9</sup> [1993] O.J. No. 44 (Gen. Div.)

<sup>10</sup> See for example: online: Joint Centre of Bioethics – Sunnybrook and Women's College Administrative Manual <[www.utoronto.ca/jcb/sunnybrook.html](http://www.utoronto.ca/jcb/sunnybrook.html)>

Where the adverse event is particularly serious (“sentinel”), a meeting with the patient, family members and the health care team may be more appropriate. Appropriate hospital representatives, such as the risk manager, should also be involved in such meetings.

**(c) When Should Disclosure Take Place?**

Disclosure of an adverse event should take place as soon as practically possible after the event has been identified, with consideration of the patient’s clinical condition. Where disclosures are made in an open and prompt manner, fears of a cover up are dispelled. This promotes ongoing trust and may reduce the chances of litigation.<sup>11</sup>

**(d) What Should be Disclosed**

There is no dispute that all adverse events, from serious surgical errors or sexual assaults to minor events, must be disclosed. However, opinion is less decided on “close calls” or errors discovered post discharge or after a full recovery. There is no clear legal obligation to disclose close calls, or “near misses”, to a patient or their substitute decision-maker where no harm has resulted. A close call without harm need not be reported however, it is probably a good practice to report all instances of harm caused even after a full recovery has occurred.

Disclosure of non-significant events, (ones that do not harm a patient), should be a matter for clinical judgement by the skilled practitioner. Such incidents may not require disclosure to the patient because they do not affect the patient's well-being. Disclosure is a matter of 'proportionality': the greater the harm or risk of harm caused by an event, the greater is the duty of the health practitioner to disclose this event to the patient and/or to the patient's substitute decision maker.<sup>12</sup>

Adverse events which are discovered after a patient’s discharge, or even following a full recovery must be disclosed. Health practitioners should be conscious of “look back” issues and the potential damage of a perceived “cover up”.

**(e) In What Manner Should Information be Disclosed?**

The nature, severity, and cause (if known) of the adverse event should be presented in a straightforward and non-judgmental manner. Patients’ or substitute decision-makers’ questions should be answered in a similar way, however, practitioners should not feel compelled to answer questions where they would be speculating or attributing blame to specific individuals. The patient or substitute decision-maker should be kept informed as further information is learned.

While speculation and superfluous detail should be avoided, this is not to say that the disclosure must be strictly technical. The strong emotions that will likely surface should be acknowledged and an expression of regret and an apology is often appropriate. As the new policy of the

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<sup>11</sup> Sunnybrooke, *supra* note 9.

<sup>12</sup> *Ibid.*

College of Physicians and Surgeons of Ontario states: “a timely and empathetic expression of sorrow or regret and condolences” may be given.<sup>13</sup>

### **(f) Reporting**

Unless addressed carefully, the disclosure and reporting of adverse events can be problematic in the event of a lawsuit. Admissions made by healthcare practitioners can, and have, been used against defendants in subsequent legal proceedings.

It is crucial that careful notes are made of any adverse event and its subsequent disclosure. What is said by all parties present to the discussion ought to be carefully recorded.

A recent Ontario court case, *Steep v. Scott*<sup>14</sup>, has introduced some uncertainty with respect to the confidentiality (or “privilege”) of quality assurance documents. The *Steep* case involved a medical malpractice proceeding against the physician and nurses involved in the labour and delivery of a baby who sustained severe brain damage at birth. The hospital had identified two Quality Assurance reports relating to a quality of care review of the circumstances surrounding the delivery. The plaintiff’s lawyers applied to the court to compel the hospital to provide the reports, recognizing that they were prepared for a Quality Assurance review.

The Court agreed with the hospital that the reports were privileged based on a four part test. The four criteria, commonly referred to as the “Wigmore criteria” after the U.S. legal expert, are:

- (i) The communications must originate in a confidence that they will not be disclosed;
- (ii) This element of confidentiality must be essential to the full and satisfactory maintenance of the relationship between the parties;
- (iii) The relationship must be one which in the opinion of the community ought to be carefully fostered; and
- (iv) The injury that would result to the relationship by the disclosure of communications must be greater than the benefit gained for the correct disposal of litigation.

The Court recognized that the reports had originated in confidence and that it was in the public interest for hospital employees to openly communicate in Quality Assurance reviews without the threat of a lawsuit. It was further acknowledged by the Court in the *Steep* case that the plaintiff had access to hospital records and could therefore access the desired information.

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<sup>13</sup> *Supra* note 5.

<sup>14</sup> (2002), 62 O.R. (3d) 173 [*Steep*].

Whether privilege will protect quality assurance documents will be decided on the facts of each case. It and cannot currently be predicted with certainty.<sup>15</sup> The *Steep* case was decided by a Master of the Court, which does not bind other masters or judges. As such, healthcare providers and risk managers should continue their efforts to improve the quality of care in their hospitals, while recognizing that their reports may not remain confidential. Extra care should be taken to avoid recording speculative comments regarding causation or blame.

The best method to protect peer review and quality assurance documentations from disclosure is to ensure that the institution has a written policy for quality assurance reviews which incorporate the above-listed “Wigmore” criteria both in its content and its implementation.

#### **IV. Putting it to Practice: A Case Study**

The following scenario was provided by Pam Marshall and Paulette Blais in their article, “When Mistakes Are Made”<sup>16</sup>:

*Joan has just returned from vacation. She is responsible for administering medication to 24 clients. As she pulls Mr. Lang’s chart and starts to prepare his morning pills, she notices that there are a number of changes to his medications. She would like more time to review the medications with him, but thinks it was probably done while she was away. As she is giving Mr. Lang the pills, he mentions that he’s not sure about all these new pills he has been prescribed. Joan reassures him that the doctor would only prescribe effective medication and says she will return later to review the medication with him. An hour later, Joan reviews Mr. Lang’s chart and realizes that he has been ordered an antibiotic to which he is allergic. This was one of the pills she had given him earlier. Joan is horrified and upset. What action should she take?*

The first step upon discovering any medical mistake is to contain the error, in this case, to assess Mr. Lang’s reaction to the antibiotic, to notify the physician and stabilize Mr. Lang’s condition. The adverse outcome should also be reported to the nursing manager. Depending on the individual hospital policy, the treating physician, a nursing manager, and/or the risk manager will inform Mr. Lang of the error as soon as he is stable. The course of events should be explained in an objective manner. The hospital’s response to the event should be outlined, and a second opinion may be offered. An expression of personal regret and an apology may be appropriate. Mr. Lang’s questions should be answered where the information is known. A follow-up meeting should be arranged to respond to any unanswered questions. Detailed reports should be completed for each of the disclosure meetings.

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<sup>15</sup> Bill 113, *supra* note 2 at section 183.3 provides that information gathered for the *bona fide* purposes of quality assurance reports may not be admitted in judicial or administrative proceedings against the speaker or any other person.

<sup>16</sup> *Supra* note 6.

## **V. Conclusion**

It is the ongoing responsibility of hospitals to reduce adverse events and improve patient safety. However, some level of error is inevitable. Accordingly, hospitals should develop a policy in respect of disclosure of adverse events prior to their occurrence. In addition, physicians and healthcare workers have a legal and professional obligation to act in their patients' best interests. This obligation includes informing patients of any adverse events. Developing policies and procedure on the disclosure of adverse events promotes compliance with legal duties and may reduce the anxiety that healthcare professionals face in already difficult times.

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