



# Legal Issues in Patient Safety: The Example of Nosocomial Infection

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## INTRODUCTION

“Preventable infections are out of control in Canadian hospitals,” declared an April 2005 headline in the *British Medical Journal*. Hospitals face less stringent infection-control monitoring than do restaurants, warned a CBC news investigation. Recent events in Canada have indeed highlighted concern with infectious disease exposure through the healthcare system: the SARS outbreak led to criticism of lax hospital infection-control practices; various Canadian hospitals discovered that improper sterilization of equipment may have exposed patients to HIV, hepatitis and other diseases; virulent *C. difficile* infections claimed patient lives; and a Montréal children’s hospital faced public concern in spring 2004 following disclosure that one of its former surgeons had died from AIDS. In an era of growing concern with patient safety in the healthcare system, these events raise important legal issues regarding liability, disclosure of information to patients and reporting to regulatory bodies, government agencies and others that have a paramount duty to protect the public from harm.

In this article, we review several key legal issues related to patient safety. Using the example of nosocomial infection, we begin by summarizing recent lawsuits that have stemmed from alleged lapses in infection-control practices. We then identify legal duties that healthcare providers and facilities owe to patients to ensure their safety. Next, we discuss disclosure quandaries that may arise in the patient safety context. If a patient has been harmed, or exposed to risk of harm, do providers have a duty to disclose that information to the patient? What about the situation of remote or theoretical risks? When errors have occurred, or where some risk of harm exists, what information must be disclosed to regulatory authorities such as professional colleges or government agencies? We describe several new legal requirements that mandate disclosure of errors and conclude by offering some thoughts on the role of law in promoting patient safety. Readers are advised that this article does not constitute legal advice and are urged to consult with legal counsel regarding specific questions or concerns.

## “SEE YOU IN COURT”

Recent years have witnessed a growing number of lawsuits aimed at seeking redress for lapses in patient safety. In early 2004, an Ontario law firm filed a class action lawsuit on behalf of patients who contracted SARS in hospitals during the second wave of the outbreak in Toronto. This claim alleges that public health officials failed to maintain sufficiently rigorous infection-control precautions. Throughout 2003, a number of Canadian hospitals notified patients that improper sterilization of equipment may have exposed them to HIV, hepatitis and other diseases. In response, many patients filed legal actions alleging that those hospitals failed to meet an acceptable standard of care. As one example, in November 2003, Sunnybrook and Women’s College Health Sciences Centre in Toronto disclosed that ultrasound equipment was not properly disinfected, placing over 900 patients at risk of infection. A \$150 million class action lawsuit filed against the hospital alleges it was negligent in failing to meet adequate sterilization standards. Following these revelations, the Ontario government ordered a province-wide audit of hospital infection-control practices and the final report was released in January 2004.

In May 2005, Health Grades Inc., a U.S. company that evaluates safety and quality concerns in health facilities, reported that rates of hospital-acquired infections in the United States rose by 20% between 2000 and 2003, contributing to around 9,500 deaths. The report suggested that facilities with higher nosocomial infection rates tend to fare worse on other measures of patient safety, “suggesting that hospital-acquired infection rates could be used as a proxy of overall hospital patient safety.” (“Medical errors...” 2005) Infection-control lapses are clearly a serious patient safety matter. Dr. Dick Zoutman, co-chair of the Ontario Provincial Infectious Diseases Advisory Committee, recently estimated that “a quarter of a million hospital-acquired infections occur every year in Canada.... And 8,000–12,000 people may die of infections year in and year out. It’s a silent epidemic of a sort, which in sheer numbers puts it at the fourth leading cause of death” (College of Physicians & Surgeons of Ontario 2005).

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## LEGAL OBLIGATIONS

Healthcare providers and facilities owe a legal duty of care to their patients. Healthcare providers must “exercise that degree of care and skill which could reasonably be expected of a normal, prudent practitioner” in the same circumstances, as explained by the Supreme Court of Canada in the 1956 case, *Crits v. Sylvester*, which remains a leading authority ([1956] S.C.R. 991). They also owe their patients a fiduciary duty to act in that patient’s best interests as set out in various court decisions, including the Supreme Court of Canada’s judgment in *McInerney v. MacDonald* ([1992] 2 S.C.R. 138). Similarly, healthcare facilities have an obligation to provide a safe environment to protect patients from harm in the course of receiving care. They have “a duty not only to establish necessary systems and protocols to promote patient safety, [they] must also take reasonable steps to ensure that ... staff (including medical staff) comply with these protocols.” (Picard and Roberts 1996).

In the context of healthcare-associated infections, what constitutes reasonable practices and protocols may be a moving target during a novel disease outbreak, particularly as infection-control measures are revised to reflect new evidence about the disease’s virulence, transmission routes and key control methods. Indeed, significant criticism has been leveled at the “incoherent and at times completely untenable” infection-control measures disseminated during the SARS outbreak (Erlick 2003). The area of infection-control is one dominated by guidelines and directives, and failure to comply with recommended practices will be one factor that may indicate a failure to meet an appropriate standard of care.

In many areas of practice, courts often look to guidelines or standards of practice to help determine the legal standard of care. In the case of *Spillane (Litigation guardian of) v. Wasserman* ([1992] O.J. No. 2607), the judge found that the defendant physicians “neglected to follow the minimum standards set out in the notices provided by the College of Physicians and the guides for physicians prepared on behalf of the Canadian Medical Association.” This fact supported the conclusion that the physicians were negligent.

The appropriateness of a healthcare practice must be evaluated against accepted standards at a particular point in time. The Supreme Court of Canada has cautioned that “courts must not, with the benefit of hindsight, judge too harshly doctors who act in accordance with prevailing standards of professional knowledge” (ter *Neuzen v. Korn*, [1995] 3 S.C.R. 674, para. 34). In a 1930s case involving an allegation that a young girl acquired smallpox infection after exposure at a Vancouver hospital, a B.C. Court of Appeal judge addressed the challenge of protecting patients during a time of uncertainty: “In view of this uncertainty and limited knowledge, while it may be difficult to provide against unknown danger, the fact that it is known that this disease may be transmitted in ways not yet under-

stood suggests the need of rigorous precautions with the view, within reasonable limits, of closing every avenue from which danger might be apprehended” (*McDaniel v. Vancouver General Hospital*, [1934] 1 D.L.R. 557, p. 566). On further appeal, the hospital was absolved of liability, as the court found the hospital had acted in accordance with existing approved practices.

A patient who can establish she suffered harm as a result of a healthcare provider’s failure to meet an appropriate standard of care may bring a negligence claim against the provider as well as the care facility. Recent examples of SARS-related litigation demonstrate that individuals may even sue provincial governments for allegedly failing to provide adequate funding to health facilities. In the context of nosocomial infection, patients may claim harm simply from exposure to a risk of infection and need not establish that they did, in fact, acquire an infection. For example, a gynecology clinic patient who is exposed to HIV or other viruses that are typically transmitted through sexual contact may suffer from the anxiety and uncertainty she experiences while awaiting test results and the restrictions on her personal life as she must protect others, including sexual partners, from possible exposure.

## DISCLOSURE OBLIGATIONS

Different types of disclosure obligations may arise where a patient has been harmed, or faces a risk of harm, through his contact with the healthcare system. These include disclosure to a patient directly, and disclosure to regulatory bodies and government agencies.

### Patient Disclosure

In regard to disclosure of medical error generally, Canadian law clearly establishes a positive duty on care providers to inform patients of errors that occur during their care, if a reasonable person in the patient’s position would want to know about the mistake (Picard Robertson 1996: 170). For example, in one case, a surgeon was successfully sued for failing to tell a patient in a timely manner that a roll of surgical gauze had been left in her abdomen (*Shobridge v. Thomas*, 1999 BCJ No. 1747). In another case, a urologist implanting a device could not locate the tubing and balloon from a previous device that had been implanted. He decided to leave it rather than operating to attempt to locate it. While he informed his patient of this, he also inaccurately told the patient this posed no risk of harm. He was found negligent for failing to advise the plaintiff of the true risks, as well as a failure to follow up appropriately (*McCann v. Hyndman*, [2003] A.J. No. 1016).

In regard to nosocomial infection, when care providers realize that patients may have been exposed to infection from equipment, other patients or healthcare workers, a legal obligation may arise to contact patients to warn them of the risk and provide advice regarding appropriate follow-up testing and care.

Existing Canadian case law requires that healthcare facilities engage in timely review to identify patients who may be at risk and employ effective communication strategies to alert them. In *Pittman Estate v. Bain* ([1994], 112 D.L.R. [4th] 482 [Ont. Gen. Div.]), a case involving a failure to inform a patient that he may have contracted HIV through a blood transfusion, an Ontario General Division Court imposed “an obligation to notify the at risk recipients in a manner and in a time commensurate with the risk to their health” (para. 546). Depending on the circumstances, this duty may be discharged by notifying the patient’s family physician about a risk. The physician then has a duty to inform the patient.

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In addition to the existing court decisions on this issue, however, Canadians may see governments taking a more active role in mandating when and what a patient should be told after such an incident. The government of Quebec has recently amended legislation to specifically address this area. In *An Act Respecting Health Services and Social Services* (R.S.Q., c. S-4.2), a specific right to be informed of an accident (defined as “an action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user ...”) has been set out for those receiving care in hospitals. Quebec has also approved codes of ethics of various health professions through legislation, thus giving them the explicit force of law. Some of these have recently been amended to include a duty to inform a patient of an error, for example: the *Code of Ethics of Physicians* (changed in 2002) (R.S.Q., c. C-26, s. 87, 2001, c. 78, s. 56), the *Code of Ethics of Pharmacists* (R.S.Q., c. P-10, c. C-26, s. 87, c. P-10, r.5) and the *Code of Ethics of Dispensing Opticians* (R.S.Q., c. O-6; c. C-26, s. 87; c. O-6, r.3.1).

While codes of ethics may not normally carry the force of law on their own (though often courts look to them to help determine legal standards), other recent steps have taken place to include an obligation to disclose errors to patients in this context. The Canadian Medical Association’s Code of Ethics was recently amended to explicitly require the disclosure of harm. This Code has been officially adopted by certain Colleges of

Physicians and Surgeons across Canada, which would assist in making a case for successful disciplinary action against a physician who failed to make such disclosure. At least one College, New Brunswick's, has made this explicit (failure to disclose would equate to professional misconduct as the regulations set out that professional misconduct includes a breach of the code of ethics).

Some Colleges have taken the added step of drafting separate guidelines or policies addressing this issue (see those in Saskatchewan, Manitoba, Ontario and Newfoundland). For example, the Newfoundland Medical Board sets out more than the duty to disclose. It also provides some guidance as to whom to disclose, when disclosure should be made and other suggestions regarding how to appropriately convey the information in question.

At least some hospitals have also begun to implement relevant policies. Two of The McGill University Health Centre hospitals instituted policies as early as 1989 and 1990, and the Centre as a whole did so in 2001 (MUHC 2001). The University Health Network in Toronto did so in May of 2005. It seems likely that given the increase in attention to patient safety that many others will likely follow suit. One could argue that a failure to create and implement such policies could be a breach of the duty owed by healthcare facilities to create a safe environment (Robertson 2002).

Questions have arisen as to whether healthcare providers have a legal duty to notify patients of extremely low or theoretical risks of harm, such as possible exposure to Creutzfeld-Jakob disease (CJD). In 2002, health officials in Saskatchewan opted to notify 71 patients about a risk of possible exposure from medical equipment that had been used on a man who subsequently died from CJD. Nova Scotia health officials took the same notification measures in 2004 based on fear that equipment may have been exposed to CJD. Concern with theoretical risk is not limited to healthcare facilities but is a major ongoing concern for blood suppliers, such as the Canadian Blood Service, and safety regulators.

In a 1997 commentary in the *Canadian Medical Association Journal*, several legal, medical and ethics experts concluded "that there is a modest legal foundation for the premise that healthcare providers have an obligation to notify former patients about the theoretical risks associated with exposure to..." infectious agents (Caulfield et al. 1997: 1391). However, ethical principles, including the imperative to protect patients from undue harm, may militate against individual notification and favour a system of public notification.

While Canadian courts have not yet ruled on the issue of disclosing theoretical risks in the healthcare setting, administrators may choose to notify patients and the public generally to preserve trust. There is growing demand for openness and transparency in regard to medical errors and administrators

would likely prefer to proactively manage the communication process rather than formulate a hasty response to provocative media stories that imply incompetence and cover-ups in the healthcare system.

In addition to disclosure to patients who may have been harmed (or exposed to harm) by past encounters with the healthcare system, providers may also have to confront the dilemma of whether to inform patients of potential risks they may face in receiving treatment. To obtain informed consent to treatment, healthcare providers have a legal duty to advise patients of material risks that a reasonable person in the patient's position would want to know (*Reibl v. Hughes*, [1980] 2 S.C.R. 880). However, does this duty extend to mandate disclosure of information such as the fact that a care provider is HIV-positive? In 2004, Québec's Collège des Médecins investigated this issue following disclosure that a former surgeon at a Montréal hospital had treated patients while HIV-positive. The College concluded that a physician with a blood-borne infection is not required to inform the patient, but the infected physician must undergo periodic review and risk assessment by an expert panel of Québec's National Institute of Public Health (Bannady 2005). Where necessary to protect patients from possible harm, the physician will receive support to modify his or her professional activities.

This policy, which does not establish mandatory patient disclosure, is consistent with a 2001 Alberta decision in which the Court of Appeal found that a surgeon with controlled epilepsy did not have a legal obligation to disclose his condition to his patient. The Court stated that Canadian law does not impose "any liability in negligence on a doctor who fails to disclose his personal medical problems in a case where those medical problems cause no harm to the patient" (*Halkyard v. Mathew* 2001, ABCA 67, para. 11).

### **Reporting to Regulatory Bodies and Government Agencies**

In addition to grappling with the issue of notifying patients of possible healthcare-associated harms, providers may face obligations to report risks and errors to regulatory officials, government agencies and others. Most healthcare facilities should have policies on the creation of incident reports. Many will have quality assurance committees to monitor and improve the quality of care provided in the facility, thus enhancing patient safety and learning from past mistakes. There will be obligations under certain policies to provide information or write reports regarding particular "incidents." All provinces to varying degrees have taken steps to protect certain information contained in these types of reviews, under certain conditions, with statutory privilege so that it cannot necessarily be used in any legal proceedings that may come about as a result of the same incident (for example, s.9 of the *Alberta Evidence Act*). However, the duty

to disclose this type of information for review purposes has not been previously legislated. This is beginning to change.

In 2002, for example, Saskatchewan became the first province in Canada to enact legislation requiring mandatory reporting of medical errors to the provincial Department of Health (*Act to Amend the Regional Health Services Act* (2004), *Saskatchewan Critical Incident Reporting Guideline and Saskatchewan Critical Incident Regulations*). Notification of “critical incidents” must be made by healthcare organizations to their regional health authorities, who in turn must notify the minister. Investigations and written reports are to follow. It will be interesting to see if other provinces decide to follow suit.

All provinces and territories have legislation mandating the reporting of deaths in certain circumstances (e.g., Manitoba’s *Fatality Inquiries Act* and Ontario’s *Coroners Act*). Though wording, and as a result the scope of what is included, in each of the Acts varies, deaths that may have been caused by negligence are reportable to medical examiners, coroners, investigators and/or the police. One of the purposes of a fatality investigation may be to prevent similar deaths in the future.

Alberta has legislation that mandates the reporting of “significant mishaps” at non-hospital surgical facilities to the health authority with which they have an agreement as well as the Minister (see *Health Care Protection Act* and the related regulation). The College of Physicians and Surgeons have amended their bylaws to allow disclosure of these mishaps by their Registrar to the relevant health authority.

Many provinces also have legislation that requires the reporting of various types of incidents that occur in care facilities (such as long-term care or child care facilities). While some of the facilities in question would not be considered healthcare facilities, reportable errors include things such as medication errors and harm suffered as a result of improper care or treatment. For example, under British Columbia’s *Community Care and Assisted Living Act* and its *Adult Care Regulations* (B.C. Reg. 536/80 including amendments up to B.C. Reg. 457/2004), licensees must report promptly to the medical health officer as well as the contact for the person in care and their primary care provider if a “reportable incident” occurs (s.10.6). Such an incident includes a medication error (Schedule 1). Saskatchewan’s *Personal Care Homes Regulations* (R.R.S. 2000, c.P-6.01, Reg. 2 as amended by Saskatchewan Regulations 69/2002 and 89/2003), mandate reporting of “serious incidents.” This includes “any occurrence, accident or injury that is potentially life threatening” as well as “any harm or suspected harm suffered by a resident as a result of unlawful conduct, improper treatment or care, harassment or neglect on the part of any person” (s. 13 (1)). Licensees must notify the “resident’s supporter,” their physician, the department responsible and the regional health authority. They are also obligated to provide a written report to the government department responsible outlining a number of things including

“any actions taken ... to solve the problems ... and to prevent recurrences of the serious incident” (s. 13(2)(b)).

Individual healthcare facilities have also launched programs to encourage health professionals to identify and remedy sources of error, including regular patient safety meetings and internal tracking of adverse events.

## ROLE OF LAW IN PROMOTING PATIENT SAFETY

Law has an important role to play in promoting patient safety. Legal rules establish standards that healthcare providers and others must meet and also deter practices that fall below an accepted standard. Principles regarding information disclosure in the healthcare context ensure that patients receive information they may need to make informed choices and to pursue claims for damages where the error that led to an adverse event was negligent. Malpractice litigation provides a mechanism through which those who have been harmed may seek redress and, as the influential 1990 Pritchard report on liability in healthcare observed, “the threat of ... litigation against health care providers for negligence contributes in a positive way to improving the quality of health care provided and reducing the frequency of avoidable health care injuries” (A Report of the Conference ... 1990).

Recent legal developments help to encourage a culture of openness regarding patient safety concerns. One example is privilege over quality assurance activities that are aimed at minimizing future errors. Further, the law mandates reporting in appropriate circumstances, both to patients, regulatory bodies and others.

The concern that disclosure of errors will cause more lawsuits is not borne out in practice. Professor Gerald Robertson observes that “[r]ecent studies in the United States have demonstrated that hospitals which introduced an active disclosure policy experienced a reduction in the incidence of malpractice litigation...[t]he lesson that the medical profession must learn is that when an error occurs, silence does not prevent litigation, it promotes it” (Robertson 2002).

The law is an important tool which should continue to be used as issues around patient safety are examined and strategies are determined to create safer systems and decrease the incidence of preventable error. The Canadian Patient Safety Institute is optimally positioned to work with the provinces and territories in examining existing law and planning for future legislative reform. (Indeed, they cite the promotion of legislative reform as an important part of their action plan and have already initiated discussions with provincial and national governments). Studying the possible harmonization of existing Acts and regulations such as quality assurance and fatality legislation would likely be fruitful. Also worthwhile would be a consideration of legislation aimed at a national surveillance program to be used in gathering necessary information to analyze and plan

with the aim of reducing error. Governments would be remiss not to follow what is happening in Saskatchewan following the passage of their novel reporting legislation and to study whether it has helped to achieve the goals of its passage, and whether they should consider similar Acts within their own jurisdictions. Finally, it would be worth reflecting on the introduction of laws which would require regional health authorities and healthcare facilities to develop policies and procedures regarding the disclosure and reporting of error, and to mandate the subsequent training of staff.

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