

To Tell the Truth: The Ethical and Legal Implications of Disclosure of Medical Error

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Introduction¹

In early 2004, Carol Smith and David Jones (as we will call them) were seriously ill patients in Intensive Care Units at the Foothills Medical Centre in Calgary.² On March 4, 2004, Carol, who was 83, died suddenly and unexpectedly.³ Just prior to her death, Carol was alert, oriented and did not seem to be in imminent danger.⁴ In these circumstances, it might have been easy to dismiss Carol's death as a result of complications from her serious underlying condition. However, an astute ICU physician investigated further and ultimately it was discovered that her death was the result of receiving potassium chloride instead of sodium chloride in her dialysate solution.⁵

As a result of this adverse event, a broader investigation was commenced and the 30 bags of improperly mixed solution were immediately taken out of use.⁶ This quick decisive action undoubtedly prevented the deaths of other patients. However, when patient care and pharmacy records were examined, it became clear that another patient had also died as a result of the improperly mixed solution.⁷ David Jones had also been a patient in the ICU at Foothills Medical Centre and had died unexpectedly a week before Carol.⁸ If Carol had not died and had her physician not been astute and diligent enough to investigate her death further, it is possible that David's death would never have been properly explained and his family would never have known what occurred.

Soon after discovering the tragic error, the health providers disclosed the error to the victims' families. In addition, after an internal investigation and consulting with the families of the victims, the Calgary Health Region (CHR) publicly

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¹ The author would like to thank the CIHR Training Program in Health Law & Policy for its generous support.

² Rob Robson, Bonnie Salsman & Jim McMenemy, *External Patient Safety Review Calgary Health Region June 2004* (Calgary: Calgary Health Region, 2004) at 5, online: Calgary Health Region <<http://www.crha-health.ab.ca/newslink/robson1.pdf>>. While the actual names of the victims have been made public, I have chosen not to use them in order to preserve the privacy of the victims' families.

³ *Ibid.* at 8.

⁴ *Ibid.*

⁵ *Ibid.*

⁶ *Ibid.*

⁷ *Ibid.*

⁸ *Ibid.*

disclosed the facts and accepted responsibility for the deaths.⁹ This decision to publicly accept responsibility, although not unprecedented, is extremely rare.¹⁰

After its own internal critical incident review, the CHR instituted a number of changes aimed at avoiding similar errors in the future.¹¹ In addition, the CHR also launched an external independent review of the incident and its broader patient safety culture and initiatives. This review culminated in a detailed report that was released June 29, 2004.¹² The report, while generally applauding the patient safety efforts of the CHR, made 66 recommendations regarding the specific incident and the broader patient safety issues facing the CHR.¹³

There are a number of extraordinary aspects of this tragic incident. While there is no doubt that a tragic preventable error occurred and that the system failed the victims and their families, the subsequent actions of the CHR in dealing with the adverse event have been impressive. On the one hand, this incident is an example of how vulnerable our systems still are to human error and highlights the need to be ever vigilant in our patient safety efforts. On the other hand, this incident is also an example of an appropriate and proactive response to error through the prompt disclosure of the error to the victims' families and the public acceptance of responsibility. In its response, the CHR did not focus primarily on damage control, but instead focused on the victims' families and learning from the error. In addition, the decision to launch an external review and publicly share its findings is an important positive step. Moreover, the Health Quality Council of Alberta and the Canadian Patient Safety Institute have been involved in various aspects of the process and will assist with spreading the lessons learned from these tragic deaths across the province and the country.

Unfortunately, proactive responses like those taken by the CHR in this situation are still the exception rather than the rule when health providers respond to medical error. In addition, while the conduct of the CHR was laudable, it should be noted that it is much easier to proactively disclose error and accept responsibility in circumstances of clear medication errors, than when dealing with other forms of error. In many circumstances of suspected error, it would be inappropriate to take action too early, as it will often not be clear whether an error even occurred, let alone what the cause of the error was. However, at the very least, the above response by the CHR should serve as an example for how health providers should respond to adverse events that result from clear error.

⁹ *Ibid.*; see also Robert V. Johnston *et al.*, "Responding to Tragic Error: Lessons from Foothills Medical Centre" (2004) 170:11 CMAJ 1659.

¹⁰ *Supra* note 2.

¹¹ Rosmin Esmail *et al.*, "Using Healthcare Failure Mode and Effect Analysis Tool to Review the Process of Ordering and Adminstrating Potassium Chloride and Potassium Phosphate" (2005) 8 *Healthc. Q.* 73.

¹² *Supra* note 2.

¹³ *Ibid.*

While patient safety and medical error have long been a concern of the health professions, it was not until the 1999 release of the *To Err is Human* report of the U.S. Institute of Medicine (IOM) that the issue received widespread public and political attention.¹⁴ Since the release of the IOM report, patient safety has been vaulted into the spotlight and is now central to reform efforts by members of the health professions, hospital administrators and governmental health agencies. All over North America, tremendous pressure is being brought to bear on all aspects of the health-care system to improve patient safety and reduce medical error.

Given the natural fallibility of humankind, the increasing complexity of our human systems and the potential for disastrous consequences if our systems fail (or we fail our systems), serious efforts must be made to reduce the incidence and cost of human error in medicine. In this paper, the unhappy relationship between health providers and the law in the context of disclosure of medical error will be discussed and analyzed.¹⁵ In particular, the ethical and legal implications of the disclosure of medical error will be examined. In addition, some areas of potential reform of the legal system and health system will also be briefly discussed.

It is important to note at the outset that when referring to disclosure of medical error, this paper is restricted to the issues involved in disclosing errors to patients and their families. While disclosing medical errors to mandatory or voluntary government or other reporting systems raises several interesting concerns, these issues are beyond the scope of this paper.¹⁶

Patient Safety and Incidence of Medical Error¹⁷

While a detailed discussion of all of the facets of medical error and patient safety are also beyond the scope of this paper, it is important to understand the true

¹⁴Linda T. Kohn, Janet M. Corrigan & Molla S. Donaldson, eds., *To Err is Human: Building a Safer Health System* (Washington D.C.: National Academy Press, 2000).

¹⁵In this paper, I will primarily focus on the medical profession with respect to error disclosure but many of the same considerations apply to the other health professions and hospitals. The primary reason for this is that when medical errors occur, rightly or wrongly, physicians are generally considered responsible. This is often true even in circumstances when the error is more properly described as a system error. It is therefore physicians who are on the front lines in the battle against medical error and who have the most to gain (or lose) from patient safety efforts.

¹⁶For a useful introductory examination of some of the benefits of, and issues involved in, mandatory government and other error reporting mechanisms, see Mimi Marchev, "Medical Malpractice and Medical Error Disclosure: Balancing Facts and Fears" (Portland, ME.: National Academy for State Health Policy, December 2003), online: National Academy for State Health Policy <http://www.nashp.org/files/medical_malpractice_and_medical_error_disclosure.pdf>; see also Paul Barach & Stephen D. Small, "Reporting and Preventing Medical Mishaps: Lessons from Non-Medical Near Miss Reporting Systems" (2000) 320:7237 *BMJ* 759; Lucian L. Leape, "Reporting of Adverse Events" (2002) 347:20 *New Eng. J. Med.* 1633; and Gautham Suresh *et al.*, "Voluntary Anonymous Reporting of Medical Errors for Neonatal Intensive Care" (2004) 113:6 *Pediatrics* 1609.

¹⁷The discussion of the incidence of medical error is a summary of a section of my paper entitled, "Patient Safety: Individual and Systemic Causes of Medical Error and the Need for Reform" 2005 [unpublished] – on file with author.

nature of the problem before embarking on an examination of the ethical and legal implications of disclosing medical error.

The first major study of medical adverse events in the U.S. was conducted in California in the early 1970's and concluded that adverse events occurred in 4.6% of all admissions.¹⁸ However, it was not until the Harvard Medical Practice Study was conducted in 1991 that medical error began to receive widespread attention in the medical community.¹⁹ This study was a retrospective analysis of over 30,000 randomly selected medical charts for patients discharged from 51 New York State hospitals in 1984.²⁰ The Harvard Study reported a disturbingly high incidence of adverse events and concluded that adverse events occurred in 3.7% of hospitalizations²¹ and that 58% of these adverse events were preventable.²² Approximately 29% of the adverse events, when viewed by a medical-legal expert were deemed to be negligent.²³ Although most of these adverse events gave rise to disability lasting less than six months, 13.6% resulted in death and 2.6% caused permanently disabling injuries.²⁴

In addition, a detailed retrospective chart analysis and review of 15,000 randomly selected admissions to Colorado and Utah hospitals during 1992 was conducted and released in 1999.²⁵ The Colorado and Utah Study found that adverse events occurred in 3% of hospitalizations in each state; 54% of these were preventable and 5.6% resulted in death.²⁶ The Colorado and Utah Study also found that 15% of surgical adverse events resulted in permanent disability or death and that 12.2% of all hospital deaths in 1992 in the two states were as a result of surgical adverse events.²⁷

If the results of the Colorado and Utah Study are extrapolated and applied to the total hospital admissions in the United States in 1997, it would imply that at least 44,000 Americans die in hospitals each year as a result of preventable medical errors.²⁸ If the results of the Harvard Medical Practice study are similarly extrapolated, the number of deaths due to preventable medical error each year in the U.S.

¹⁸ California Medical Association, *Report of the Medical Insurance Feasibility Study* (San Francisco: The California Medical Association, 1977).

¹⁹ Troyen A. Brennan *et al.*, "Incidence of Adverse Events and Negligence in Hospitalized Patients. Results of the Harvard Medical Practice Study I" (1991) 324:6 *New Eng. J. Med.* 370.

²⁰ *Ibid.* at 370.

²¹ *Ibid.* at 371.

²² Lucian L. Leape *et al.*, "Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study II" (1991) 324:6 *New Eng. J. Med.* 377.

²³ *Ibid.* at 377.

²⁴ *Supra* note 19 at 371.

²⁵ Atul A. Gawande *et al.*, "The Incidence and Nature of Surgical Adverse Events in Colorado and Utah in 1992" (1999) 126:1 *Surgery* 66.

²⁶ *Ibid.* at 70.

²⁷ *Ibid.*

²⁸ *Supra* note 14 at 31.

may be as high as 98,000.²⁹ By way of comparison, even based on the lower extrapolated number, the number of deaths attributable to medical error is greater than the eighth leading cause of death in the United States³⁰ and is roughly equivalent to a large commercial airliner crashing every second day.

In Canada, a relatively small study of adverse events in hospitals in Ontario was released in 1999.³¹ However, the first and only national Canadian adverse events study was released in May 2004.³² The methods used by the Canadian researchers in the national study were based on the protocol developed by the Harvard Study. The Canadian researchers randomly selected four acute care hospitals in each of five provinces. In total, the Canadian Study reviewed 3745 charts and concluded that an adverse event occurred in 7.5% of hospital admissions in Canada.³³ Of the 255 patients who experienced one or more adverse events, 106 (41.6%) were judged to have adverse events that were highly preventable.³⁴ With respect to the consequences of adverse events, the Canadian Study concluded that most (64.4%) of the adverse events resulted in no physical impairment or disability or in a minimal to moderate impairment.³⁵ However, the Canadian Study also concluded that 5.2% of the adverse events resulted in permanent disability and 15.9% resulted in death.³⁶ By extrapolation, the researchers concluded that in 2000 between 9,250 and 23,750 deaths due to adverse events could have been prevented.³⁷

In addition to the adverse event studies conducted in the U.S. and Canada, adverse event studies have been conducted in the United Kingdom³⁸, Australia³⁹, New Zealand⁴⁰ and Denmark⁴¹. While there are interesting differences in the rates of adverse events among the various studies, all conclude that injury due to medical error is a serious problem.

²⁹ *Ibid.*

³⁰ *Ibid.*

³¹ Duncan Hunter & Namrata Bains, "Rates of Adverse Events Among Hospital Admissions and Day Surgeries in Ontario from 1992 to 1997" (1999) 160:11 CMAJ 1585.

³² G. Ross Baker *et al.*, "The Canadian Adverse Events Study: The Incidence of Adverse Events Among Hospital Patients in Canada" (2004) 170:11 CMAJ 1678.

³³ *Ibid.* at 1681.

³⁴ *Ibid.*

³⁵ *Ibid.*

³⁶ *Ibid.* at 1681-1682.

³⁷ *Ibid.* at 1684.

³⁸ Charles Vincent, Graham Neale & Maria Woloshynowych, "Adverse Events in British Hospitals: Preliminary Retrospective Record Review" (2001) 322:7285 BMJ. 517.

³⁹ Ross McL Wilson *et al.*, "The Quality in Australian Health Care Study" (1995) 163:9 Med. J. Aust. 458.

⁴⁰ Peter Davis *et al.*, "Adverse Events in New Zealand Public Hospitals I: Occurrence and Impact" (2002) 115:1167 The New Zealand Medical Journal 271.

⁴¹ Schioler T. *et al.*, "Incidence of Adverse Events in Hospitals: A Retrospective Study of Medical Records" (2002) 164 Ugeskr Laeger 4377.

Ethical Duty to Disclose

The ethical imperative “first do no harm” has been a foundational aspect of the medical profession since Hippocratic times. Nonmaleficence, the contemporary articulation of the ethical obligation to avoid causing harm, is not restricted to deliberate harm.⁴² Harm committed with the intent of healing is no less prohibited by the principle of nonmaleficence than malicious harm.⁴³ Harm from errors, system flaws, complications, accidents and known risks must all be avoided to the fullest extent possible.

However, the ethical imperative of nonmaleficence, which applies to all physicians, provides only half of the ethical answer in cases of medical error. What this principle does not deal with is what a physician must ethically do when harm is done to a patient. Since the dawn of the modern physician-patient relationship, it is difficult to see how a compelling argument could be made that doctors do not have an ethical duty to disclose errors to their patients. Doctors have long held a privileged position in society and are placed in a special position of trust vis-à-vis their patients. Physicians also hold a special expertise which is well beyond the layperson’s understanding. Without disclosure by the physician or another health professional, many, perhaps most, medical errors would remain undiscovered by the patient. It is all too easy for patients to assume that adverse outcomes are simply an unfortunate result of their underlying disease or a natural risk of the treatment they received. Moreover, physicians are in a special position to either tacitly or expressly encourage these erroneous assumptions.

Surprisingly, within the medical profession, the scope of the duty to disclose medical error remains controversial and adherence to that duty is by no means universal. However, ethicists clearly endorse the full disclosure of medical error to patients.⁴⁴ It is also clear from several studies that patients overwhelmingly want to be told explicitly when a medical error has occurred and wish to be provided with detailed information regarding the nature of the error, why it happened and how recurrences will be prevented.⁴⁵ Nevertheless, it appears from the available

⁴²Erin Egan, “Patient Safety and Medical Error: A Constant Focus in Medical Ethics” (2004) 6:3 *Virtual Mentor*, online: *Virtual Mentor – Online Journal of the American Medical Association* <<http://www.ama-assn.org/ama/pub/category/print/12046.html>>.

⁴³*Ibid.*

⁴⁴See for example, Fred Rosner *et al.*, “Disclosure and Prevention of Medical Errors: Committee on Bioethical Issues of the Medical Society of the State of New York” (2000) 160:14 *Archives of Internal Medicine* 2089; See also J. Banja, “Moral Courage in Medicine – Disclosing Medical Error” (2001) 17:2 *Bioethics Forum* 7; Philip C. Hebert, Alex V. Levin & Gerald Robertson, “Bioethics for Clinicians: 23. Disclosure of Medical Error” (2001) 164:4 *CMAJ* 509.

⁴⁵Amy B. Witman, Deric M. Park & Steven B. Hardin, “How Do Patients Want Physicians to Handle Mistakes? A Survey of Internal Medicine Patients in an Academic Setting” (1996) 156:22 *Archives of Internal Medicine* 2565; see also Thomas H. Gallagher *et al.*, “Patients’ and Physicians’ Attitudes Regarding the Disclosure of Medical Errors” (2003) 289:8 *JAMA* 1001; Melaine Hingorani, Tina Wong & Gilli Vafidis, “Patients’ and Doctors’ Attitudes to Amount of Information Given After Unintended Injury During Treatment: Cross Sectional, Questionnaire Survey” (1999) 318 *BMJ* 640; Cherri Hobgood

evidence that full disclosure of medical error may be uncommon.⁴⁶ For example, in the Wu *et al.* study, 76% of the physicians interviewed said they had not disclosed a serious error to a patient.⁴⁷ In another study, higher incidence of disclosure was found, yet 22% of the physicians surveyed said that they would not disclose an error that led to the patient's death.⁴⁸ Perhaps not surprisingly, the researchers also found that the likelihood of disclosure decreased as the severity of the harm to the patient increased.⁴⁹

The most well documented, and likely the most important reason for this hesitancy to disclose medical error, is the concern of the medical profession about litigation.⁵⁰ Less important and less convincing reasons for this lack of disclosure are concerns over the extent of the information that individual patients and their families would actually want, and whether or not full disclosure of the error could do harm to the patient or their family.⁵¹ Of course, in situations where further health care is required as a result of the error, any persuasiveness that these justifications may have had disappears. Clearly, in these situations, patients must be given full information about the medical error in order to make informed follow-up treatment decisions. Without this information, it is highly questionable whether the patient's consent to the further treatment could be considered informed. If not, the consent would be vitiated and the health care providers could be liable in negligence and/or battery.

In a recent article, Thomas H. Gallagher reviews some of the ethical issues surrounding the disclosure of medical error and argues that a consensus regarding the minimum standard for error disclosure does not yet exist.⁵² While Gallagher seems to accept that there is an ethical duty to disclose medical error, he argues that a minimum standard for error disclosure "seems artificial".⁵³ Gallagher's apparent justification for arguing against a minimum standard for error disclosure is that

et al., "Medical Errors – What and When: What Do Patients Want to Know?" (2002) 9 Academic Emergency Medicine 1156; C.A. Vincent, T. Pincus & J.H. Scurr, "Patients' Experience of Surgical Accidents" (1993) 6 Quality Health Care 277.

⁴⁶ See for example, Robert J. Blendon *et al.*, "Views of Practicing Physicians and the Public on Medical Errors" (2002) 347:24 New Eng. J. Med. 1933; See also Hingorani *et al.*, *ibid.*; Albert W. Wu *et al.*, "Do House Officers Learn from their Mistakes?" (1991) 265:16 JAMA 2089; D.H. Novack *et al.*, "Physicians' Attitudes Toward Using Deception to Resolve Difficult Ethical Problems" (1989) 261:20 JAMA 2980.

⁴⁷ Wu *et al.*, *ibid.*

⁴⁸ Matthew P. Sweet & James L. Bernat, "A Study of the Ethical Duty of Physicians to Disclose Errors" (1997) 8 J. Clin. Ethics 341.

⁴⁹ *Ibid.*

⁵⁰ Gallagher *et al.*, *supra* note 45 at 1003; see also Harris Interactive Inc., "Common Good Fear of Litigation Study the Impact on Medicine – Final Report April 11, 2002" *The Harris Poll*, online: Common Good <<http://cgood.org/assets/attachments/57.pdf>> .

⁵¹ Gallagher *et al.*, *ibid.* at 1006.

⁵² Thomas H. Gallagher, "Content of Medical Error Disclosures" (2004) 6:3 Virtual Mentor, online: Virtual Mentor – Online Journal of the American Medical Association

<<http://www.ama-assn.org/ama/pub/category/print/12053.html>>.

⁵³ *Ibid.*

there is a lack of consensus about the scope of disclosure and the variable nature of the desire of patients to receive health information.⁵⁴ With respect, both justifications seem highly questionable. It is not necessary for a clear and unequivocal consensus about the exact scope of disclosure to exist before an ethical duty to disclose arises. Moreover, it is important to note that Gallagher's article was published some four months after the Council on Ethical and Judicial Affairs of the American Medical Association issued a report outlining physicians' ethical responsibilities to prevent harm and disclose medical error.⁵⁵ From the nature and tone of this report, it appears that, at least as of December 2003, the Council on Ethical and Judicial Affairs felt that there was sufficient consensus to warrant an amendment to the AMA *Code of Medical Ethics*. In addition, to use the fact that some patients may wish more disclosure than others as a reason to limit disclosure to all patients is highly questionable.

Perhaps it is because of the controversy discussed above that the issue of an express duty to disclose medical error has only recently been directly dealt with in the codes of ethics of the American Medical Association and the Canadian Medical Association. This is in stark contrast to the position of the legal profession, which has a long standing ethical duty to disclose errors to clients and a strong tradition of self reporting. As both professions are self regulating and as such are custodians of the public trust, the long delay in the inclusion of an express duty to disclose in medical codes of ethics is puzzling.

As stated above, in 2003 the AMA Council on Ethical and Judicial Affairs (CEJA) delivered a report on the ethical responsibilities of physicians dealing with medical error. In the report, the Council quotes from Opinion 8.12 of the *Code of Medical Ethics*, which states:

Patients have a right to know their past and present medical status and to be free of any mistaken beliefs concerning their conditions. Situations occasionally occur in which a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment. In these situations, the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred. ... This obligation holds even though the patient's medical treatment or therapeutic options may not be altered by the new information.⁵⁶

⁵⁴ *Ibid.*

⁵⁵ American Medical Association, Report of the Council on Ethical and Judicial Affairs, *Ethical Responsibility to Study and Prevent Error and Harm in the Provision of Health Care*, Report 2-A-03 (Chicago, IL: American Medical Association, 2003), online: American Medical Association <<http://www.ama-assn.org/ama1/pub/upload/mm/369/2a03.pdf>>.

⁵⁶ American Medical Association, Opinion of the Council on Ethical and Judicial Affairs, *Ethical Responsibility to Study and Prevent Error and Harm in the Provision of Health Care*, Opinion 1-I-03 (Chicago, IL: American Medical Association, 2003), online: American Medical Association <http://www.ama-assn.org/ama1/pub/upload/mm/369/ceja_1203c.pdf>.

Opinion 8.12 was issued in 1981 and last updated in June 1994. Based on a plain reading of this binding Opinion, it is difficult to see an ethical justification for the failure of physicians to disclose at least all of the relevant facts of a medical error or adverse event. However, based on the above discussion and the CEJA report and recommendations, it was obviously felt that further clarity was required. Accordingly, at the 2003 annual meeting, the AMA House of Delegates adopted the recommendations of the CEJA report and issued Opinion 1-I-03 that was included in the 2004 edition of the *AMA Code of Medical Ethics*.⁵⁷ In Opinion 1-I-03, the CEJA deals specifically with the scope of the duty to disclose medical error as follows:

(3) Physicians must offer professional and compassionate concern toward patients who have been harmed ... An expression of concern need not be an admission of responsibility. When patient harm has been caused by an error, physicians should offer a general explanation regarding the nature of the error and the measures being taken to prevent similar occurrences in the future. Such communication is fundamental to the trust that underlies the patient-physician relationship, and may help reduce the risk of liability.⁵⁸

Opinion 1-I-03 also deals more generally with the ethical responsibility of physicians in dealing with medical error. The Opinion supports a legally protected medical error review process and states that physicians should play a central role in identifying, reducing and preventing health-care errors. The Opinion also calls on physicians to participate in the development of reporting mechanisms that emphasize education and systems change.⁵⁹ Specifically, physicians are encouraged to: help establish and participate in effective, confidential and legally protected reporting mechanisms; develop means for objective review and analysis of errors and to conduct appropriate investigations into the causes of harm to patients; ensure that the results of investigations of errors and any proposed preventative measures, are conveyed to all relevant individuals; and identify and promptly report impaired and/or incompetent colleagues so that rehabilitation, retraining or disciplinary action can occur.⁶⁰ The Opinion also reinforces that physicians have a responsibility to provide for continuity of care if a patient who has been harmed during the course of their health care wishes to be treated by another physician.⁶¹ Finally, the Opinion encourages physicians to seek changes in the current legal system to ensure that all errors in health care can be safely and securely reported and studied as a learning experience for all participants in the health system, “without threat of discoverability, legal liability, or punitive action.”⁶² While these

⁵⁷ *Ibid.*

⁵⁸ *Ibid.*

⁵⁹ *Ibid.*

⁶⁰ *Ibid.*

⁶¹ *Ibid.*

⁶² *Ibid.*

modifications and specific enunciations by the AMA are important and welcome, it remains to be seen whether the medical profession will answer the ethical challenge to fully disclose medical error.

In Canada, until 2004, the Canadian Medical Association's *Code of Ethics* was silent on the issue of whether or not Canadian physicians had an ethical duty to disclose medical error to their patients. Before the CMA *Code of Ethics* was updated in 2004, the only way to argue that the Code contained an ethical obligation to disclose medical error was that this obligation was implicit in other enunciated principles.⁶³ Prior to 2004, the only two paragraphs of the CMA *Code of Ethics* that were potentially applicable were paragraph 2 ("Treat all patients with respect; do not exploit them for personal advantage.") and paragraph 12 ("Provide your patients with the information they need to make informed decisions about their medical care, and answer their questions to the best of your ability.")⁶⁴

In 2004, the CMA updated its *Code of Ethics* and included paragraph 14 to deal specifically with the issue of medical error and disclosure of medical error. Paragraph 14 states: "Take all reasonable steps to prevent harm to patients; should harm occur, disclose it to the patient."⁶⁵ Accordingly, even if it could be argued that the existence of an ethical duty to disclose medical error was uncertain in Canada prior to 2004, it is now clear that such a duty exists.

In addition, several provincial Colleges of Physicians and Surgeons have instituted policies for their members regarding the disclosure of medical error.⁶⁶ For example, in February 2003, the Council of the Ontario College of Physicians and Surgeons (CPSO) approved a policy entitled "Disclosure of Harm".⁶⁷ The stated purpose of the policy is to affirm the College's position that patients are entitled to be informed of all aspects of their health including a right to disclosure of harm that may have occurred to them during the course of receiving health care.⁶⁸ The CPSO also specifically states that it is not the intent of the policy to address issues concerning the cause of the harm suffered by a patient or the attribution of blame.⁶⁹

It is interesting that the CPSO and the CMA both chose the terminology of "harm" as opposed to "error" or "adverse event". Under either the CPSO policy or

⁶³ Gerald B. Robertson, "When Things Go Wrong: The Duty to Disclose Medical Error" (2002) 28 Queen's L.J. 353 at 354.

⁶⁴ *Ibid.*

⁶⁵ Canadian Medical Association, *Code of Ethics*, (Ottawa: Canadian Medical Association, 2004), online: Canadian Medical Association <http://www.cma.ca/index.cfm/ci_id/2419/la_id/1.htm>.

⁶⁶ As of January 2006, the Colleges in Ontario, Newfoundland, New Brunswick, Saskatchewan and Manitoba have all instituted disclosure policies.

⁶⁷ The College of Physicians & Surgeons of Ontario, *Disclosure of Harm*, Policy #1-03, online: College of Physicians & Surgeons of Ontario <<http://www.cpso.on.ca/Policies/disclosure.htm>>.

⁶⁸ *Ibid.*

⁶⁹ *Ibid.*

the CMA *Code of Ethics*, it would appear that physicians do not have an ethical duty to disclose error that does not cause harm. While the CMA *Code of Ethics* does not define harm, the CPSO policy defines harm as follows:

Harm is defined broadly as an unexpected or normally avoidable outcome that negatively affects the patient's health and/or quality of life, which occurs (or occurred) in the course of health care treatment and is not due directly to the patient's illness.⁷⁰

From a practical perspective, the distinction between errors that cause harm and those that do not, makes sense so as to allow physicians and health care providers to refrain from disclosing "near misses" that do not result in harm to patients. In general terms, it may be ethical to refrain from advising a patient that they have been the subject of a "near miss" medical error. For example, in a situation where a patient was almost provided a lethal dose of a drug but the nurse caught it in time, arguably there is no ethical duty to inform the patient. However, consider the situation where a patient receives a non-lethal overdose of a narcotic pain medication that is caught a few minutes later and reversed with Narcan; the patient is unaware of the error and the health care team is not able to discern any obvious, ill effects directly related to the overdose. In this situation, it is highly questionable whether it would be ethical to refrain from disclosing the error to the patient even though it is unclear whether their health or quality of life was affected.

In fact, in many cases, it may not be easily discernible whether an error caused harm or whether the patient's post treatment symptoms resulted from their underlying condition. In addition, whether an event is "unexpected", "normally avoidable", "negatively affects the patient's health and/or quality of life" or "is not directly due to the patient's illness" are all matters that are open to interpretation. In these circumstances, leaving the subjective determination of whether harm resulted from error in the hands of the physician who erred raises obvious ethical concerns.

In setting out its "Disclosure of Harm" policy, the CPSO also stated five key principles to assist physicians in these difficult situations, which can be summarized as follows:

1. The patient is entitled to be kept informed about his or her health care, including information about harm suffered.
2. The obligation to disclose harm flows from the fiduciary nature of the physician-patient relationship. Disclosure of harm ensures that the patient's harm can be appropriately treated in a timely manner.
3. The patient is entitled to be informed about harm suffered even when such disclosure might prompt a complaint or a claim.

⁷⁰ *Ibid.*

4. Professional judgment is required to determine when an unintended outcome of care negatively impacts a patient and therefore is significant enough to require disclosure.
5. Not all harm is preventable and is not necessarily indicative of substandard care.⁷¹

In light of these policies, the CPSO set out its policy for the disclosure of harm as follows:

When a physician becomes aware, while treating a patient, that the patient has suffered harm in the course of receiving health care, he or she should consider whether the harm does or can be reasonably expected to negatively affect the patient's health and/or quality of life. If it does, then it is the physician's obligation to inform the patient about the harm sustained.⁷²

In an appendix to the disclosure policy, the CPSO Council provides recommendations on how to disclose harm to patients. The CPSO Council acknowledges that disclosing harm to patients may not be easy for physicians but stresses that the lack of disclosure may cause further harm.⁷³ The CPSO Council advocates a brief, non-technical factual description of what occurred and suggests the avoidance of speculation.⁷⁴ Interestingly, the CPSO policy advises physicians to try to avoid attributing blame or ascribing responsibility, but suggests that a timely and empathetic expression of sorrow or regret may be appropriate and should not be taken as an admission of liability or fault.⁷⁵ Unfortunately, the legal validity of the last statement based on the current law in Canada is questionable. However, the issue of apology and some suggestions for legal reform will be dealt with later in this paper.

Another recent development in the area of disclosure of medical error in Alberta is the proposed framework for the disclosure of medical error being developed by the Health Quality Council of Alberta (HQCA). The HQCA is in the process of an extensive consultation with stakeholders regarding the content of the proposed Provincial Framework for Disclosure of Harm to Patients and Families ("Framework"). Given that the proposed Framework is still in the development stage and final wording has not been publicly released, it would not be appropriate to discuss the current draft in any detail.⁷⁶ However, some of the key principles behind the initiative can be discussed.

⁷¹ *Ibid.*

⁷² *Ibid.*

⁷³ *Ibid.*

⁷⁴ *Ibid.*

⁷⁵ *Ibid.*

⁷⁶ Although details on the Framework are currently unavailable, future information on the initiative by the HQCA can be found on the HQCA website at: http://www.hqca.ca/pages/Quality/Collaborat_q/Initiatives.html.

The purpose behind the HQCA project is to provide a framework that will facilitate disclosure of medical errors by all health providers and health regions within the province. The Framework is intended to eliminate any requirement for legislative action in the area of disclosure of medical error. The Framework will be voluntary and each health region will be entitled to develop their own specific policies and procedures in accordance with their own particular needs. Importantly, the proposed Framework will primarily focus on adverse events that cause harm and will likely make disclosure of adverse events that do not cause harm (“near misses”) discretionary. Moreover, in addition to focusing on the needs and rights of the patient, the Framework will also likely make the support of physicians and other health providers throughout the disclosure process a priority.

In addition, one of the key aspects of the Framework will be that the patient should be provided with an apology or expression of regret as an integral part of the disclosure conversation. This suggestion will undoubtedly create a great deal of controversy. Of great concern to physicians, other health professionals and defence lawyers are the legal ramifications of an apology during the disclosure conversation. Depending on the content of the apology and the context, it could be considered an admission and entered as compelling evidence against the health provider in subsequent civil litigation. In addition, given that physicians are independent contractors and are generally separately insured, there are significant concerns that comments made by physicians in disclosure conversations could be attributed to the hospital or health region thereby engaging their liability. The reverse is also true in that comments or apologies made by employees of the hospital could directly or indirectly implicate the physicians involved in the care of the patient.

In response to concerns regarding apologies, it has been suggested that any apology should be simply an expression of regret and not an attribution or acceptance of responsibility. While this may be of some assistance from the perspective of a legal admission, it is questionable whether this type of expression of regret would satisfy patients. There is a clear distinction between a statement by a health provider that “we are sorry that you have suffered harm” and “we are sorry that there was a mistake in our central pharmacy and you were provided with the wrong medication”. The first type of apology is akin to an apology to one’s spouse that “I am sorry you are angry” instead of a true apology such as “I am sorry I forgot our anniversary”.⁷⁷ The first type of apology would satisfy few patients and the second type of apology would certainly be preferred by most. In circumstances where the cause of an error is clearly known, it may be preferable to provide a full apology while refraining from attributing individual blame. However, unless the Legislature enacts an apology privilege, which will be discussed further below, true apologies in disclosure conversations will retain significant legal risks. On the other hand, in circumstances of clear error where liability is unlikely to be seriously in issue, there is likely little to lose on the part of health providers in making a full apology. On

⁷⁷ A completely hypothetical example of course.

the contrary, if the patient is provided with a full explanation and a sincere apology, it is possible that litigation will be avoided altogether. However, physicians and health providers would be well advised to consult legal counsel prior to making any statement over and above a bare expression of regret.⁷⁸

Although there are significant concerns regarding the implementation of any proposed disclosure framework, it should be recognized that the HQCA initiative is simply an attempt to put forward a procedure for physicians, health providers, hospitals and health regions to meet their ethical and legal obligations to disclose medical errors when they occur. Successful implementation of any framework will require cooperation and assistance from the legal profession as well as systemic changes to the health professions and medical system to promote and foster a culture of safety and an environment where disclosure of error is effectively encouraged.

It should also be noted that many hospitals across the country have practices that are expected to be followed regarding disclosure of error and several have put in place formal policies. The Royal Victoria Hospital in Montreal instituted a formal protocol for disclosure of medical error as early as 1989.⁷⁹ This was followed soon after by the Sunnybrook & Women's College Health Sciences Centre in Toronto.⁸⁰ Another of the McGill University Health Centre ("MUHC") hospitals instituted a policy in 1990 and the entire MUHC group did so in 2001.⁸¹ In addition, the entire University Health Network in Toronto also put a formal protocol in place in May of 2005.⁸² Although other hospitals across the country have no doubt followed suit, what is necessary is a national program to ensure that all hospitals and health regions have disclosure policies in place.

While timely, proactive disclosure of error and appropriate apologies are the right thing to do and must be pursued, we must be careful not to raise unrealistic expectations with respect to their impact on preventing litigation. There will remain many cases where patients and families of victims will pursue litigation in any event. Some will pursue litigation to recover economic losses that have resulted from the adverse event. Others will have significant ongoing needs and will sue to recover the costs of their future care. Others may sue primarily because of the emotional trauma suffered as a result of the medical error. Others may sue because

⁷⁸ Although the argument would be unlikely to succeed, it is possible that an insurer could take the position that a full apology may breach the cooperation clause of the applicable insurance policy. As a result, it would be prudent for the health providers involved to consult with the appropriate insurers before a full apology is made. For a detailed discussion of this issue see: John D. Banja, "Does Medical Error Disclosure Violate the Medical Malpractice Insurance Cooperation Clause?" (2004) 3 *Advances in Patient Safety* 371, online: U.S. Dept. of Health, Agency for Healthcare Research and Quality <<http://www.ahrq.gov/downloads/pub/advances/vol3/Banja.pdf>>.

⁷⁹ A. Peterkin, "Guidelines Covering Disclosure of Errors Now in Place at Montreal Hospital" (1990) 142 *CMAJ* 984.

⁸⁰ *Supra* note 63 at 361.

⁸¹ Tracey M. Bailey & Nola M. Ries, "Legal Issues in Patient Safety: The Example of Nosocomial Infection" (2005) 8 *Healthc.Q.* 140 at 143.

⁸² *Ibid.*

they remain unsatisfied with the explanation given or that no individuals were held personally accountable. A recent example of this dissatisfaction occurred in Hamilton Ontario. Following the death of 11-year-old Claire Lewis, the Hamilton Health Sciences Centre (“HHSC”) issued an apology and stated: “We have identified serious care and system issues and have concluded that her death could have been avoided. For that, we offer our profound apologies.”⁸³ Notwithstanding these laudable actions by HHSC, the Lewis family remained unsatisfied and commenced a lawsuit primarily because they felt that there was no individual accountability in the system.⁸⁴ Unfortunately, there will always be patients and families that are unsatisfied with the explanations and apologies given and who will continue to pursue litigation. However, this fact cannot affect the pursuit of the goal of timely error disclosure and appropriate apologies.

Ultimately, when faced with a medical error that caused harm, a physician, at a minimum, has an ethical obligation to provide professional and compassionate concern and to promptly disclose an error when it occurs. The disclosure discussion should include an explanation of the nature and factual circumstances of the error as well as any measures being taken to prevent similar occurrences in the future. In appropriate circumstances, the patient should also be provided with an apology. A physician then has an ethical obligation to advise the patient of any impact that the error had on the patient’s condition and to provide the patient with the appropriate treatment options. Further, if it appears that the patient has lost trust in the physician, the physician has an ethical obligation to refer the patient to another physician and to provide continuity of care.

Legal Duty to Disclose

In common law Canada, it has been clearly established that a physician who has made an error has a legal duty to disclose that error to the patient or their family or guardian. This legal duty was initially derived from the principles of informed consent. The test for disclosure under the informed consent principles was the same as the test for whether or not risks must be disclosed to patients in obtaining their informed consent (i.e. if the error is something that a reasonable person in the position of the patient would want to know).⁸⁵ In this respect, the legal duty to disclose was simply a logical extension of the doctrine of informed consent. Clearly, if the patient is entitled to know the risks of a procedure and what could go wrong prior to giving their consent, it follows that they would be entitled to know if something has in fact gone wrong, regardless of whether it was unanticipated. However, the courts have now also incorporated fiduciary principles and have held that the legal duty to disclose is a fiduciary obligation of physicians. While informed

⁸³ Ken Kilpatrick, “Apology Marks New Era in Response to Medical Error, Hospital Says” (2003) 168:6 CMAJ 757.

⁸⁴ *Ibid.*

⁸⁵ Ellen I. Picard & Gerald B. Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 3rd ed. (Toronto: Carswell, 1996) at 170.

consent principles remain part of the analysis, as discussed below, the recent cases have primarily focused on the fiduciary nature of the duty to disclose. What remains unclear in the case law is the extent to which the legal duty to disclose will be extended to hospitals and their employees. As of yet, no court has expressly extended the legal duty to disclose to nurses or hospitals; in fact, as we will see later, the only Canadian case to discuss the issue, stated that nurses had no duty to disclose.⁸⁶ Despite this, a legal duty to disclose on the part of hospitals and nurses would seem to be a logical extension of the principles underlying the legal duty imposed on physicians and will be discussed further below.

Interestingly, the government of Québec has recently amended legislation to specifically address the issue of a duty to disclose. In *An Act Respecting Health Services and Social Services*, a specific right to be informed about an “accident” has been set out for patients in hospitals.⁸⁷ Québec has also approved several professional codes of ethics (which include duties to disclose) through legislation thus giving them the force of law.⁸⁸ As a result, it is clear that the legal duty to disclose exists in both Québec and common law Canada.

Although there is a relative paucity of cases dealing with the specific duty of physicians to disclose medical error, the earliest Canadian case to expressly enunciate this duty was *Stamos v. Davies*.⁸⁹ In that case, the defendant surgeon punctured the plaintiff’s spleen during the course of attempting to perform a lung biopsy. As a result of this error, the spleen had to be removed later, requiring an additional surgery. The lung biopsy also had to be redone. The physician never advised the plaintiff that he had struck the spleen. Instead, the physician advised the plaintiff that he had no result from the biopsy as he had not obtained what he wanted. When asked by the plaintiff what he had obtained, the physician replied that he had obtained “something else” and that the biopsy had to be redone.

In *Stamos*, the Court based its analysis generally on informed consent principles and held that there was a legal duty to disclose the error.⁹⁰ In the circumstances, the Court held that the physician had been less than candid with the plaintiff and had breached his legal duty to disclose the error. However, since the defendant’s breach of the legal duty to disclose was failing to disclose the injury to the spleen, this breach obviously could not have contributed to the primary injury to the plaintiff. In fact, the Court must also have found that the failure to disclose did not cause any injury to the plaintiff at all given that no damages were awarded for this breach. It is interesting to note that the Court in *Stamos* did not address the

⁸⁶ *Shobridge v. Thomas*, [1999] B.C.J. No. 1747, (1999), 47 C.C.L.T. (2d) 73 at para. 95 (B.C.S.C.) [*Shobridge*]

⁸⁷ R.S.Q., c. S-4.2.

⁸⁸ *Supra* note 81 at 142.

⁸⁹ (1985), 52 O.R. (2d) 10, 21 D.L.R. (4th) 507 (H.C.) [*Stamos* cited to O.R.]; see also *Kiley-Nikkel v. Danais*, [1992] A.J. no 1836, 16 C.C.L.T. (2d) 290 (Que. Sup. Ct.); and *Kueper v. McMullin* (1986), 30 D.L.R. (4th) 408, 37 C.C.L.T. 318 (N.B.C.A.).

⁹⁰ *Stamos, ibid.*

issue of breach of fiduciary duty or punitive damages and restricted its analysis on the issue of the failure to disclose to informed consent principles.⁹¹

As discussed above, another legal basis for requiring disclosure of medical error arises out of the fiduciary nature of the physician-patient relationship. As a fiduciary, a physician has a duty of utmost good faith towards their patient.⁹² This fiduciary relationship has been held in several cases to include a duty on the physician to inform the patient if something goes wrong, or if an error occurs during the patient's treatment.⁹³

In *Vasdani*, the defendant physician operated on the wrong level of the plaintiffs back.⁹⁴ The surgery occurred in 1977 and although the defendant physician realized that he had operated at the wrong level of the plaintiff's back in 1978, he never disclosed this to the plaintiff. It was only in 1985 that the plaintiff discovered from a third-party that the defendant physician had operated at the wrong level. In *Vasdani*, the Court cited *Stamos* but primarily based its analysis on fiduciary principles. The Court held that the defendant physician had clearly breached his duty to disclose to the plaintiff but struggled with the damages that should flow from the breach. In the end, the Court could find causation only for the delay in the plaintiff being able to bring his claim. Accordingly, the Court awarded damages in an amount equivalent to the difference in the plaintiff's entitlement to prejudgment interest.⁹⁵ The Court also refused to award punitive damages as it held that there was no evidence to conclude that the conduct of the defendant was sufficiently outrageous to attract an award of punitive damages. The Court also considered whether an award for damages should be made solely as a result of a breach of fiduciary duty even when causation of specific damage is lacking, but ultimately refused to award additional damages.

In *Gerula*, the defendant physician also operated on the wrong portion of the plaintiff's back.⁹⁶ Subsequently, the defendant physician altered the hospital records in order to conceal his error and then performed the operation on the disc that should have been treated in the first place. The trial judge held that the physician had breached his fiduciary duty to the plaintiff, awarded solicitor client costs but refused to award punitive damages. The Court of Appeal upheld the trial judge's finding on liability and reduced the award of solicitor client costs. The Court of Appeal also discussed the principles involved in determining when punitive dam-

⁹¹ *Ibid.*

⁹² *McInerney v. MacDonald*, [1992] 2 S.C.R. 138, 93 D.L.R. (4th) 415 at paras. 19-22; see also opinion of McLachlin J. (dissenting as to quantum) in *Norberg v. Wynrib*, [1992] 2 S.C.R. 226, 92 D.L.R. (4th) 449 at 486.

⁹³ See for example, *Vasdani v. Sehmi*, [1993] O.J. No. 44, 37 A.C.W.S. (3d) 856 at para. 33 (Gen. Div.) [*Vasdani* cited to O.R.]; *Gerula v. Flores* (1995), 126 D.L.R. (4th) 506 [1995] O.J. No. 2300 at 525-526, (C.A.) [*Gerula* cited to D.L.R.] and *supra* note 86 at paras. 98-100.

⁹⁴ *Vasdani*, *ibid.* at para. 28.

⁹⁵ *Ibid.* at paras. 38-41.

⁹⁶ *Gerula*, *supra* note 93 at 509.

ages are appropriate and went on to award \$40,000 in punitive damages as a result of the physician's dishonest conduct.⁹⁷

In *Shobridge*, the defendant physician, Dr. Thomas, performed abdominal surgery on Ms. Shobridge on September 13, 1995.⁹⁸ During the surgery, Dr. Thomas placed a six foot long unrolled abdominal roll in the upper abdomen to pack the bowel away from the operative field. Unfortunately, the abdominal roll was not included in the preoperative surgical count by the nurses and was left inside Ms. Shobridge at the end of her surgery. It was not until December 4, 1995 that, while performing another surgery to remove an abdominal fistula and a deep abdominal wall abscess, Dr. Thomas discovered the abdominal roll and removed it.⁹⁹ When the nurses advised Dr. Thomas that the removal of the abdominal roll should be charted and an incident report filled out, Dr. Thomas told them there was to be no paperwork regarding the abdominal roll. One of the nurses insisted that her nursing supervisor be told about the incident and Dr. Thomas said he would speak to the nursing supervisor the following morning. Dr. Thomas never spoke to the supervisor and no incident report was filled out. In addition, Dr. Thomas did not refer to the abdominal roll in his operative report for the December 4, 1995 surgery.¹⁰⁰ Despite having several opportunities to tell Ms. Shobridge about the abdominal roll in the time prior to her discharge on December 10, 1995, Dr. Thomas did not disclose the error. Ms. Shobridge was re-admitted on December 17, 1995 with abdominal pain and again Dr. Thomas did not disclose the error. Ms. Shobridge then requested a transfer to another hospital on December 20, 1995 for further treatment regarding her abdominal pain and in the consultation report he prepared for the other surgeon, Dr. Thomas failed to mention the abdominal roll.¹⁰¹

Ultimately, when it appeared that Dr. Thomas was not going to disclose the error, the nurses that were involved in the December 4, 1995 surgery went to a supervisor under the pretence of using this situation as an anonymous example to raise a concern about using non radio-opaque sponges and gauze. When the supervisor pressed the issue, Dr. Thomas agreed to meet with a Vice President of the hospital and was advised to tell Ms. Shobridge about the error. Finally, on February 6, 1996, some five months after the original surgery and two months after the abdominal roll was discovered, Ms. Shobridge was told about the error. From the notes of the disclosure meeting cited by the trial judge, it appears that Ms. Shobridge received a brief explanation of what had occurred and did not receive any sort of apology or expression of regret from Dr. Thomas or the hospital.¹⁰² This case appears to be one of those cases where there would have been very little legal downside to apologize and it could have had a significant impact on the well being

⁹⁷ *Ibid.* at 526-527.

⁹⁸ *Supra* note 86.

⁹⁹ *Ibid.* at paras. 24-26.

¹⁰⁰ *Ibid.* at para. 27.

¹⁰¹ *Ibid.* at para. 32.

¹⁰² *Ibid.* at para. 42.

of the patient and her desire to commence a lawsuit. Given that liability for the retained abdominal roll was virtually certain (although apportionment remained an issue), even if an apology was taken as an admission of fault, it would have had little or no impact on the ultimate outcome of the litigation. Further, a more timely explanation and apology would almost certainly have prevented the aggravated and punitive damages awarded in this case.

Not surprisingly, in the result, Dr. Thomas was held to be in breach of his duty to disclose for waiting two months before informing Ms. Shobridge that an abdominal roll had been left inside her abdomen during surgery. As a result of the breach of the duty to disclose and Dr. Thomas' conduct in trying to conceal the error, the Court awarded aggravated damages of \$25,000 and punitive damages of \$20,000.¹⁰³

One of the most interesting aspects of the *Shobridge* case is the fact that the Court held that the nurses (and presumably by extension the hospital) had no legal duty to disclose the error.¹⁰⁴ Kirkpatrick J. made the following comments about the legal duty to disclose on the part of the physician and the nurses:

There is no question that Dr. Thomas owed a duty of care to Ms. Shobridge to tell her, as his patient, what had happened. *The nurses, on the other hand, owed no such duty. Their duty was to complete an incident report in accordance with hospital policy. They knew it was Dr. Thomas' duty to inform his patient, not their duty.*¹⁰⁵

Given that the Court in *Shobridge* also found that the O.R. nurses were responsible for the accuracy of the surgical sponge count, it is surprising that the Court also held that there was no duty to disclose on the part of the nurses. While it is true that the physician-patient relationship remains the primary legal relationship, it is clear that nurses and hospitals also have a legal duty of care to their patients.¹⁰⁶ In *Shobridge*, the Court ultimately held Dr. Thomas and the nurses equally responsible for the failure to remove the abdominal roll. As a result, it seems inconsistent to hold Dr. Thomas entirely responsible for disclosing an error that he was only 50% responsible for.

One potential reason for this inconsistency is that the duty to disclose is derived from informed consent principles as well as fiduciary principles. As it was Dr. Thomas' responsibility to obtain informed consent and adequately explain the procedure as well as the risks, presumably one could argue that it was therefore his responsibility to disclose that something in fact had gone wrong. In addition, while fiduciary duties have been imposed on physicians, no such duties as of yet have

¹⁰³ *Ibid.* at paras. 138,144.

¹⁰⁴ *Ibid.* at para. 95.

¹⁰⁵ *Ibid.* [emphasis added].

¹⁰⁶ *Supra* note 85 at 366-367.

been expressly imposed on nurses or hospitals by Canadian courts. Accordingly, the Court in *Shobridge* clearly must have been of the view that the fiduciary duty to disclose in these circumstances was Dr. Thomas' and did not extend to the nurses or the hospital.

In addition, the approach taken by the Court in *Shobridge* with respect to the legal duty on nurses and hospitals to disclose error is in contrast to an *obiter* statement made by the English Court of Appeal in *Lee v. South West Thames Regional Health Authority*.¹⁰⁷ In the context of an application regarding the discoverability of a document, the following analysis is found:

It should never be forgotten that we are here concerned with the hospital-patient relationship. The recent decision of the House of Lords in *Sidaway v. Bethlem Royal Hospital Governors*, [1985] 1 All ER 643, [...] affirms that a doctor is under a duty to answer his patient's questions as to the treatment proposed. *We see no reason why this should not be a similar duty in relation to hospital staff.* [...] *Why, we ask ourselves, is the position any different if the patient asks what treatment he has in fact had?* Let us suppose that a blood transfusion is in contemplation. The patient asks what is involved. [...] He consents. Suppose that, by accident, he is given a quantity of air as well as blood and suffers serious ill effects. Is he not entitled to ask what treatment he in fact received, *and is the doctor and hospital authority not obliged to tell him, "in the event you did not only get a blood transfusion. You also got an air transfusion"?* Why is the duty different before the treatment from what it is afterwards?¹⁰⁸

This analysis has been cited with approval by Justice Krever in *Stamos*.¹⁰⁹ However, Justice Krever made no comment about the potential duty of the hospital to disclose the error.

In the end, it is an open question as to whether or not in Canada a legal duty to disclose error will be imposed on nurses, other health professionals and hospitals. However, given the recent movement towards more open error disclosure and the increasingly interdisciplinary approach to medicine, it is likely, in the right case, that other health professionals or hospitals would be held to a legal duty to disclose separate and apart from the legal duty of the physician. While fiduciary obligations have not yet been imposed on nurses and hospitals in Canada, a strong argument could be made that nurses and hospitals do in fact have fiduciary obligations to their patients separate and apart from the obligations of the physicians. Prudent nursing managers and hospital administrators should keep this potential legal duty in mind

¹⁰⁷ [1985] 2 All ER 385 [*"Lee"*].

¹⁰⁸ *Ibid.* at 389-390 [emphasis added].

¹⁰⁹ *Stamos*, *supra* note 89.

and should seek legal advice when contemplating their obligations to disclose medical errors.

Another interesting issue with respect to the legal duty to disclose error is the proper scope of that duty. In particular, is it necessary to disclose an error that causes no harm to the patient? None of the cases discussed above deal with the scope of the legal duty to disclose, particularly in “near miss” cases. As discussed above, the scope of the ethical duty to disclose is limited to errors that cause harm to the patient and there does not yet exist an ethical duty to disclose a “near miss”. However, this is not clear with respect to the legal duty to disclose. As discussed above, the legal duty to disclose has primarily developed out of informed consent principles. Accordingly, one cannot simply state that there is no legal duty to disclose in circumstances where the patient has not suffered harm. The particular facts of each case must be examined to see if a reasonable person in the circumstances of the patient would want to be advised of the “near miss”.¹¹⁰ Through this analysis, many, perhaps most, “near misses” would not be required to be disclosed given that “ignorance is bliss” and it could be argued that most of us would not want to be told of potential errors that were averted. However, the closer the potential error comes to actually causing harm, the more likely a court would find that there is a legal duty to disclose. In addition to this informed consent analysis, it would be interesting to see whether a court would extend the fiduciary obligation of the physician to disclose a near miss. Practically speaking, there is little legal downside to disclosing a “near miss” as the likelihood of a lawsuit is minimal given the nominal or nonexistent damages that would be available to the patient.

In the result, the scope of the legal duty to disclose is similar to the scope of the ethical duty to disclose discussed above, but potentially extends to circumstances where no harm is suffered. In any event, there is no legal duty to advise the patient that there has been negligence or a lack of skill.¹¹¹ The legal duty is only to advise the patient as to what occurred, in a factual sense.¹¹² From a review of the above cases, it is also clear that not only will the courts enforce a general and fiduciary duty to disclose medical errors; they may also award aggravated or punitive damages in cases of flagrant breaches or where the conduct of the physician is deserving of sanction. Accordingly, physicians should not allow extraneous factors and concerns about civil liability to interfere with their legal and ethical duties to disclose medical error; if they do, they do so at their peril.

¹¹⁰For example, consider the potassium chloride cases at the Foothills Medical Centre discussed in the introduction to this paper. If the errors in the solutions had been caught in the central pharmacy, should all patients that were scheduled to receive the improper solution be advised of the “near miss”? What about if the improper solution was hung at the patient’s bedside and the flow of the IV was stopped by a nurse before it reached the patient’s bloodstream; should that patient be told? In both situations no harm was caused to the patient yet the second patient’s confidence in the care being provided is much more likely to be shaken. This, in and of itself, could be sufficient reason for a court to hold that the patient in the second scenario ought to have been told given that a reasonable patient in those circumstances may wish to consider their treatment options including transfer to a different facility.

¹¹¹*Fehr v. Immaculata Hospital*, [1999] A.J. No. 1317, 1999 ABQB 865 at para. 34 (Q.B.) (cited to QL).

¹¹²*Ibid.*

Non-Disclosure as a Cause of Medical Error and Resistance to Disclosure

The failure by the medical profession and other health professionals to openly report errors, to effectively use errors as a learning experience and to adequately communicate the errors and their potential solutions within the hospital and with other institutions, is a major cause of medical error. As a result of these failures, systemic and individual errors that could be prevented by open communication and dissemination of information continue to occur. These issues are closely related to the resistance to error disclosure to patients by the medical profession and other health professionals. All of these issues are communication failures that are primarily a result of the culture and education of the medical profession, physicians' need for infallibility and their largely unfounded fear of litigation.

In medical school and residency, physicians are taught and socialized to strive for error-free practice.¹¹³ In diagnosis, treatment and everyday hospital practice, perfection is emphasized and the message is clear: mistakes are unacceptable.¹¹⁴ Physicians are expected to practice, often under extremely difficult circumstances, in an error-free manner. As a result of these expectations, both internal and external, physicians feel that they must be infallible and often view errors as failures of character.¹¹⁵ While the unrealistic nature of these expectations of infallibility is self-evident to individuals outside of the medical profession, it seems that physicians still struggle to attain the unattainable. According to Chassin:

The sheer number of specific interventions that good care requires is beyond the ability of any unaided human being to recall and act on effectively. Yet the dominant modes of practice still expect this impossible degree of accomplishment.¹¹⁶

We have created systems that depend on idealized standards of performance that require individual physicians, nurses, and pharmacists to perform tasks at levels of perfection that cannot be achieved by human beings.¹¹⁷

In addition, clinical professors, usually specialists and experts in their fields, reinforce this concept of infallibility.¹¹⁸ These physicians are all role models for their medical students and must be encouraged to more openly discuss medical error and promote an acceptance of the fallibility of the medical profession. If this is not

¹¹³ Lucian L. Leape, "Error in Medicine" (1994) 272:23 JAMA 1851 at 1851; see also Cheri Hobgood, Amando Hevia & Paul Hinchey, "Profiles in Patient Safety: When an Error Occurs" (2004) 11 Academic Emergency Medicine 766.

¹¹⁴ *Ibid.*

¹¹⁵ *Ibid.*

¹¹⁶ M. Chassin, "Is Healthcare Ready for Six-Sigma Quality?" (1998) 76 Milbank Quarterly 565 at 576.

¹¹⁷ *Ibid.* at 577.

¹¹⁸ Leape, *supra* note 113 at 1852.

done, every new generation of physician that graduates medical school, will continue to do so ill-prepared to deal with the inevitability of medical error and the fallibility of the medical profession and the health system. Learning how to disclose errors, to apologize to injured patients, to ensure that their needs are met and to confront the emotional impact of mistakes on physicians should become an integral part of medical education and senior physicians, as role models, should lead by example.¹¹⁹

It is also likely that the need of physicians to be infallible also creates pressure to be intellectually dishonest and to cover up mistakes rather than disclose them.¹²⁰ The structure of medical practice, particularly in hospitals, further perpetuates these problems. The existence of a “blame culture” means that physicians typically feel that disclosure of an error will lead to increased supervision or surveillance and the potential of censure or privileges difficulties. Unfortunately, these feelings are often warranted given that many hospitals and health regions remain reactive as opposed to proactive with respect to their patient safety efforts. Physicians also rarely feel able to discuss errors openly with their peers out of concern for direct ramifications, as well as concerns that their peers will regard them as incompetent or careless.

However, it would be wrong to mistake this hesitancy to disclose medical errors as evidence of a lack of caring on the part of the physicians involved. On the contrary, physicians are often emotionally devastated by serious mistakes that harm or kill patients.¹²¹ This emotional impact and feelings of shame, guilt, depression and anxiety as a result of medical error, are exacerbated by the “perfectionist” culture of medicine.¹²² Physicians are often left alone to struggle with their feelings of guilt regarding medical error and rarely have a forum to discuss these feelings in a positive and healing manner. Lucian Leape had the following comment on the impact of medical error on physicians:

Physicians feel responsible for deaths due to errors, which is appropriate and key to physicians’ professionalism. But we also feel shame and guilt, which is inappropriate and misguided, since errors are rarely due to carelessness.¹²³

¹¹⁹N. Berlinger & A.W. Wu, “Subtracting Insult from Injury: Addressing Cultural Expectations in the Disclosure of Medical Error” (2005) 31:2 *J. Med. Ethics* 106.

¹²⁰N. McIntyre & K.B. Popper, “The Critical Attitude in Medicine: The Need for a New Ethics” (1983) 287:6409 *Br. Med. J.(Clin. Res. Ed.)* 1919.

¹²¹John F. Christensen, Wendy Levinson & Patrick M. Dunn, “The Heart of Darkness: The Impact of Perceived Mistakes on Physicians” (1992) 7:4 *J. Gen. Intern. Med.* 424; See also O.G. Aasland & R. Forde, “Impact of Feeling Responsible for Adverse Events on Doctors’ Personal and Professional Lives: The Importance of Being Open to Criticism from Colleagues” (2005) 14:1 *Qual. Saf. Health Care* 13; Craig Pollack *et al.*, “Helping Clinicians Find Resolution after a Medical Error” (2003) 12:2 *Camb.Q. Healthc. Ethics* 203.

¹²²*Ibid.*

¹²³Lucian L. Leape, “Institute of Medicine Medical Error Figures Are Not Exaggerated” (2000) 284 *JAMA* 95 at 97.

In order for medical error to be addressed in any meaningful way, physicians must be allowed to be human and must be provided with a non-punitive, non-judgmental method to disclose and discuss medical error.¹²⁴ It is true that many medical departments and specialties have “Mortality and Morbidity” conferences where poor patient outcomes are presented. However, the focus of these conferences tends to be on the particular medical aspects of the treatment and condition as opposed to an examination of the error and its etiology. Physicians must be socialized, educated and trained to be more open and honest in their discussions about medical error and to routinely disclose them.¹²⁵ In this way, other physicians and other members of the health care team will be provided with an opportunity to learn from previous medical errors and prevent them from happening in the future. Any medical reporting system must not scapegoat individual physicians even though “blaming individuals is emotionally more satisfying than targeting institutions.”¹²⁶ It is only through an open system of error disclosure that we can truly learn from medical error and make the systemic changes necessary to reduce the incidence of adverse events.

However, some authors go further and argue that the more open and non-punitive environment for medical error disclosure discussed above, requires that physicians not be held individually accountable for most medical errors. It is argued that this is appropriate because most errors are, in substance, systemic errors.¹²⁷ In their article, Deskin and Hoye refer to the approach of focusing on individual accountability of physicians as the “bad apple” approach. According to them, “bad apple” physicians should not be targeted, especially when it is now recognized that the traditional responses to error are no longer enough.¹²⁸ According to Deskin and Hoye:

Removing bad apples in a system that is constantly in flux and can be influenced by so many participants from the blunt end only reduces the practitioner base, it doesn't necessarily remove any barriers to error.¹²⁹

While it is agreed that less punitive and more just responses to medical error must be pursued, physicians should not be immune from ramifications resulting from their errors. This is particularly true in the rare cases of recklessness when the

¹²⁴ Albert W. Wu, “Medical Error: The Second Victim. The Doctor Who Made the Mistake Needs Help Too” (2000) 320:7237 *BMJ* 726.

¹²⁵ Helen Lester & Jonathan Q. Tritter, “Medical Error: A Discussion of the Medical Construction of Error and Suggestions for Reforms of Medical Education to Decrease Error” (2001) 35:9 *Med. Educ.* 855; See also Dina Pilpel, Razia Schor & Jochanan Benbassat, “Barriers to Acceptance of Medical Error: The Case for a Teaching Program” (1998) 32:1 *Med. Educ.* 3; and Françoise Baylis, “Error in Medicine: Nurturing Truthfulness” (1997) 8 *J. Clin. Ethics* 336.

¹²⁶ James Reason, “Human Error: Models and Management” (2000) 320 *BMJ* 768; See also Bryan A. Liang, “A System of Medical Error Disclosure” (2002) 11:1 *Qual. Saf. Health Care* 64.

¹²⁷ See for example William C. Deskin & Robert E. Hoye, “Another Look at Medical Error” (2004) 88:3 *J. Surg. Oncol.* 122.

¹²⁸ *Ibid.* at 128.

¹²⁹ *Ibid.* at 128.

safety and well being of the patient is disregarded. Patients who feel they have been harmed as a result of medical error can and should seek legal redress through the tort system. If the physician or health provider has been negligent in committing the error, then the patient should be appropriately compensated through settlement or judgment.

However, the internal responses to medical error are more problematic in that there are several competing priorities involved in responding to medical errors. Of primary importance is the investigation of the causes of the error and the resultant attempt to modify policies or behaviour to ensure that the error is not committed again. In addition, hospitals and health administrators have a duty to review the conduct of individual health providers and make recommendations regarding changes to privileges, discipline or retraining. Traditionally, this has been a difficult process for the health provider to go through as there has been an inordinate emphasis on the individual aspects of the error as opposed to systemic causes. To put it another way, there has been a tendency to focus on individuals as opposed to systemic causes because it is easier and less expensive to discipline an individual than it is to make fundamental changes to the system. Unfortunately, this approach has led to a blame culture where individual health providers are extremely hesitant to report errors when they occur. This in turn has led to a situation where errors are widely under-reported.¹³⁰

Instead, what is required is a balanced and just approach that focuses on the systemic causes of the error as opposed to individual scapegoating. At the same time, this balanced approach must also look at the individual, and in appropriate cases make recommendations regarding retraining, restrictions to privileges, and in the most serious cases, professional discipline. Many articles written in this area advocate a “blame-free” culture as a means of promoting free and open disclosure of medical error. In my view, this is an over simplification of the problem and fails to address the competing interests of disclosure on the one hand and quality assurance and discipline on the other. It is true that hospitals and health administrators must focus on fostering a system where responses to error are not only just, but they are seen to be just by members of the health professions. Individual health providers must also not be made scapegoats of medical error. However, appropriate and just responses to errors can include discipline, retraining or suspension of privileges, but should only include criminal prosecution in extremely rare cases.¹³¹ As a self-regulating profession, medicine must continue to fulfill its obligation to the public to ensure the competence of its individual members. What is critical is that our responses to individuals who commit errors form part of an overall system

¹³⁰ *Supra* note 46.

¹³¹ Although criminal prosecution of physicians for medical error has traditionally been very rare, it is becoming more common, which is an extremely distressing trend. See the unfortunate example of a British Doctor convicted of manslaughter by gross negligence for a fatal medication error described in, Jon Holbrook, “The Criminalization of Fatal Medical Mistakes: A Social Intolerance of Medical Mistakes has Caused them to be Criminalized” (2003) 327:7424 *BMJ* 1118.

of accountability that focuses on the systemic aspects of error as opposed to individual blame.

In his candid and honest book, *Complications: A Surgeon's Notes on an Imperfect Science*, Dr. Atul Gawande explores the many ways that medicine can fall short of expectations and highlights that medicine is subject to the same limitations as are all human enterprises.¹³² In fact it is telling that the titles of the three Parts of the book are "Fallibility", "Mystery" and "Uncertainty".¹³³ Dr. Gawande's book, as well as Craig A. Miller's book, *The Making of a Surgeon in the 21st Century*,¹³⁴ should be mandatory reading for all politicians and government officials who deal with the health system as well as all lawyers who practice in the area of medical malpractice. These books provide invaluable insight into the medical education system and the uncertainty and fallibility of modern medicine.

While most physicians would agree with the axiom "to err is human", and recognize that some amount of error is inevitable in medicine, they have difficulty understanding that not every error is negligent. As a result, fear of being sued consistently comes up as one of the primary concerns of physicians in managing and disclosing medical errors.¹³⁵ However, studies have consistently shown that only an extremely small minority of patients injured by medical error actually file a lawsuit.¹³⁶ In fact, the Harvard Study found that less than 2% of negligent adverse events led to malpractice claims.¹³⁷ Other studies have concluded that there are eight times as many instances of negligence as there are lawsuits in the U.S. and fourteen instances of negligence for every successful claim.¹³⁸ It has been shown that what

¹³² Atul Gawande, *Complications: A Surgeon's Notes on an Imperfect Science* (New York: Picador, 2002).

¹³³ *Ibid.* While Dr. Gawande provides many refreshing insights into medicine, the health-care system and its relationship with the law, some of the most interesting and frightening insights are found in his section on medical education: "Education of a Knife". In this section, Dr. Gawande discusses the traditional process of medical education of "see one, do one, teach one" and admits that patients sometimes pay the price for novice mistakes or inexperience. Dr. Gawande also openly admits that the true scope of the involvement of medical students and residents in patient care is often glossed over by physicians and hospitals. Dr. Gawande also agrees that if patients truly knew the scope of the involvement of residents in their care, they would often be unlikely to consent. In addition, if a resident under the supervision of a senior physician makes an error, Dr. Gawande admits that it is unlikely that the patient would be provided full information regarding the involvement of the resident in the error.

¹³⁴ Craig A. Miller, *The Making of a Surgeon in the 21st Century* (Nevada City: Blue Dolphin Publishing, 2004).

¹³⁵ *Supra* note 50.

¹³⁶ Marshall B. Kapp, "Medical Error Versus Malpractice" (1997) 1 DePaul J. Health Care L. 751 at 765; see also A. Localio *et al.*, "Relation between Malpractice Claims and Adverse Events Due to Negligence: The Results of the Harvard Medical Practice Study III" (1991) 325 New Eng. J. Med. 245; and Troyen A. Brennan, Colin M. Sox & Helen R. Burstin, "Relation Between Negligent Adverse Events and the Outcomes of Medical-Malpractice Litigation" (1996) 335:26 New Eng. J. Med. 1963.

¹³⁷ A. Localio *et al.*, *ibid.*

¹³⁸ Charles Vincent, Magi Young & Angela Phillips, "Why Do People Sue Doctors? A Study of Patients and Relatives Taking Legal Action" (1994) 343:8913 Lancet 1609.

patients really want is an explanation of what happened to them, reassurance that steps have been taken to rectify the problem, and an apology.¹³⁹

In a 1994 study into why patients sue their doctors, the researchers concluded that patients taking legal action primarily wanted greater honesty, appreciation of the severity of the trauma they had suffered and assurances that lessons had been learned from their experiences.¹⁴⁰ Four main themes emerged from the analysis of the reasons for litigation: standards of care – both patients and their families wanted to prevent similar incidents in the future; explanation – state what happened, how it happened and why; compensation – for financial losses, pain and suffering or to provide future care for the injured person; and, accountability – that an individual or organization should be held responsible.¹⁴¹ At the end of the survey, patients were asked a final question as to whether, once the original incident had occurred, anything could have been done to prevent them from feeling the need to take legal action. A significant percentage of respondents answered yes to this question (41.4%).¹⁴² Interestingly, in these responses, the primary actions that could have prevented litigation were: explanation and apology (37%) and correction of mistake (25%); yet only 17% cited compensation.¹⁴³ The results of this study would seem to indicate that an increase in the disclosure of medical error would not necessarily cause a corresponding increase in the number of lawsuits filed, and in fact may reduce them.

A more recent study of the views of approximately 1000 New England patients regarding the disclosure of medical error was released in 2004.¹⁴⁴ The results of this study confirmed that full disclosure after a medical error reduces the likelihood that patients will change physicians, improves patient satisfaction, increases trust in the physician, and results in a more positive emotional response.¹⁴⁵ The researchers also asked the patients, in responding to the various scenarios presented in the study, whether full disclosure would have had an impact on whether they sought legal advice. The researchers found that full disclosure had a statistically significant effect on the likelihood of seeking legal advice in only one of the scenarios presented (a missed allergy error with a serious clinical outcome).¹⁴⁶ The researchers were therefore only able to conclude that full disclosure may reduce the

¹³⁹ *Ibid.*; see also G.B. Hickson *et al.*, “Factors That Prompted Families to File Medical Malpractice Claims Following Perinatal Injuries” (1992) 267:10 JAMA. 1359; and Nancy Berlinger, “Broken Stories: Patients, Families, and Clinicians after Medical Error” (2003) 22 Literature and Medicine 230.

¹⁴⁰ Vincent, Young, & Phillips, *ibid.*

¹⁴¹ *Ibid.*

¹⁴² *Ibid.*

¹⁴³ *Ibid.*

¹⁴⁴ Kathleen M. Mazor *et al.*, “Health Plan Members’ Views about Disclosure of Medical Errors” (2004)

140 Ann. Intern. Med. 409.

¹⁴⁵ *Ibid.* at 416.

¹⁴⁶ *Ibid.*

likelihood that patients will seek legal advice under some, but not all, circumstances.¹⁴⁷

Nevertheless, physicians continue to mistrust the legal process and risk managers focus more on reducing potential liability than on reducing error.¹⁴⁸ In light of this, the medical and legal professions need to do a much better job at educating physicians about the myths, truths and real risks of medical malpractice litigation. If physicians were better informed and less concerned about malpractice litigation, they would be much more likely to disclose medical errors to their patients and hospital administrators.¹⁴⁹ This would in turn lead to a more open system where errors could be learned from, not minimized, avoided and denied. In addition, this would lead to a more positive, open environment where physicians would feel more free to discuss their errors with colleagues. As a result, the negative impact of error on physicians would be substantially reduced. Moreover, patients would also benefit from information being provided in a more open and timely fashion.

While many physicians mistrust lawyers, it is ironic that the legal profession and the justice system in many ways have been easier on the medical profession than it has been on itself. By refusing to apply hindsight, by not holding physicians to a standard of infallibility but only to the standard of a reasonable physician in similar circumstances, and by consistently upholding the principle that an error in judgement is not negligent without proof of a breach of the standard of care, the legal profession and the justice system have consistently protected the medical profession from being held to a standard of perfection.

In order to facilitate and foster a new openness on the part of physicians in the disclosure of medical error, the legal profession and risk managers must also get on board. The conventional wisdom of risk managers and the traditional advice of defence counsel to be circumspect and to disclose only the minimum facts necessary needs to be set aside. In order not to be an impediment to progress of appropriate responses to medical error, defence counsel must advise physicians and other health providers to fully disclose the facts of the adverse event. In any event, there is little justification for not disclosing the relevant facts when the physician or health provider would be required to disclose them in examinations for discovery if a claim is filed. This is especially true when disclosing the facts at an early stage may have the added positive effect of avoiding a lawsuit being commenced at all.

However, care must be taken by the health providers to only disclose, at an early stage, information that they know to be factual. This is one of the most difficult

¹⁴⁷ *Ibid.*

¹⁴⁸ Edward A. Dauer, "A Therapeutic Jurisprudence Perspective on Legal Responses to Medical Error" (2003) 24 *J. Legal Med.* 37 at 39.

¹⁴⁹ K. James Sangston, "I'll Tell You What Happened if You Promise Not to Sue Me – Will No-Fault Liability Improve Patient Safety Through Increased Reporting of Medical Errors?" (2003) 19 *Ga. St.U. L. Rev.* 1227.

issues for health providers to deal with when disclosing adverse events. While it is recognized that there is an ethical and legal duty to disclose the adverse event, often not all facts will be known at the time of the disclosure conversation. Health providers must be careful not to speculate and should avoid detailed discussions of opinion until the clinical picture is clearer. Unfortunately this is easier said than done given that patients will naturally have many questions about what happened to them, why it happened and who is to blame. Health providers who will be having these discussions need to be trained to deal with these questions in a positive and effective manner without implicating the care provided.

While a general framework like the HQCA initiative discussed above would be a positive development, the method and scope of disclosure of medical error must be modified as necessary depending on the particular circumstances of each case. The appropriateness of the role of the individual health providers involved as well as how much information to share with the patient must be determined on a case by case basis. Each hospital and health region should also have specifically trained individuals available to assist with and coordinate the disclosure process. To the greatest extent possible, full information regarding the facts of the adverse event should be provided to the patient in a sensitive manner and in a timely fashion. In addition, the health provider most responsible for the care of the patient should either lead the disclosure discussion or be in attendance at the meeting in order to put the patient at ease and answer any questions they may have. If an appropriate, sensitive and timely disclosure process is followed in the aftermath of an adverse event, it will not only ensure that the ethical and legal obligations of the health providers are met, it will go a long way towards meeting the needs of the patient for information. In addition, if this process is followed and includes an apology, the likelihood of a lawsuit may actually be decreased.

Legal Reform

One area of legal reform that would have a significant positive impact on disclosure of medical error would be the inclusion of a statutory privilege for disclosure of medical error and apologies in the provincial and Federal evidence acts. In order to encourage openness and full disclosure in internal incident reviews as well as reviews of the conduct and competence of physicians, the current quality assurance and peer review protection should also be maintained. If the statements made by physicians in disclosing medical error and apologizing for the error were deemed to be privileged and could not be used in subsequent civil litigation against them or the hospital, it would provide a significant incentive for physicians and hospital administrators to be more forthright after an adverse event. Victims of medical error often state that one of their primary frustrations and reasons for instituting legal proceedings is evasiveness and lack of communication by physicians.¹⁵⁰ Given that physicians currently have good reason to be concerned that any apologies made by them would be construed as admissions of liability in subsequent

¹⁵⁰ *Supra* note 139.

civil proceedings¹⁵¹, the statutory privilege would free physicians to apologize and provide patients with the information that they desire.

An apology and disclosure privilege would allow physicians to more freely address the concerns raised by patients and would have a significant positive impact on the emotional well-being of the patient and/or their families. In addition, upon reviewing the available evidence, it appears that early, full disclosure may also have the added benefit of reducing the likelihood of a lawsuit.¹⁵² Colorado has recently instituted an apology law and, although it remains to be seen whether it will have a significant impact on the disclosure of error, the experience of victims of medical error, or the number of lawsuits filed, it is certainly a step in the right direction.¹⁵³

Another area of legal reform that is often advocated is the replacement of the tort medical liability system with a no-fault system. Although it is possible that a no-fault system would potentially be less likely to be a barrier to disclosure of medical error, this is by no means clear. On the other hand, the implementation of a no-fault system for medical malpractice claims would be problematic. In addition, compensation generally falls fairly low on the priority list of reasons why patients sue and a no-fault system will not address many of the patients' other issues any better than the tort system.¹⁵⁴ Moreover, medical malpractice litigation is almost never as clear-cut as most motor vehicle or workplace accident cases, which are areas where no-fault schemes have been relatively successful.

Unfortunately, the current practice of medicine is not an exact science and physicians and the health care system should not be forced to become, in essence, insurers of positive medical outcomes. Unless governments and health authorities are prepared to provide compensation to patients every time there is an unexpected or adverse outcome as a result of medical treatment, a complicated investigation involving expert opinions will often be required to determine whether the adverse event was preventable. Given the sheer volume of adverse events discussed above, the complexity and cost involved in administering such a system and the bureaucracy involved to determine appropriate awards, treatment plans etc., would be staggering.¹⁵⁵

¹⁵¹ However, I could not find any Canadian cases where an apology was expressly used as an admission in a finding of liability against a physician.

¹⁵² There is a clear consensus in the research that patients wish to be told about medical error at an early stage and desire an apology if appropriate. However, there is conflicting evidence regarding whether early, open disclosure in fact reduces the likelihood of lawsuits. Some authors suggest that it may – see for example Witman *et al.*, *supra* note 45; *supra* note 149; and Steve S. Kraman & Ginny Hamm, "Risk Management: Extreme Honesty May Be the Best Policy" (1999) 131:12 *Ann. Intern. Med.* 963. Some authors are not so sure – see for example *supra* note 144.

¹⁵³ Jonathan R. Cohen, "Toward Candor After Medical Error: The First Apology Law" (2004) 5 *Harv. Health Pol'y Rev.* 21.

¹⁵⁴ Vincent, Young & Phillips, *supra* note 138.

¹⁵⁵ The CMPA, in its recent detailed report regarding the medical liability system in Canada and the potential for reform, determined that a no-fault system in Canada would be prohibitively expensive. See: The Canadian Medical Protective Association, *Medical Liability Practices in Canada: Towards the*

In addition, one of the most compelling arguments against a no-fault regime for medical malpractice litigation is the fact that physicians' professional reputations are at stake and any payments made to their patients would imply some degree of fault. Furthermore, unless the current system of credentialing and assignment of privileges is drastically changed, payments made under a no-fault regime may have significant ramifications to physicians' careers without the full investigation that the current tort system provides.

Another area of the law that needs to be re-examined is the protection of quality assurance activities. Once a potential medical error has occurred, in most hospitals an internal investigation is commenced by a quality assurance committee. The mandate of these committees is to review adverse events or incidents that have occurred and make recommendations as to how future similar incidents could be avoided. The proceedings of these committees are confidential and individual members of the health care team are often required to provide information directly to the committee to assist the investigation. All jurisdictions in Canada have enacted legislation that prohibits the admissibility of information, documents or records that arise out of a quality assurance review by an appropriately constituted quality assurance committee. In Alberta, the statutory protection for quality assurance activities is found in section 9 of the *Alberta Evidence Act (AEA)*.¹⁵⁶ In addition, there is some limited protection against the disclosure of quality assurance information in the *Health Information Act*¹⁵⁷ and quality assurance information is specifically exempted from applications under the *Freedom of Information and Protection of Privacy Act*¹⁵⁸. As the protection of section 9 of the *AEA* only applies once an action has been commenced, the other information legislation within the province must be relied upon with respect to disclosure prior to the commencement of an action. Unfortunately, the statutory framework lacks clarity and comprehensiveness and legislative amendments are required to properly protect quality assurance information. In addition, peer review protections should be reviewed and further protection for individual health providers that disclose the errors of others should be examined. While the risk of civil liability for these individuals is admittedly very low, civil immunity for error disclosure could assist in further encouraging disclosure of medical error.

Quality assurance investigations are critical to the proper functioning of the health care system as it is a primary method by which lessons are learned and improvements are made. The proper functioning of these committees requires confidentiality and in certain circumstances there can be a tension (real or perceived) between the ethical and legal duty of physicians to disclose adverse events and their obligations to keep quality assurance activities confidential. However,

Right Balance – A Report Prepared by the Canadian Medical Protective Association August 2005 at 15, online: CMPA <http://www.cmpa-acpm.ca/portal/cmpa_docs/english/content/issues/common/piaa/pdf/com_medical_liability_canada-e.pdf>.

¹⁵⁶ R.S.A. 2000 c. A-18.

¹⁵⁷ See for example section 11 (1) & (2), *Health Information Act* R.S.A. 2000 c. H-5.

¹⁵⁸ Section 4 (1)(c), *Freedom of Information and Protection of Privacy Act* R.S.A. 2000 c. F-25.

this tension can be ameliorated by clear policies on what information is required to be disclosed to the patient after an adverse event. Any information that would normally be found on the patient's chart should be disclosed and any information relating to the quality assurance investigation should be kept confidential.

Ultimately, what is necessary is a debate among the stakeholders regarding the appropriate level of discretion regarding the disclosure of quality assurance information. In my view, the current prohibition against disclosure of quality assurance information that relates to a Health Services Provider (as defined) contained in section 11 (2) of the *HIA* should be maintained. In addition, a new provision should be added to the *HIA* that prohibits disclosure of all quality assurance information and opinions with the exception of recommendations made by the quality assurance committee. A further provision should be added that provides that disclosure of recommendations of quality assurance committees cannot be compelled but is discretionary. Admittedly, in order to facilitate these changes, further modifications to the scope of the *HIA* and its definition of Health Information will have to be made to ensure that quality assurance information such as opinions and recommendations fall within the scope of the legislation. Until these or similar modifications are made to the statutory framework in Alberta, there will remain inadequate protection of quality assurance activities. As a result, efforts at improving patient safety and reducing adverse events will be hindered by limitations on the free and open exchange of ideas, opinions and recommendations within the quality assurance process.

Conclusions

If we are to make significant strides towards reducing medical error and increasing patient safety, health providers must feel less constrained in disclosing medical errors both to patients and to hospital administrators. In order to facilitate increased disclosure, significant cultural and educational changes to hospitals and the health professions are required. Health professionals must be socialized and educated to discuss errors in an open and forthright manner with a view to learning from them and promoting positive systemic change. Health administrators must also build and foster a system of just responses to medical error. It must also be recognized that most errors are system errors and that individual scapegoating is counterproductive from a patient safety perspective. It is only in this way that full discussion and investigation of every medical error and near miss will occur. This will then allow physicians and hospital administrators to learn from the errors and make systemic changes in order to prevent similar errors from occurring in the future.

In order to promote the disclosure of medical error, the legal profession must also take positive steps to remove legal barriers to disclosure. As a starting point, an error disclosure and apology privilege should be added to the provincial and Federal evidence acts. Currently, physicians and health care providers have good reason to be concerned that any discussion that they have with a patient in disclosing a medical error could be used against them in a subsequent lawsuit. Most physicians would want to apologize to the patient after a medical error has occurred, but feel

constrained as this apology may be considered to be an admission that could be relied upon by the patient in a negligence action. It is also clear that most victims of medical error primarily want an explanation and an apology. By facilitating these discussions and appropriate apologies, an apology/disclosure privilege would provide some protection for physicians and would also facilitate a more positive experience for patients and their families. Further, the legal profession should be creative and work closely with the medical and other health professions to come up with other innovative mechanisms to promote and enhance patient safety. In the end, enhanced patient safety is in the interests of all and with sufficient will and leadership by the health professions, legal profession and government, we can all ultimately benefit from a safer and more effective health care system.

